

# Product Specifications

**Brand** : Klinion®  
**Product** : Skin Adhesive

## Product description

Klinion® Skin Adhesive is a sterile, liquid topical skin adhesive for professional use, containing a monomeric (2-octyl cyanoacrylate) Surgiseal® formulation and the colorant D & C Violet #2. The applicator is comprised of a plastic button contained within a plastic vial with an attached applicator tip. The Stylus® applicator is contained in a secondary blister pack with a Tyvek closer.

## Intended use

Klinion® Skin Adhesive is intended for topical applications only to hold closed easily approximated skin edges of wounds from surgical incisions including punctures from minimally invasive surgery and simple, thoroughly cleansed, trauma induced lacerations. Klinion® Skin Adhesive may be used in conjunction with, but not in place of, deep dermal sutures.

## Classification

Class IIa under MDD article 9, Annex IX, Rule 4.

## Packaging & Product Reference

Product Reference	Description	Size (*)	Piece(s)	Inner Carton	Outer Carton
40115500	Klinion® Skin Adhesive	0.5 ml	1	12 (12 x 1)	576 (48 x 12 x 1)

\*Sizes are approximate

Product Reference	Description	Size (*)	EAN Piece(s)	EAN Inner Carton	EAN Outer Carton
40115500	Klinion® Skin Adhesive	0.5 ml	N/A	8715343749142	8715343749135

\*Sizes are approximate

# Product Specifications

## Features

- Ready to use in 3 simple steps
- Stylus® applicator ensures easy application
- Quick dry time of 60 seconds
- Can be used for 15-20 minutes after depressing the ampule into the applicator sleeve
- Forms a microbial barrier
- Storage at ambient temperatures
- Single use
- Sterile

## Precautions

- It should not be applied to wet wounds and/or on the eye.
- It is not absorbable and therefore should not be used below the skin as it may cause a foreign body reaction.
- It should not be used in high skin tension areas or across areas of increased skin tension, such as knuckles, elbows or knees, unless the joint will be immobilized during the skin healing period, or unless skin tension has been removed by application of another wound closure device (e.g. sutures or skin staples) prior to application of the adhesive.
- It should not be used on wound sites that will be subjected to repeated or prolonged moisture or friction.
- Do not apply liquid or ointment medications or other substances to the wound after closure with the adhesive, as these substances weaken the polymerized film and allow for wound dehiscence.

## Contra-indications

- Do not use on any wounds with evidence of microbial bacterial or fungal infections or gangrene.
- Do not use on mucosal surfaces or across mucocutaneous junctions, or on skin which may be regularly exposed to body fluids or with dense natural hair.
- Do not use on patients that have a hypersensitivity to cyanoacrylates or formaldehyde.

# Product Specifications

## Product components

- 2-octyl cyanoacrylate (C<sub>12</sub>H<sub>19</sub>NO<sub>2</sub>)
- Colorant D&C Violet #2 (C<sub>21</sub>H<sub>15</sub>NO<sub>3</sub>)

## Presence of specific components

Component	Present
Latex	No
Phthalates	No
Substances of animal origin	No
Substances of human origin	No
Blood or blood derivatives	No
Medicinal substances	No
Heavy metals	No

## Sterilization

Terminally sterilized by ethylene oxide.

The filled ampoule component is terminally sterilized by irradiation.

## Storage conditions

The products should be stored in a cool, well ventilated, and dry place away from direct sunlight.

Recommended storage temperatures are at or below 30 °C.

## Shelf life

2 years from production date, when stored under specified conditions.

# Product Specifications

Picture



REF 40115500

Approval	Name	Date	Signature
Product Manager			
QA-Manager			