

eSensor[®] XT-8 Reagent Pack Material Safety Data Sheet (MSDS)

MSDS Prepared on:	04 Oct 2013
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SECTION 1: CHEMICAL IDENTIFICATION

Name: eSensor[®] XT-8 Reagent Pack

Proprietary: Yes

Applicable GenMark Dx Products include:

- eSensor[®] CF Genotyping Test
- eSensor[®] Warfarin Sensitivity Test
- eSensor[®] Thrombophilia Risk Test
- eSensor[®] Respiratory Viral Panel
- eSensor[®] 2C19 Genotyping Test
- eSensor[®] HCV Genotyping Test
- eSensor[®] HCVg *Direct* Test
- eSensor[®] 3A4/3A5 Genotyping Test

SECTION 2: HAZARDOUS INGREDIENTS

Component 1: PCR Mix	
Hazardous Ingredients:	CAS #:
Tris EDTA (Ethylenediamine Tetra-acetic Acid)	60-00-4
Magnesium Chloride	7786-30-3
Ammonium Sulfate	7783-20-2

Component 2: Taq Polymerase or RVP Enzyme Mix (eSensor[®] Respiratory Viral Panel only) **or HCVg** *Direct* **Enzyme Mix** (eSensor HCVg *Direct* Test only)

Hazardous Ingredients:	CAS #:
Glycerol, 50%	56-81-5

Component 4: MS2 Internal Control (eSensor[®] Respiratory Viral Panel only) <u>Hazardous Ingredients:</u> None



Component 5: Amplicon Dilution Solution (ADS) (eSensor [®] HCV Genotyping Te <u>Hazardous Ingredients:</u> Sodium Azide	st only) CAS #: 26628-22-8
Component 6: Exonuclease	
Hazardous Ingredients:	CAS #:
Glycerol, 50%	56-81-5
Component 7: eSensor[®] Test Signal Buffer <u>Hazardous Ingredients:</u> Guanidine Hydrochloride Ethyl Alcohol	CAS #: 50-01-1 64-17-5
Component 8: Buffer-1 Hazardous Ingredients: None	
Component 9: Buffer-2 Hazardous Ingredients: Sodium Perchlorate	CAS #: 7601-89-0

Kit components contain unlisted proprietary ingredients which are non-hazardous

SECTION 3:	HAZARDS IDENTIFICATION
CAUTION! CAUSES IRRITATION TO SKIN, EYES, AND RESPIRATORY TRACT. HARMFUL IF SWALLOWED OR INHALED. OXIDIZING LIQUIDS.	
HEALTH RATING:	1 – Slight
FLAMMABILITY RATING:	1 – Slight
REACTIVITY RATING:	1 – Slight
CONTACT RATING:	2 – Moderate
SKIN CONTACT:	Causes irritation, redness, and minor pain upon repeated skin exposure.
EYE CONTACT:	Causes irritation, redness and pain to the eyes.
INHALATION:	Causes mucous membrane and respiratory tract irritation.
INGESTION:	Causes gastro-intestinal tract irritation, nausea, vomiting, diarrhea, and CNS depression.
CHRONIC EXPOSURE:	Target organs: skin, eyes and kidneys. Material may aggravate pre-existing skin disorders.



SECTION 4:	FIRST AID MEASURES
SKIN CONTACT:	Immediately flush exposed skin with potable water for at least 15 minutes while removing contaminated clothing. Seek medical attention if irritation develops. Wash contaminated clothing before use.
EYE CONTACT:	Immediately flush the eyes with potable water for at least 15 minutes . Seek medical attention immediately.
INHALATION:	Remove to fresh air. If victim is not breathing, give artificial respiration. If breathing is difficult, seek medical attention.
INGESTION:	Get medical attention immediately. Induce vomiting immediately as directed by a physician. If vomiting occurs naturally, wash out mouth of the conscious victim.
SECTION 5:	FIRE AND EXPLOSION CONTROL MEASURES
FIRE:	Materials are not considered to be a fire hazard. Liquid dries to leave a residue that may support a fire when combined with combustible materials and reducing agents. Material will emit hazardous fumes under fire conditions.
EXPLOSION:	Not considered to be an explosion hazard.
EXTINGUISHING MEDIA:	Water, CO_2 , Dry chemical, Foam.
SPECIAL INFORMATION:	Wear a National Institute for Occupational Safety and Health (NIOSH) approved self contained breathing apparatus with a full face piece operated in the pressure demand mode, along with the appropriate protective clothing.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Ventilate the area of the leak or spill. Wear the appropriate personal protective equipment as specified in section 8. Contain the spill. Absorb spilled liquids with an inert absorbing material and place in the appropriate waste container. See section 13 for disposal considerations.

SECTION 7: HANDLING AND STORAGE

Store frozen components away from sources of ignition and combustible/flammable materials. Protect from physical damage. Handle using recommended protective equipment.



SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

ACGIH/OSHA PERMISSIBLE	
EXPOSURE	
LIMITS:	Not established.
RESPIRATORY	
PROTECTION:	Respiratory protection is not needed with normal use and storage.
VENTILATION:	Normal laboratory Heating, Ventilating and Air Conditioning (HVAC) systems are considered adequate ventilation for normal use.
PROTECTIVE GLOVES:	Protective gloves such as nitrile or latex.
EYE PROTECTION:	American National Safety Institute (ANSI) approved safety glasses. If splashing or spraying liquids are anticipated, ANSI approved chemical splash goggles are recommended.
OTHER PROTECTIVE	
EQUIPMENT:	An emergency eyewash and safety shower should be available.
HYGIENIC PRACTICES:	Wash hands thoroughly with soap and water after handling materials. Launder contaminated clothing prior to re-use.
SECTION 9:	PHYSICAL AND CHEMICAL PROPERTIES

COMPONENT 1: PCR mix

ODOR: Odorless APPEARANCE: Clear liquid pH: 8.0 M.P: >-20°C DENSITY: 1.0 g/mL

COMPONENT 2: RVP PCR mix (eSensor® Respiratory

Viral Panel only) ODOR: Odorless APPEARANCE: Clear viscous liquid pH: 8.7 M.P: >-20°C DENSITY: 1.0 g/mL

<u>COMPONENT 3</u> : Taq Polymerase	<u>COMPONENT 4</u> : HCVg Direct Test Enzyme Mix
ODOR: Odorless	(eSensor HCVg Direct Test only)
APPEARANCE: Clear viscous liquid	ODOR: Odorless
pH: 5.5 to 8.0	APPEARANCE: Clear viscous liquid
M.P: <-20°C	pH: 5.5 to 8.0
DENSITY: 3.1 g/mL	M.P: <-20°C
	DENSITY: 3.1 g/mL



<u>COMPONENT 5</u>: RVP Enzyme mix (eSensor[®] Respiratory

Viral Panel only) ODOR: Odorless APPEARANCE: Clear viscous liquid pH: 9.0 M.P: <-20°C DENSITY: 3.1 g/mL

<u>COMPONENT 7</u>: Amplicon Dilution Solution (ADS)

(eSensor[®] HCV Genotyping Test only) ODOR: Odorless APPEARANCE: Clear liquid pH: 6.0 to 8.0 M.P: Unknown DENSITY: 1.0 g/mL

COMPONENT 9: Signal Buffer

ODOR: Pungent APPEARANCE: Clear liquid pH: 8.7 M.P: >-20°C DENSITY: 1.0 g/mL

COMPONENT 11: Buffer-2

ODOR: Odorless APPEARANCE: Clear liquid pH: Unknown M.P: >-20°C DENSITY: 1.4 g/mL

COMPONENT 6: MS2 Internal Control (eSensor

Respiratory Viral Panel only) ODOR: Odorless APPEARANCE: Clear liquid pH: 7.0 to 8.0 M.P: N/A DENSITY: unknown

COMPONENT 8: Exonuclease

ODOR: Odorless APPEARANCE: Clear viscous liquid pH: 5.5 to 8.0 M.P: <-20°C DENSITY: 3.1 g/mL

COMPONENT 10: Buffer-1

ODOR: Odorless APPEARANCE: Amber liquid pH: 7.1 M.P: >-20°C DENSITY: Unknown

SECTION 10:	STABILITY AND REACTIVITY
STABILITY:	Stable under normal conditions of use and storage.
INCOMPATIBILITIES:	Strong acids, reducing agents, organic materials, finely powdered materials, Furan 2- Peroxycarboxylic acid.
HAZARDOUS DECOMPOSITION PRODUCTS:	Carbon Monoxide, Carbon Dioxide, Nitrogen Oxides, Chlorine gas, Hydrochloric acid vapor.
HAZARDOUS POLYMERIZATION:	Will not occur.
CONDTIONS TO AVOID: Heat, fire, incompatibles.	

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SECTION 11: TOXICOLOGICAL INFORMATION

Data not available.

SECTION 12: ECOLOGICAL INFORMATION

Data not available.

SECTION 13: DISPOSAL CONSIDERATIONS

Waste materials should be disposed of as hazardous waste. Waste should be segregated with compatible waste streams. Do not dispose of in municipal waste. Contact a licensed hazardous waste transportation and disposal service to safely and legally dispose of this material. Waste must be classified and disposed of in accordance with all Federal, State and local environmental regulations.

SECTION 14: TRANSPORTATION INFORMATION

Not regulated. This product does not contain hazardous compounds in quantities that require special handling precautions.

SECTION 15: REGULATORY INFORMATION

Data not available.

SECTION 16: OTHER INFORMATION

The above information is believed to be accurate and represents the best information currently available to GenMark Diagnostics, Inc. However, we make no warranty, express or implied, with respect to such information and we assume no liability as a result of its use. Users should make their own investigation to determine the suitability of this information for their particular purposes. GenMark Diagnostics, Inc. shall not be held liable for any damage or losses resulting from the use of or contact with this product.

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