

MATERIAL SAFETY DATA SHEET

PRODUCT NAME: Aqualizer mouthpiece

COMPONENTS:

A. Proprietary formulation plastic laminate generally recognized as safe followed by their listings in 21CFR:

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|--------------------------|----------|
| 1. Nylon | 177.1500 |
| 2. Polyethylene | 177.1520 |
| 3. Polyurethane Adhesive | 175.105 |

B. Polyethylene Foam 177.1520 or 177.1350

C. Fluid: deionized water

PHYSICAL DATA:

A. Nylon:

Physical state: Flexible sheet

Odor threshold, melting & boiling points, vapor pressure, evaporation rate, volatility, solubility, N/A

Appearance: Clear, colorless

B. Polyethylene:

Physical states: 1. Clear colorless flexible sheet 2. White foam flexible sheet

Odor threshold, melting & boiling points, vapor pressure, evaporation rate, volatility, solubility, N/A

C. Solvent Free Polyurethane Adhesive:

Odor threshold, melting & boiling points, vapor pressure, evaporation rate, volatility, solubility, N/A

HEALTH HAZARD OF INDIVIDUAL COMPONENTS & LAMINATE FILM: None

HEALTH HAZARDS OF ORAL USE OF THE AQUALIZER:

1. Risk of swallowing: None in individuals with an unimpaired gag reflex. The Aqualizer should not be worn by individuals with abnormal or absent gag reflexes.
2. Irritation of Oral Tissues: Options if tissue irritation develops:
 - a. The Aqualizer can be switched to the opposing arch to relieve pressure on the irritated tissues.
 - b. The Aqualizer can be removed until tissues heal & then reinserted.
 - c. Use of the Aqualizer can be discontinued.
3. Allergic Reactions: One possible mild allergic reaction has been reported in over 1,000,000 usages. Should an allergic reaction occur, discontinue use of the Aqualizer.
4. There is no BPA, phthalates, polycarbonates, silicone or latex in the Aqualizer.

STORAGE & HANDLING: Store away from heat. Aqualizers have a shelf life of approximately 1 year, stored at room temperature. The shelf life of Aqualizers may be extended to approximately 3 years by storing them frozen. Warm the frozen Aqualizer before inserting it into the mouth.

CLEANING: Wash daily with soap & water.