



## Instructions for Use (IFU)

**Product Name:** UltraSAFE Fixative

**Product Description:** Case of two 10% NBF (Neutral Buffered Formalin) plastic containers

**Catalog Number:** 107US2.5

**Unit of Measure:** Case of two 2.5-gallon jugs

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### 1. Intended Use

UltraSAFE Fixative is a ready-to-use 10% Neutral Buffered Formalin fixative solution intended for the preservation of biological tissue specimens.

UltraSAFE Fixative serves as a primary fixative, stabilizing cellular and tissue morphology for downstream histological processing and analysis.

UltraSAFE Fixative is formulated for use in In-Vitro-Diagnostic medical devices.

UltraSAFE Fixative is designed for use at full strength without the need for dilution or the addition of other agents.

UltraSAFE Fixative is designed for use in Milestone Medical's UltraSAFE instrument, an automated formalin dispenser.

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### 2. Summary and Explanation

UltraSAFE Fixative is 10% neutral buffered formalin and serves as a cross-linking fixative, preserving tissue morphology by forming covalent bonds between amino groups in proteins and other biomolecules. This cross-linking stabilizes cellular structures, halts autolysis, and prevents microbial degradation. The neutral buffering minimizes acidity, helping maintain tissue integrity and preventing excessive hardening or pigment artifact formation during fixation.

Proper fixation with UltraSAFE Fixative preserves tissue architecture by stabilizing cellular and subcellular structures. Adequately fixed specimens are expected to exhibit well-preserved morphology, minimal autolysis, and precise histological details following routine processing and staining.

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### 3. Materials Required but Not Provided

UltraSAFE Fixative is ready to use and therefore does not require any dilutions.

## 4. Warnings and Precautions

Appropriate personal protective equipment (PPE), including chemical-resistant gloves and eye protection, must be worn when handling this product. Use only in a well-ventilated area, such as a chemical fume hood or Milestone's UltraSAFE unit, to minimize exposure to harmful vapors. Avoid skin and eye contact, and do not ingest. Follow standard laboratory safety protocols and refer to the Safety Data Sheet (SDS) for additional information.

The product is intended for use by specialized technical personnel.

Carefully read the information concerning Hazard Statements and Safety Advice stated on the label.

Consult the Safety Data Sheet (SDS) for risk information, precautionary measures to be taken during use, first aid instructions, and hazard information in case of accidental release.

Do not use it if the packaging is damaged.

UltraSAFE Fixative is produced according to uniform and controlled methods, as specified in Quality Control Specifications. During and after use, handle all materials following Good Laboratory Practice.

Any other use of the product not detailed in this IFU is considered improper and relieves the manufacturer of responsibility.

In the event of a serious accident, it is required to inform the competent Authority and Milestone by writing to the e-mail address: [applications@milestonemed.com](mailto:applications@milestonemed.com)

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## 5. Storage and Stability

UltraSAFE Fixative is contained in a plastic bottle for light protection, featuring a sealed, tamper-proof cap. Store tightly closed, away from light, in a cool, dry place.

Store at room temperature.

The shelf life of the product is 24 months in undamaged packaging and under correct storage conditions. After opening the tank, the reagent can be used until the expiration date indicated on the package.

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## 6. Procedures for Use

Tissue specimens should be placed in UltraSAFE Fixative (10% Neutral Buffered Formalin) immediately after removal from the body to preserve cellular detail and tissue morphology. Prompt fixation helps prevent autolysis, putrefaction, and other undesirable post-excision changes.

Always follow institutional protocols and applicable regulations for specimen labeling, handling, and the transport of biohazards.

Use UltraSAFE Fixative in Milestone Medical's UltraSAFE device according to the manufacturer's instructions, as outlined in the operating manual.

Tissue specimens may be stored in UltraSAFE Fixative for extended periods. Prolonged storage in the fixative will not result in over-hardening or significant tissue shrinkage under normal conditions.



Before using for any other purposes, contact our Applications team by emailing: [applications@milestonemed.com](mailto:applications@milestonemed.com)

## 7. Waste disposal



Handle with care and store in a cool, dry space using a tightly closed container. Vapors may collect in empty containers. Treat empty containers as hazardous.



Waste material should be handled in accordance with your institutional policies and in compliance with all applicable federal, state, and local regulations.




For further information, please refer to the Safety Data Sheet (SDS).

## 8. Manufacturer Information

**EK Industries (EKI)**  
1403 Herkimer Street  
Joliet, IL 60432  
1-800-283-4244

## 9. Symbols and Definitions

	Instructions with this symbol are important and require more attention
	Biohazard: be careful when you execute the procedure marked with this symbol: danger of biohazard contamination
	IVD medical device according to 2017/746 Regulation (EU)
	Reference number
	Lot number
	Manufacturer
	Expiration date

	<p><b>DANGER</b>  <b>H334:</b> May cause allergy or asthma symptoms or breathing difficulties if inhaled  <b>H317:</b> May cause an allergic skin reaction  <b>H340:</b> May cause genetic defects  <b>H350:</b> May cause cancer  <b>H360:</b> May damage fertility or the unborn child  <b>H372:</b> Causes damage to organs through prolonged or repeated exposure  <b>H373:</b> May cause damage to organs through prolonged or repeated exposure  <b>P201:</b> Obtain special instructions before use  <b>P280:</b> Wear protective gloves/protective clothing/eye protection/face protection  <b>P308+P313:</b> IF exposed or concerned: Get medical advice/attention</p>
	<p><b>WARNING</b>  <b>H314:</b> Causes severe skin burns and eye damage  <b>H290:</b> May be corrosive to metals  <b>P260:</b> Do not breathe dust/fume/gas/mist/vapors/spray  <b>P280:</b> Wear protective gloves/protective clothing/eye protection/face protection.  <b>P301+P330+P331:</b> IF SWALLOWED: Rinse mouth. Do NOT induce vomiting  <b>P305+P251+P338:</b> IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing</p>
	<p><b>WARNING</b>  <b>H302:</b> Harmful if swallowed  <b>H315:</b> Causes skin irritation  <b>H319:</b> Causes serious eye irritation  <b>H335:</b> May cause respiratory irritation  <b>H336:</b> May cause drowsiness or dizziness  <b>H317:</b> May cause an allergic skin reaction  <b>P261:</b> Avoid breathing dust/fume/gas/mist/vapors/spray  <b>P280:</b> Wear protective gloves/eye protection  <b>P305+P351+P338:</b> IF IN EYES: Rinse cautiously with water for several minutes</p>

For further information or clarity, please contact our applications team by emailing: [applications@milestonemed.com](mailto:applications@milestonemed.com) or calling 1-866-995-5300.