



## Aqualizer Safety Data Sheet (SDS)

### PRODUCT NAME: Aqualizer mouthpiece

#### COMPONENTS:

A. Proprietary formulation plastic laminate generally recognized as safe (GRAS) followed by their listings in the US FDA 21 CFR 177:

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

B. Polyethylene Foam 177.1520 or 177.1350

C. Fluid: sterile water

#### PHYSICAL DATA:

A. Nylon:

Physical state: Flexible sheet

Odor threshold, melting & boiling points, vapor pressure, volatility, solubility: GRAS

Appearance: Clear, colorless

B. Polyethylene:

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

Odor threshold, melting & boiling points, vapor pressure, volatility, solubility: GRAS

C. Solvent Free Polyurethane Adhesive:

Physical states: Clear, colorless gel layer adhesive

Odor threshold, melting & boiling points, vapor pressure, evaporation rate, volatility, solubility: GRAS

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 severe allergic reaction and one possible mild allergic reaction has been reported in over 3,000,000 units sold. Should an allergic reaction occur, immediately discontinue use of the Aqualizer.

4. There are no BPA, phthalates, polycarbonates, silicone, or latex used in manufacture of the Aqualizer.

5. The Aqualizer is not intended for long-term use and is not intended to replace a permanent oral splint, a dental restoration, or other necessary professional treatment.

STORAGE & HANDLING: Stored away from sun light or heat, Aqualizers have a shelf life of 18 months, stored at room temperature. The shelf life of Aqualizers may be extended by storing them frozen. Warm the frozen Aqualizer before inserting it into the mouth.

CLEANING: Wash daily with soap & water.

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