

# ThinPrep® Stain Orange G Solution

## Instructions for Use

R<sub>x</sub>only



### **INTENDED USE**

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

### **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, Isopropanol, and Orange G dye. CAS 64-17-5, CAS 67-56-1, CAS 67-63-0

### **WARNINGS**

**Danger.** Contains Ethanol, Methanol, Isopropanol.

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.

P280—Wear protective gloves/protective clothing/eye protection/face protection.

P260—Do not breathe vapors.

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.

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## **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.

## **PERFORMANCE CHARACTERISTICS**

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

## **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](http://www.hologicds.com) for the entire Safety Data Sheet.

# ThinPrep® Stain Orange G Solution

Following is an explanation of the symbols that may appear on your product.

Symbol	Title	Description	Standard information
	Manufacturer	Indicates the medical device manufacturer, as defined in the EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.1.1
	Consult instructions for use	Indicates the need for the user to consult the instructions for use.  When used to indicate an instruction to consult an electronic instructions for use (eIFU), this symbol is accompanied by an eIFU indicator. This indicator may represent the manufacturer's eIFU website or an appropriate indication on the use of eIFU. The indicator may be placed either alongside, beneath or surrounding the symbol.	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.4.3
	<i>In vitro</i> diagnostic medical device	Indicates a medical device that is intended to be used as an <i>in vitro</i> diagnostic medical device	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.5.1
	Authorized representative in the European Community	Indicates the authorized representative in the European Community.	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.1.2
	Catalogue Number	Indicates the manufacturer's catalogue number so that the medical device can be identified	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.1.6
	Use-by date	Indicates the date after which the medical device is not to be used.	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.1.4
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.1.5
	Temperature limit	Indicates the upper and lower limit of temperature to which the medical device can be safely exposed.	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.3.7
	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.4.2

And this product is marked with the following pictograms:

	Flammable		Irritant, Respiratory Tract Irritation, Dermal Sensitizer		Respiratory Sensitizer, Target Organ Toxicity
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