CASCO BAY MOLDING
23 September 2020

BIOCOMPATIBILITY ATTESTATION

SILBIONE LSR 4350 HC A&B

Elkem Silicones' Silbione® LSR 4350 is a member of a family of Silbione® LSRs for which biocompatibility testing has been conducted. Elkem's Silbione® LSR 4350 has been tested to the requirements of USP Class VI and/or ISO 10993 for skin contact healthcare applications or healthcare applications less than 30-day implantation. The specific biocompatibility tests conducted for this material are the following:

1. Cytotoxicity (ISO 10993-5)
2. Acute Systemic Toxicity (ISO 10993-11)
3. 7-Day Implantation study with macroscopic evaluation, without histopathology – (USP Class VI)
4. Ames mutagenicity (DMSO and saline extracts) (ISO 10993-3)
5. Intracutaneous Toxicity (USP Class VI)

LSR 4350 successfully passed all tests conducted. In addition to the tests described above, several additional tests were conducted on a substantially equivalent member of Elkem Silicones' Silbione® LSRs, Silbione® LSR 4340. Silbione® LSR 4340 successfully passed all tests conducted. The additional tests include:

1. Hemolysis (ASTM)
2. Pyrogenicity (USP Class VI)
3. Sensitization (allergenic) potential (LLNA Assay, ISO 10993)
4. 28-Day Implantation study (USP Class VI)

By analogy, Silbione® LSR 4350 also is considered to be non-hemolytic, non-sensitizing and non-pyrogenic.

As with all healthcare products, the manufacturer of the device must determine the suitability of the material and of the device utilizing the material. They are also responsible for assuring that the device utilizing the material is safe and effective for the prescribed use and meets all relevant regulatory requirements.

Certified by Elkem Silicones' Product Stewardship Department

Creation date: June 2019
Valid until: June 2022

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