



*a member of the Roche Group*

## Material Safety Data Sheet

Material Name: HybClear

MSDS ID: VEN-098

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

#### Manufacturer Information

VENTANA MEDICAL SYSTEMS INC.  
1910 E. Innovation Park Drive  
Tucson, AZ 85755  
Phone: (520) 887-2155

EMERGENCY TELEPHONE NUMBER:  
(800) 424-9300 (USA/Canada)  
CHEMTREC: +1 (703) 527-3887 (International)

#### Material Name: HybClear

##### Product Number(s)

780-4572, 06300324001

##### Product Use

clinical

### \*\*\* Section 2 - Hazards Identification\*\*\*

**NFPA Ratings: Health: 2 Fire: 1 Reactivity: 0**

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

#### Preparation

Repr.Cat.2; R:61

#### Risks

May cause harm to the unborn child.

#### EMERGENCY OVERVIEW

**Physical Form:** liquid

**Major Health Hazards:** respiratory tract irritation, skin irritation, eye irritation, reproductive effects

#### POTENTIAL HEALTH EFFECTS

##### Inhalation

**Short Term:** irritation, nausea, vomiting, stomach pain, headache, dizziness, lung congestion, unconsciousness

**Long Term:** irritation, nausea, headache, kidney damage, liver damage, unconsciousness

##### Skin

**Short Term:** irritation, itching

**Long Term:** irritation, reproductive effects

##### Eye

**Short Term:** irritation, tearing, blurred vision, eye damage

**Long Term:** irritation, eye damage

##### Ingestion

**Short Term:** gastrointestinal irritation, nausea, vomiting, stomach pain, weight loss, headache, dizziness, diarrhea, reproductive effects

**Long Term:** kidney damage, liver damage, reproductive effects

#### OSHA Regulatory Status

This material is 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) |
|---------------|-----------------------------------------------|---------|-----------|----------------|
| 75-12-7       | Formamide<br>200-842-0                        | 40-70   | T         | R:61           |
| Not Available | Non-hazardous component                       | 10-30   | ---       | ---            |
| 7647-14-5     | Sodium chloride<br>231-598-3                  | 1-5     | Xi        | R:36           |
| 60-00-4       | Ethylenediamine tetraacetic acid<br>200-449-4 | 0.1-1   | Xi        | R:36           |
| 9002-92-0     | Brij 35<br>500-002-6                          | <0.1    | ---       | ---            |

## \*\*\* 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

carbon dioxide, regular dry chemical, regular foam, water

### 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:** hydrogen chloride, oxides of carbon, oxides of nitrogen, oxides of phosphorus, oxides of sodium, 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. Keep unnecessary people away, isolate hazard area and deny entry.

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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

#### Formamide (75-12-7)

|                        |                                                                                                     |
|------------------------|-----------------------------------------------------------------------------------------------------|
| <b>ACGIH:</b>          | 10 ppm TWA<br>Skin - potential significant contribution to overall exposure by the cutaneous route  |
| <b>NIOSH:</b>          | 10 ppm TWA; 15 mg/m3 TWA<br>Potential for dermal absorption                                         |
| <b>OSHA:</b>           | 20 ppm TWA; 30 mg/m3 TWA<br>30 ppm STEL; 45 mg/m3 STEL                                              |
| <b>Austria:</b>        | 18 ppm STEL (4 X 15 min); 32 mg/m3 STEL (4 X 15 min)<br>9 ppm TWA; 16 mg/m3 TWA<br>skin notation    |
| <b>Belgium:</b>        | 10 ppm TWA; 18 mg/m3 TWA<br>Skin                                                                    |
| <b>Denmark:</b>        | 10 ppm TWA; 18 mg/m3 TWA<br>Potential for cutaneous absorption                                      |
| <b>Finland:</b>        | 20 ppm STEL; 37 mg/m3 STEL<br>10 ppm TWA; 19 mg/m3 TWA<br>Potential for cutaneous absorption        |
| <b>France:</b>         | 20 ppm TWA; 30 mg/m3 TWA                                                                            |
| <b>Germany (DFG):</b>  | skin notation                                                                                       |
| <b>Greece:</b>         | 30 ppm STEL; 45 mg/m3 STEL<br>20 ppm TWA; 30 mg/m3 TWA<br>skin - potential for cutaneous absorption |
| <b>Ireland:</b>        | 30 ppm STEL; 45 mg/m3 STEL<br>20 ppm TWA; 30 mg/m3 TWA                                              |
| <b>Portugal:</b>       | 10 ppm TWA [VLE-MP]<br>skin - potential for cutaneous exposure                                      |
| <b>Spain:</b>          | 10 ppm TWA [VLA-ED]; 19 mg/m3 TWA [VLA-ED]<br>skin - potential for cutaneous exposure               |
| <b>Sweden:</b>         | 10 ppm LLV; 20 mg/m3 LLV<br>15 ppm STV; 30 mg/m3 STV<br>Skin notation                               |
| <b>United Kingdom:</b> | 30 ppm STEL; 56 mg/m3 STEL<br>20 ppm TWA; 37 mg/m3 TWA                                              |

### 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.

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

|                                      |               |                                |               |
|--------------------------------------|---------------|--------------------------------|---------------|
| <b>Physical State:</b>               | Liquid        | <b>Appearance:</b>             | Liquid        |
| <b>Physical Form:</b>                | liquid        | <b>Odor:</b>                   | Not available |
| <b>Odor Threshold:</b>               | Not available | <b>pH:</b>                     | 7.4           |
| <b>Melting/Freezing Point:</b>       | Not available | <b>Boiling Point:</b>          | Not available |
| <b>Decomposition:</b>                | Not available | <b>Flash Point:</b>            | Not flammable |
| <b>Evaporation Rate:</b>             | Not available | <b>LEL:</b>                    | Not available |
| <b>UEL:</b>                          | Not available | <b>Vapor Pressure:</b>         | Not available |
| <b>Vapor Density (air = 1):</b>      | Not available | <b>Density:</b>                | 1.19 mg/L     |
| <b>Specific Gravity (water = 1):</b> | Not available | <b>Water Solubility:</b>       | miscible      |
| <b>Log KOW:</b>                      | Not available | <b>Coeff. Water/Oil Dist.:</b> | Not available |
| <b>Auto Ignition:</b>                | Not available | <b>Viscosity:</b>              | Not available |
| <b>Volatility:</b>                   | 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

bases, combustible materials, halogenated compounds, metals, oxidizing materials

### Decomposition Products

**Thermal decomposition or combustion products:** hydrogen chloride, oxides of carbon, oxides of nitrogen, oxides of phosphorus, oxides of sodium, 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:

#### **Formamide (75-12-7)**

Inhalation LC50 Rat >3900 ppm 6 h; Oral LD50 Rat >5000 mg/kg

#### **Sodium chloride (7647-14-5)**

Inhalation LC50 Rat >42 g/m<sup>3</sup> 1 h; Oral LD50 Rat 3 g/kg; Dermal LD50 Rabbit >10 g/kg

#### **Ethylenediamine tetraacetic acid (60-00-4)**

Oral LD50 Rat 1700 mg/kg

#### **Brij 35 (9002-92-0)**

Oral LD50 Rat 1 g/kg

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## RTECS Acute Toxicity (selected)

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

### Formamide (75-12-7)

Inhalation: >3900 ppm/6 hour Inhalation Rat LC50

Oral: 4000 mg/kg Oral Rat LD50; 5577 mg/kg Oral Rat LD50; 5570 mg/kg Oral Rat LD50

Skin: 17 gm/kg Skin Rabbit LD50

### Sodium chloride (7647-14-5)

Oral: 3000 mg/kg Oral Rat LD50

### Ethylenediamine tetraacetic acid (60-00-4)

Oral: 30 mg/kg Oral Mouse LD50

## Acute Toxicity Level

### Formamide (75-12-7)

Toxic: inhalation

Moderately Toxic: ingestion

Slightly Toxic: dermal absorption

### Sodium chloride (7647-14-5)

Moderately Toxic: ingestion

### Ethylenediamine tetraacetic acid (60-00-4)

Moderately Toxic: ingestion

### Brij 35 (9002-92-0)

Moderately Toxic: ingestion

Slightly Toxic: ingestion

## Irritation/Corrosivity

respiratory tract irritation, skin irritation, eye irritation

## RTECS Irritation

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

### Formamide (75-12-7)

100 mg Eyes Rabbit severe

### Sodium chloride (7647-14-5)

100 mg/24 hour Eyes Rabbit moderate; 10 mg Eyes Rabbit moderate; 500 mg/24 hour Skin Rabbit mild

## Local Effects

### Formamide (75-12-7)

Irritant: inhalation, skin, eye

### Sodium chloride (7647-14-5)

Irritant: eye

### Ethylenediamine tetraacetic acid (60-00-4)

Irritant: inhalation, skin, eye

### Brij 35 (9002-92-0)

Irritant: eye

## 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 information available for the mixture.

## RTECS Mutagenic

The components of this material have been reviewed, and RTECS publishes data for one or more components.

## Reproductive Effects

Available data characterizes this substance as a reproductive hazard.

## RTECS Reproductive Effects

The components of this material have been reviewed, and RTECS publishes data for one or more components.

## Tumorigenic

No information available for the mixture.

## RTECS Tumorigenic

The components of this material have been reviewed, and RTECS publishes data for one or more components.

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## Medical Conditions Aggravated by Exposure

high blood pressure, kidney disorders

## \*\*\* Section 12 - Ecological Information\*\*\*

### Component Analysis - Aquatic Toxicity

#### Formamide (75-12-7)

**Fish:** 96 Hr LC50 Brachydanio rerio: 9135 mg/L [static]; 96 Hr LC50 Leuciscus idus: 4600-9300 mg/L [static]

**Algae:** 72 Hr EC50 Desmodesmus subspicatus: >500 mg/L; 96 Hr EC50 Desmodesmus subspicatus: >500 mg/L

**Invertebrate:** 48 Hr EC50 Daphnia magna: >500 mg/L

#### Sodium chloride (7647-14-5)

**Fish:** 96 Hr LC50 Lepomis macrochirus: 5560-6080 mg/L [flow-through]; 96 Hr LC50 Lepomis macrochirus: 12946 mg/L [static]; 96 Hr LC50 Pimephales promelas: 6020-7070 mg/L [static]; 96 Hr LC50 Pimephales promelas: 7050 mg/L [semi-static]; 96 Hr LC50 Pimephales promelas: 6420-6700 mg/L [static]; 96 Hr LC50 Oncorhynchus mykiss: 4747-7824 mg/L [flow-through]

**Invertebrate:** 48 Hr EC50 Daphnia magna: 1000 mg/L; 48 Hr EC50 Daphnia magna: 340.7 - 469.2 mg/L [Static]

#### Ethylenediamine tetraacetic acid (60-00-4)

**Fish:** 96 Hr LC50 Lepomis macrochirus: 34-62 mg/L [static]; 96 Hr LC50 Pimephales promelas: 44.2-76.5 mg/L [static]

**Algae:** 72 Hr EC50 Desmodesmus subspicatus: 1.01 mg/L

**Invertebrate:** 48 Hr EC50 Daphnia magna: 113 mg/L [Static]

### 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.

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## \*\*\* 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

This material contains one or more of the following chemicals required to be identified under SARA Sections 302/304 (40 CFR 355 Appendix A), SARA Section 313 (40 CFR 372.65), CERCLA (40 CFR 302.4), TSCA 12(b), and/or require an OSHA process safety plan.

#### Ethylenediamine tetraacetic acid (60-00-4)

CERCLA: 5000 lb final RQ; 2270 kg final RQ

### SARA 311/312

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

### U.S. State Regulations

The following components appear on one or more of the following state hazardous substances lists:

| Component / EC Number            | CAS     | CA  | MA  | MN  | NJ  | PA  |
|----------------------------------|---------|-----|-----|-----|-----|-----|
| Formamide                        | 75-12-7 | Yes | Yes | Yes | Yes | Yes |
| Ethylenediamine tetraacetic acid | 60-00-4 | Yes | Yes | No  | Yes | Yes |

### 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:

#### Formamide (75-12-7)

0.1 %

#### Brij 35 (9002-92-0)

1 %

### WHMIS Classification

D2A, D2B.

### 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

#### Formamide (75-12-7)

ID Number 1509, hazard class 1 - low hazard to waters

#### Sodium chloride (7647-14-5)

ID Number 270, hazard class 1 - low hazard to waters

#### Ethylenediamine tetraacetic acid (60-00-4)

ID Number 104, hazard class 2 - hazard to waters

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## Brij 35 (9002-92-0)

ID Number 670, hazard class 2 - hazard to waters

## EU Marking and Labelling

### Symbols

T Toxic

### Risk Phrases

R61 May cause harm to the unborn child.

### Safety Phrases

S45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

S53 Avoid exposure - obtain special instructions before use.

## 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.

#### Ethylenediamine tetraacetic acid (60-00-4)

60 >=1 %

#### 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.

### 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; 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



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## Full text of R phrases in Section 3

**R36** Irritating to eyes.

**R61** May cause harm to the unborn child.

## 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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**New MSDS:** 12/17/2010

**MSDS Update:** 10/24/2011

End of Sheet VEN-098