



a member of the Roche Group

Material Safety Data Sheet

Material Name: CINtec® p16 Histology

MSDS ID: VEN-186

*** Section 1 - Chemical Product and Company Identification***

Manufacturer Information

VENTANA MEDICAL SYSTEMS INC.
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(800) 424-9300 (USA/Canada)
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Material Name: CINtec® p16 Histology

Product Number(s)

06695221001, 705-4713, 06695230001, 725-4713, 06695248001, 805-4713, 06695256001, 825-4713

Product Use

clinical

*** Section 2 - Hazards Identification***

NFPA Ratings: Health: 1 Fire: 1 Reactivity: 0

Hazard Scale: 0 = Minimal 1 = Slight 2 = Moderate 3 = Serious 4 = Severe

Preparation

Xi; R:43

Risks

May cause sensitization by skin contact.

EMERGENCY OVERVIEW

Physical Form: liquid

Major Health Hazards: No significant target effects reported.

POTENTIAL HEALTH EFFECTS

Inhalation

Short Term: no information on significant adverse effects

Long Term: no information on significant adverse effects

Skin

Short Term: irritation, allergic reactions

Long Term: no information on significant adverse effects

Eye

Short Term: irritation

Long Term: no information on significant adverse effects

Ingestion

Short Term: no information on significant adverse effects

Long Term: no information on significant adverse effects

OSHA Regulatory Status

This material is not considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).

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*** Section 3 - Composition/Information on Ingredients***

CAS #	Component / EU Number	Percent	Symbol(s)	Risk Phrase(s)
Not Available	Non-hazardous	60-100	---	---
9002-92-0	BRIJ 35 500-002-6	<0.2	---	---
55965-84-9	Mixture, 3(2H)-isothiazolone, 5-chloro-2-methyl- with 2-methyl-3(2H)-isothiazolone	<0.01	T N	R:23/24/25-34- 43-50/53

*** Section 4 - First Aid Measures***

Inhalation

If adverse effects occur, remove to uncontaminated area. Give artificial respiration if not breathing. Get immediate medical attention.

Skin

Wash contaminated areas with soap and water. Thoroughly clean and dry contaminated clothing before reuse. Get medical attention, if needed.

Eyes

Flush eyes with plenty of water for at least 15 minutes. Then get immediate medical attention.

Ingestion

If swallowed, get medical attention.

*** Section 5 - Fire-Fighting Measures***

See Section 9 for Flammability Properties

Flammable Properties

Slight fire hazard.

Extinguishing Media

regular dry chemical, carbon dioxide, regular foam, water

Unsuitable Extinguishing Media

None known.

Protective Equipment and Precautions for Firefighters

Wear full protective fire fighting gear including self contained breathing apparatus (SCBA) for protection against possible exposure.

Fire Fighting Measures

Move container from fire area if it can be done without risk. Avoid inhalation of material or combustion by-products.

Hazardous Combustion Products

Thermal decomposition or combustion products: oxides of carbon, oxides of nitrogen, oxides of sulfur

Sensitivity to Mechanical Impact

Not sensitive

Sensitivity to Static Discharge

Not sensitive

*** Section 6 - Accidental Release Measures***

Occupational Spill/Release

Absorb with sand or other non-combustible material. Collect spilled material in appropriate container for disposal.

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*** Section 7 - Handling and Storage***

Handling Procedures

Wash thoroughly after handling.

Storage Procedures

Store and handle in accordance with all current regulations and standards. Keep separated from incompatible substances.

*** Section 8 - Exposure Controls/Personal Protection***

Exposure Limits

Mixture, 3(2H)-isothiazolone, 5-chloro-2-methyl- with 2-methyl-3(2H)-isothiazolone (55965-84-9)

Austria: 0.05 mg/m3 TWA
skin notation
Skin sensitizer

Ventilation

Provide adequate ventilation. Ensure compliance with applicable exposure limits.

PERSONAL PROTECTIVE EQUIPMENT

Eyes/Face

Safety glasses or goggles are recommended when there is a potential for eye contact. Provide an emergency eye wash fountain and quick drench shower in the immediate work area.

Protective Clothing

Lab coat or apron.

Glove Recommendations

Wear appropriate chemical resistant gloves.

Respiratory Protection

No respirator is required under normal conditions of use.

*** Section 9 - Physical and Chemical Properties***

Physical State:	Liquid	Appearance:	liquid
Physical Form:	liquid	Odor:	Not available
Odor Threshold:	Not available	pH:	7.7
Melting/Freezing Point:	Not available	Boiling Point:	Not available
Decomposition:	Not available	Flash Point:	not flammable
Evaporation Rate:	Not available	LEL:	Not available
UEL:	Not available	Vapor Pressure:	Not available
Vapor Density (air = 1):	Not available	Density:	1.005 g/mL
Specific Gravity (water = 1):	Not available	Water Solubility:	miscible
Log KOW:	Not available	Coeff. Water/Oil Dist.:	Not available
Auto Ignition:	Not available	Viscosity:	Not available
Volatility:	Not available		

*** Section 10 - Stability and Reactivity***

Chemical Stability

Stable at normal temperatures and pressure.

Conditions to Avoid

Avoid heat, flames, sparks and other sources of ignition. Avoid contact with incompatible materials.

Materials to Avoid

oxidizing materials

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Decomposition Products

Thermal decomposition or combustion products: oxides of carbon, oxides of nitrogen, oxides of sulfur

Possibility of Hazardous Reactions

Will not polymerize.

*** Section 11 - Toxicological Information***

Acute and Chronic Toxicity

Component Analysis - LD50/LC50

The components of this material have been reviewed in various sources and the following selected endpoints are published:

BRIJ 35 (9002-92-0)

Oral LD50 Rat 1 g/kg

Mixture, 3(2H)-isothiazolone, 5-chloro-2-methyl- with 2-methyl-3(2H)-isothiazolone (55965-84-9)

Oral LD50 Rat 53 mg/kg

RTECS Acute Toxicity (selected)

The components of this material have been reviewed, and RTECS publishes the following endpoints:

BRIJ 35 (9002-92-0)

Oral: 1 gm/kg Oral Rat LD50; 8600 mg/kg Oral Rat LD50; 8600 mg/kg Oral Rat LD50; 4150 mg/kg Oral Rat LD50

Acute Toxicity Level

BRIJ 35 (9002-92-0)

Moderately Toxic: ingestion

Slightly Toxic: ingestion

Mixture, 3(2H)-isothiazolone, 5-chloro-2-methyl- with 2-methyl-3(2H)-isothiazolone (55965-84-9)

Toxic: ingestion

Irritation/Corrosivity

RTECS Irritation

The components of this material have been reviewed, and RTECS publishes the following endpoints:

BRIJ 35 (9002-92-0)

6 mg/3 day(s) intermittent Skin Human moderate; 10 mg Eyes Rabbit; 100 mg Eyes Rabbit; 750 ug/24 hour Eyes Rabbit severe; 100 mg Skin Rabbit; 75 mg/24 hour Skin Rabbit mild; 500 mg/24 hour Skin Rabbit mild; 500 mg/24 hour Skin Rabbit moderate; 1 percent Skin Woman

Local Effects

BRIJ 35 (9002-92-0)

Irritant: eye

Mixture, 3(2H)-isothiazolone, 5-chloro-2-methyl- with 2-methyl-3(2H)-isothiazolone (55965-84-9)

Corrosive: inhalation, skin, eye, ingestion

Target Organs

Mixture, 3(2H)-isothiazolone, 5-chloro-2-methyl- with 2-methyl-3(2H)-isothiazolone (55965-84-9)

immune system (sensitizer)

Carcinogenicity

Component Carcinogenicity

None of the substances in this preparation are listed by ACGIH, OSHA, NIOSH, NTP, IARC, Austria, Belgium, Denmark, France, Germany, Ireland, Italy, Netherlands, Portugal, Spain, Sweden, or United Kingdom.

Mutagenic

No data available for the mixture.

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Reproductive Effects

No data available for the mixture.

Tumorigenic

No data available for the mixture.

Medical Conditions Aggravated by Exposure

None known.

*** Section 12 - Ecological Information***

Component Analysis - Aquatic Toxicity

No ecotoxicity data are available for this product's components.

Mobility

No data available for the mixture.

Persistence & Degradation

No data available for the mixture.

Bioaccumulative Potential

No data available for the mixture.

*** Section 13 - Disposal Considerations***

Disposal Methods

Dispose in accordance with all applicable regulations.

Component Waste Numbers

The U.S. EPA has not published waste numbers for this product's components.

*** Section 14 - Transport Information***

US DOT Information

Not regulated.

TDG Information

Not regulated.

ADR Information

Not regulated.

RID Information

Not regulated.

IATA Information

Not regulated.

ICAO Information

Not regulated.

IMDG Information

Not regulated.

*** Section 15 - Regulatory Information***

U.S. Federal Regulations

None of this products components are listed under SARA Sections 302/304 (40 CFR 355 Appendix A), SARA Section 313 (40 CFR 372.65), or CERCLA (40 CFR 302.4), TSCA 12(b), or require an OSHA process safety plan.

SARA 311/312

Acute Health: No Chronic Health: No Fire: No Pressure: No Reactive: No

U.S. State Regulations

None of this product's components are listed on the state lists from CA, MA, MN, NJ or PA.

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California Proposition 65

Not regulated under California Proposition 65

Canadian Regulations

This product has been classified in accordance with the criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by the CPR.

Canada WHMIS

The following components are identified under the Canadian Hazardous Products Act Ingredient Disclosure List:

BRIJ 35 (9002-92-0)

1 %

WHMIS Classification

Not a Controlled Product under Canada's Workplace Hazardous Material Information System.

European Regulations

This preparation has been classified for the European Union according to Annex VI Directives 67/548/EEC and 99/45/EC.

Germany Water Classification

BRIJ 35 (9002-92-0)

ID Number 670, hazard class 2 - hazard to waters

Mixture, 3(2H)-isothiazolone, 5-chloro-2-methyl- with 2-methyl-3(2H)-isothiazolone (55965-84-9)

ID Number 2959, hazard class 3 - severe hazard to waters

EU Marking and Labelling

Risk Phrases

R43 May cause sensitization by skin contact.

Symbols

Xi Irritant

Safety Phrases

S24 Avoid contact with skin.

S37 Wear suitable gloves.

S60 This material and its container must be disposed of as hazardous waste.

Japanese Regulations

Japan Designated Chemical Substances (PRTR Law)

The following components are subject to reporting requirements as specified by the "Law Concerning Reporting, etc. of Releases to the Environment of Specific Chemical Substances and Promoting Improvements in Their Management" and are included in the "Pollutant Release and Transfer Register (PRTR)" of designated chemicals.

BRIJ 35 (9002-92-0)

407 >=1 %

Japan Poisonous and Deleterious Substances

No components of this material are specified as poisonous or deleterious substances, as regulated by Japan under the Poisonous and Deleterious Substances Control Law.

Industrial Safety and Health Law - Flammable Materials

No components of this material are specifically identified in Table 6-2 of the Enforcement Order of the Industrial Safety and Health Law which, if used in the workplace, require designation of an Operations Chief during confined space work and periodic machine inspections.

Industrial Safety and Health Law - Label Disclosure

No components of this material are specifically required to be indicated on a container label as specified by Article 18 of the Enforcement Order of the Industrial Safety and Health Law.

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Industrial Safety and Health Law - Organic Solvents

No components of this material are specifically identified in Table 6-2 of the Enforcement Order of the Industrial Safety and Health Law which, if used in the workplace, require designation of an Operations Chief during confined space work and periodic machine inspections.

*** Section 16 - Other Information***

Key / Legend

ACGIH - American Conference of Governmental Industrial Hygienists; ADR - European Road Transport; AU - Australia; BOD - Biochemical Oxygen Demand; C - Celsius; CA - Canada; CAS - Chemical Abstracts Service; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CN - China; CPR - Controlled Products Regulations; DFG - Deutsche Forschungsgemeinschaft; DOT - Department of Transportation; DSL - Domestic Substances List; EEC - European Economic Community; EINECS - European Inventory of Existing Commercial Chemical Substances; EPA - Environmental Protection Agency; EU - European Union; F - Fahrenheit; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; ICAO - International Civil Aviation Organization; IDL - Ingredient Disclosure List; IDLH - Immediately Dangerous to Life and Health; IMDG - International Maritime Dangerous Goods; JP - Japan; Kow - Octanol/water partition coefficient; KR - Korea; LEL - Lower Explosive Limit; LOLI - List Of Lists™ - ChemADVISOR's Regulatory Database; MAK - Maximum Concentration Value in the Workplace; MEL - Maximum Exposure Limits; NFPA - National Fire Protection Agency; NIOSH - National Institute for Occupational Safety and Health; NJTSR - New Jersey Trade Secret Registry; NTP - National Toxicology Program; NZ - New Zealand; OSHA - Occupational Safety and Health Administration; PH - Philippines; RCRA - Resource Conservation and Recovery Act; RID - European Rail Transport; RTECS - Registry of Toxic Effects of Chemical Substances®; SARA - Superfund Amendments and Reauthorization Act; STEL - Short-term Exposure Limit; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act; TWA - Time Weighted Average; UEL - Upper Explosive Limit; US - United States

Full text of R phrases in Section 3

R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.

R34 Causes burns.

R43 May cause sensitization by skin contact.

R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Other Information

Limitations: The information and recommendations set forth in this MSDS are believed to be correct as of this date. Ventana Medical Systems, Inc. makes no warranty with respect to the content of this MSDS and disclaims all liability from reliance thereon.

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End of Sheet VEN-186