



Allergy/Asthma Products

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SUMMARY OF SAFETY AND EFFECTIVENESS

The E-Z SPACER® Mask (Small) uses FDA approved materials: Dynaflex G2706 Kraton thermoplastic rubber designed for medical applications, and 21 CFR 178.3297 colorant pigments as specified by the Food and Drug Administration (Colorants for polymers). The E-Z SPACER Mask is injected molded with cavity I.D. mask (E-Z SPACER®MASK (Small) for identification.

Dynaflex G2706 elastomers are used in a wide variety of injection molded and extruded parts. Kraton polymers and compounds carry a number of different FDA approvals and have found use in many medical applications. Some characteristics of the polymers that have made them attractive to the medical parts manufacturer include: low extractables, cleanliness, dimensional stability, good vapor and gas transmission properties, ease of sterilization, chemical inertness and softness.

In addition, Kraton rubber is used in a currently marketed spacer with mask, the AeroChamber® manufactured by Monaghan Medical Corporation in Plattsburgh, NY 12901. The AeroChamber with Mask uses Kraton rubber at its end plate where the aerosol medication is inserted and administered.

In addition to using FDA approved grade materials for the E-Z SPACER Mask, we conducted fatigue testing. The E-Z SPACER Mask was attached to the E-Z SPACER device. The E-Z SPACER with Mask was opened and closed 1,460 times based on using the product four times per day. The E-Z SPACER Mask was washed following patient instructions based on cleaning once a week. The Mask was evaluated every 50 cycles. There were no signs of breakdown.

The E-Z SPACER Mask has easy to follow patient instructions for cleaning, operating, and safety precautions.

Particle size studies are submitted showing E-Z SPACER with Mask and without.

The manufacturing sites are UNI-TECH of SAN DIEGO, 730 Opper Street, Escondido, CA 92025, and COMPLEX TOOLING & MOLDING, 10948 Willow Court, San Diego, Ca 92127. These sites are in compliance with the GMP regulations (21 CFR Part 820).

After conducting a reasonable search of information known and available about spacer devices, we found no problems associated with safety and effectiveness.


Tom Evangelist
Vice-President