

SILBIONE® BIOMEDICAL ADH1 M200

Implant Grade Adhesive (>29 days)

Technical Data Sheet n°1 – October/2018

Description

SILBIONE® Biomedical ADH1 M200 is a single component silicone adhesive designed specifically for applications where a high strength elastic bond to silicone, polyester, metals, polyurethane, and other substrates is needed. **SILBIONE® Biomedical ADH1 M200** cures at room temperature by exposure to ambient moisture to form a tough, elastic bond. During curing, acetic acid is released as a by-product. **SILBIONE® Biomedical ADH1 M200** contains no tin, solvents or plasticizers and is designed to self-level.

Key benefits

- Tin-free
- High cohesion and adhesive strength
- Improves productivity and efficiency with fast curing
- Versatility in adhesion to many substrates,
e.g., silicone, polyurethane, polyester, aluminum, titanium, etc.
- One part, ambient cure, easy to use, no need for heat or humidity

Typical properties

| Properties | Unit | Value |
|------------------|---------|---------------------------------|
| Appearance | | Colorless, clear to translucent |
| Tack Free Time | Minutes | 7 |
| Durometer | Shore A | 27 |
| Tensile Strength | psi | 475 |
| Elongation | % | 375 |
| Tear Strength | ppi | 50 |
| Specific Gravity | | 1.05 |

Please note: The typical properties are not intended for use in preparing specifications. Please contact our local Sales Department for assistance in writing specifications.

Processing

SILBIONE® BIOMEDICAL ADH1 M200 is supplied as a single component adhesive

Cure:

Surfaces to be bonded with adhesive should be pre-scrubbed thoroughly with a clean, soft sponge or soft-bristled brush in hot water-soap solution to remove possible surface contaminants. Do not use synthetic detergents or oil-based soaps.

Rinse with copious amounts of hot water, then rinse with distilled water and dry thoroughly. Apply **SILBIONE® BIOMEDICAL ADH1 M200** adhesive and then mate the surfaces together with light pressure. A bond thickness of 0.010" minimum is recommended to achieve optimum strength. Initial cure is typically achieved in 10 minutes. Ultimate cure and optimal physical properties will be achieved after 24-120 hours at 25°C and ambient moisture.

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Regulation

Biocompatibility Testing

SILBIONE® BIOMEDICAL brand materials have been tested according to, or are substantially equivalent to, materials that have been tested according to ISO 10993/USP Class VI for:

- Cytotoxicity
- Skin Sensitization
- Skin Irritation (ISO 10993)
- Intracutaneous Toxicity (USP)
- Systemic Toxicity
- Mutagenicity
- Hemolysis
- Pyrogenicity (USP)
- 12-Week Implant

FDA Master Files

Master Files (MAFs) in support of **SILBIONE® BIOMEDICAL** brand products are on file with the U.S.FDA. Customers interested in referencing these files must contact an Elkem Silicones representative.

Limitation

The purchaser has the sole responsibility to select a particular Elkem Silicones product and determine its application suitability. The purchaser also has the sole responsibility to comply with all applicable statutory, regulatory and industry requirements and standards for compatibility, extractability, testing, safety, efficacy and labelling.

Packaging

SILBIONE® BIOMEDICAL ADH1 M200 is available in 175ml (6oz), 375ml (12 oz) cartridges, and 18 Kg Pails.

Storage and shelf life

When stored in original packaging at a temperature of between 5°C (40°F) and 32°C (90°F), **SILBIONE® BIOMEDICAL ADH1 M200** may be stored for up to 12 months for date of manufacture. Comply with the storage instructions and expiry date marked on the packaging. Beyond this date, Elkem Silicones no longer guarantees that the products meet the sales specifications.

Safety

Please consult the Safety Data Sheet of **SILBIONE® BIOMEDICAL ADH1 M200**.

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Warning to the users

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