

ThinPrep™ Stain Orange G Solution

Instructions for Use

UK
CA CE



INTENDED USE

ThinPrep™ Stain Orange G Solution is intended to be used in a Papanicolaou staining procedure in conjunction with any ThinPrep Stain Nuclear Stain, ThinPrep Stain Rinse Solution, ThinPrep Stain Bluing Solution, and ThinPrep Stain EA Solution. For professional use.

SUMMARY AND EXPLANATION

ThinPrep Orange G Solution is an alcoholic solution that serves to stain the cytoplasm of cells on slide preparations for cytologic evaluation.

PRINCIPLES OF PROCEDURE

When used in conjunction with the ThinPrep staining solutions and cytologic slide preparations, ThinPrep Orange G Solution will stain the cytoplasm of cells without interfering with nuclear staining and morphology.

COMPOSITION

An alcoholic solution of Ethanol, Methanol, and Isopropyl Alcohol. CAS 64-17-5, CAS 67-56-1, CAS 67-63-0

The solution contains Orange G dye.

WARNINGS

Danger. Flammable. Contains Ethanol, Methanol, Isopropyl Alcohol.

H302. Harmful if swallowed.

H312. Harmful in contact with skin.

H319. Causes serious eye irritation.

H371. May cause damage to organs.

H225. Highly flammable liquid and vapor.

For In Vitro Diagnostic Use. Not for external or internal use in humans or animals. Cannot be made non-poisonous.

PRECAUTIONS

P210. Keep away from heat/sparks/open flames/hot surfaces.– No smoking.

P280. Wear protective gloves and eye/face protection.

P260. Do not breathe dust/fume/gas/mist/vapours/spray.

P308 + P313. IF exposed or concerned: Get medical advice/attention.

P301 + P310. IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.

P305 + P351 + P338. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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P303 + P361 + P353. IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.

P304 + P340. IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.

P403 + P233. Store in a well-ventilated place. Keep container tightly closed.

P370 + P378. In case of fire: Use dry sand, dry chemical or alcohol-resistant foam to extinguish.

P501. Dispose of contents/container in accordance with local/regional/national/international regulation.

Wash thoroughly after handling. Keep container closed when not in direct use. Use with adequate ventilation. Results with non-ThinPrep cytology samples have not been evaluated. Do not use if primary packaging is damaged.

PRETREATMENT

No reconstitution, mixing or dilution is required.

STORAGE

Store ThinPrep Orange G Solution at 15°C (59°F) to 30°C (86°F) in the container provided. Do not use ThinPrep Orange G Solution beyond the expiration date marked on the container.

APPEARANCE AND INTEGRITY

Clear, non-sterile solution.

SPECIMEN COLLECTION AND PREPARATION

For use with gynecologic cytology samples that have been processed on any ThinPrep™ Processor.

PROCEDURE

See the ThinPrep Stain User's Manual for specific staining protocols.

LIMITATIONS OF PROCEDURE

Must be used according to the instructions provided in the ThinPrep Stain User's Manual. ThinPrep Orange G Solution cannot be substituted with any other solution.

SAFETY AND PERFORMANCE CHARACTERISTICS

When used as directed, ThinPrep Orange G Solution will stain the cytoplasm of cells in cytologic slide preparations.

If any serious incident occurs related to this device or any components used with this device, report it to Hologic Technical Support and the competent authority local to the patient and/or user.

Refer to the ThinPrep Imaging System operator's manual.

DISPOSAL

Dispose in accordance with all applicable regulations.

















FIRST AID MEASURES

IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. See www.hologicds.com for the entire Safety Data Sheet.

Revision History

Revision	Date	Description
AW-24894-002 Rev. 001	3-2022	Clarify instructions. Add instructions regarding reporting serious incidents.

ThinPrep™ Stain Orange G Solution

 Manufacturer	 Use by	 Flammable
 Consult instructions for use	 Batch code	 Irritant, Respiratory Tract Irritation, Dermal Sensitizer
 <i>In vitro</i> diagnostic medical device	 Temperature limitation	 Respiratory Sensitizer, Target Organ Toxicity
 Authorised representative in the European Community	 Open here	 Quantity
 Catalogue number	 Made in USA	EtOH Ethanol
 Product meets the requirements for CE marking in accordance with EU-IVD Regulation 2017/746	 UK Conformity Assessed (Great Britain)	

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