

Traditional 510(k) for Exofin[®] High Viscosity Topical Skin Adhesive

510(k) Summary

This 510(k) summary is prepared in accordance with 21 CFR 807.92.

1. Submitter

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2. Device

Device Proprietary Name: Exofin[®] High Viscosity Topical Skin Adhesive

Common or Usual Name: Topical Skin Adhesive

Classification Name: Tissue Adhesive (21 CFR 878.4010)

Regulatory Class: Class II

Product Code: MPN

3. Predicate Device

Legally marketed devices to which equivalence is claimed:

Device Name: Exofin[®] High Viscosity Tissue Adhesive

510(k) Clearance: K152476

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4. Device Description

Exofin[®] High Viscosity Topical Skin Adhesive is a sterile liquid topical skin adhesive containing a monomeric (2-octyl cyanoacrylate) formulation for rapid polymerization, and the colorant D&C Violet #2 which aids in visualization during application. It is provided in a single-use, aluminum, collapsible tube fitted with a polyethylene-based applicator tip. The applicator tip consists of three components, a connector fitted with a self-puncturing cap, porous disk and soft elastomeric brush, used to apply and spread the adhesive evenly. The adhesive and applicator tip are packaged together in a polyethylene terephthalate glycol plastic blister pack and sealed with a labeled Tyvek[®] blister backer. When applied to the skin, the adhesive is distributed through the applicator tip in a syrup-like viscosity and polymerizes within minutes. The increased viscosity in **Exofin[®]** High Viscosity Topical Skin Adhesive is intended to reduce the risk of unintended placement of the adhesive during application due to migration of the liquid adhesive from the wound site. In-vitro studies have shown that **Exofin[®]** High Viscosity Topical Skin Adhesive acts as a barrier to microbial penetration when the adhesive film remains intact. Clinical studies were not conducted to demonstrate microbial barrier properties and a correlation between microbial barrier properties and a reduction in infection have not been established.

5. Intended Use

Exofin[®] High Viscosity Topical Skin Adhesive is intended for topical application only to hold closed easily approximated skin edges of wounds from surgical incisions, including incisions from minimally invasive surgery, and simple, thoroughly cleansed, trauma-induced lacerations. **Exofin[®]** High Viscosity Topical Skin Adhesive may be used in conjunction with, but not in place of, deep dermal sutures.

6. Comparison of Technological Characteristics with the Predicate Device

The technological characteristics of **Exofin[®]** High Viscosity Topical Skin Adhesive and the predicate device are similar. Both devices:

- are 2-octyl cyanoacrylate-based, rapid polymerizing, liquid adhesive formulations
- contain D&C violet #2 colorant to aid in visualization during application
- provide an applicator tip that comprises of a connector, porous disk and soft elastomeric brush
- polymerizes within minutes of application
- maintain skin edge approximation and provide a microbial barrier
- are sterilized by a two-stage process with a sterility assurance level of 10^{-6}

In addition to a change to the proprietary name, the differences between **Exofin[®]** High Viscosity Topical Skin Adhesive and the predicate include:

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- slight modification to the formulation
- increased viscosity

These differences do not raise different questions of safety and effectiveness.

7. Performance and Safety Data

Testing was performed in accordance with the FDA Class II Special Controls Guidance Document: Tissue Adhesive for the Topical Approximation of Skin.

Performance Testing

The following tests were performed on Exofin[®] High Viscosity Topical Skin Adhesive to demonstrate substantial equivalence:

- Wound Closure Strength (ASTM F2458-05)
- Adhesive Strength in Tension (ASTM F2258-05)
- T-Peel Adhesion Strength (ASTM F2256-05)
- Lap-Shear Strength (ASTM F2255-05)
- Heat of Polymerization
- Hydrolytic Degradation
- Viscosity
- Microbial Barrier Properties
- Applicator Torque Strength and Expression Force
- Setting (Tack-Free) Time

In these studies, Exofin[®] High Viscosity Topical Skin Adhesive met all performance criteria.

Biocompatibility Testing

The biological evaluation of Exofin[®] High Viscosity Topical Skin Adhesive was performed in accordance with ISO 10993-1, “Biological Testing of Medical Devices – Part 1: Evaluation and testing within a risk management process ” for a device intended for prolonged contact (>24 hours – 30 days) with breached or compromised skin surface. The results of the studies, listed below, demonstrate that Exofin[®] High Viscosity Topical Skin Adhesive is safe for its intended use.

- Cytotoxicity
- Sensitization
- Intracutaneous Irritation
- Acute Systemic Toxicity
- Pyrogenicity
- Systemic Toxicity Study and Local Tissue Response Following Full-Thickness Incisions in Rat, 14 days

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8. Conclusion

Exofin[®] High Viscosity Topical Skin Adhesive was evaluated in accordance with the Class II Special Controls Guidance Document: Tissue Adhesive for the Topical Approximation of Skin.

Exofin[®] High Viscosity Topical Skin Adhesive is substantially equivalent to Exofin[®] High Viscosity Tissue Adhesive with regard to indications for use, mechanism of action and performance characteristics. Both devices contain the same principle chemical ingredient, 2-Octyl cyanoacrylate. Both devices were shown to be equivalent in all performance and safety tests. Therefore, the slight change in formulation does not raise different questions of safety and effectiveness.
