

## SAFETY DATA SHEETS

**This SDS packet was issued with item:**

078904855

N/A

Hespan®

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## 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

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### Material Identification

Weight Average Molecular Weight: approximately 600,000 Daltons  
Sterile, nonpyrogenic injectable solution

### Tradenames and Synonyms

HESPAN® (6% hetastarch in 0.9% sodium chloride injection)

### Company Identification

#### Manufacturer/Distributor:

B. Braun Medical Inc.  
2525 McGaw Avenue  
P.O. Box 19791  
Irvine, CA 92623-9791

#### Phone Numbers:

Product Information: 1-800-854-6851  
Medical Emergency: 1-800-854-6851

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## 2. COMPOSITION/INFORMATION ON INGREDIENTS

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### Components

The composition of each 100 mL is as follows:

Hetastarch	6.0 g
Sodium Chloride, USP	0.9 g
Water for Injection, USP	qs

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## 3. HAZARDS IDENTIFICATION

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### Potential Health Effects

The pharmacological action of HESPAN is related to its chemical characteristics and requires intravenous infusion of large volumes (> 500 mL) of HESPAN. Because HESPAN is not biologically active, occupational exposure to HESPAN is not expected to result in adverse effects.

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**Carcinogenicity Information**

None of the components present in this material at concentrations equal to or greater than 0.1% are listed by IARC, NTP, OSHA or ACGIH as a carcinogen.

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**4. FIRST AID MEASURES**

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**First Aid****INHALATION**

If vapor or mist is inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician.

**SKIN CONTACT**

In case of contact, wash skin with soap and water. Wash contaminated clothing before reuse. If itching or abnormal skin conditions develop and persist, call physician.

**EYE CONTACT**

In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Call a physician.

**INGESTION**

If swallowed, immediately give two glasses of water and induce vomiting. Never give anything to an unconscious person. Call a physician.

**Notes to Physicians**

HESPAN is indicated in the treatment of hypovolemia when plasma volume expansion is desired. It is not a substitute for blood or plasma and is not inherently biologically active. Adverse effects from the occupational handling and use of HESPAN is very unlikely.

If ingested and patient is conscious, induction of emesis may be indicated. Gastric lavage may be indicated if the patient is unconscious.

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## 5. FIRE FIGHTING MEASURES

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### Flammable Properties

Not a fire or explosion hazard.

### Extinguishing Media

Water, Foam, Dry Chemical, CO<sub>2</sub>

### Fire Fighting Instructions

Evacuate personnel to a safe area. Keep personnel removed and upwind of fire. Wear self-contained breathing apparatus.

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## 6. ACCIDENTAL RELEASE MEASURES

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### Safeguards (Personnel)

NOTE: Review FIRE FIGHTING MEASURES and HANDLING (PERSONNEL) sections before proceeding with clean-up. Use appropriate PERSONAL PROTECTIVE EQUIPMENT during clean-up.

### Spill Clean-up

Soak up with sawdust, sand, oil dry or other absorbent material.

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## 7. HANDLING AND STORAGE

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### Handling (Personnel)

Avoid breathing vapors or mist. Avoid contact with eyes, skin, or clothing. Wash thoroughly after handling.

### Storage

Do not store or consume food, drink, or tobacco in areas where they may become contaminated with this material.

Avoid excessive heat. Protect from freezing. Recommended storage at room temperature 25 deg C (77 deg F); however, brief exposure up to 40 deg C (104 deg F) does not adversely affect the product.

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**8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

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**Engineering Controls**

Avoid excessive heat.

**Personal Protective Equipment**EYE/FACE PROTECTION

Wear safety glasses. Wear full-face protection, when judged that the possibility exists for eye and face contact due to spraying/splashing of solutions.

RESPIRATORS

Wear an appropriate NIOSH/MSHA approved air purifying respirator or positive pressure air-supplied respirator in situations where a respirator is judged appropriate.

PROTECTIVE CLOTHING

Wear impervious clothing made from Neoprene or Tyvek, such as gloves, apron, boots, jumpsuit, or whole bodysuit, as appropriate.

**Exposure Guidelines****Exposure Limits**

HESPAN

PEL (OSHA) None Established

TLV (ACGIH) None Established

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**9. PHYSICAL AND CHEMICAL PROPERTIES**

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**Physical Data**

% Volatiles:	93.1 WT%
Solubility in Water	Miscible
Approximate pH	3.5 – 7.0

HESPAN is a clear, pale yellow to amber solution. Exposure to prolonged adverse storage conditions may result in a change to a turbid deep brown or the formation of a crystalline precipitate.

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**HOW SUPPLIED:**

HESPAN is supplied sterile and nonpyrogenic in 500 mL intravenous plastic infusion containers.

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**10. STABILITY AND REACTIVITY**

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**Chemical Stability**

Stable at normal temperatures and storage conditions.

**Incompatibility with Other Materials**

None reasonably foreseeable.

**Decomposition**

Decomposition will not occur, if handled and stored properly.

**Polymerization**

Polymerization will not occur.

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**11. TOXICOLOGICAL INFORMATION**

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**Animal Data**

HESPAN has not been evaluated for adverse effects in animal studies by the inhalation, dermal, or ocular routes of exposure. Consequently, the potential hazards associated via these routes are unknown.

**Oral Data**

LD50: > 100 mL/kg (mouse)

**Intravenous Data**

LD50: > 12 g/kg (mouse)

**Teratogenicity/Developmental Toxicity**

Hespan®

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**11. TOXICOLOGICAL INFORMATION (cont.)**

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HESPAN was not teratogenic when given intravenously to rabbits at doses ranging from 10 to 40 mL/kg/day. However, it caused low birth weights at all doses, as well as an increased incidence of vaginal hemorrhaging and abortions in the 20 mL/kg/day treatment group. Maternal toxicity was evident at 40 mL/kg/day as 10 out of 13 of the dams died before study completion.

LD50 is the median dose at which lethality occurred in 50% of the animals tested following oral exposure or exposure by injection.

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**12. DISPOSAL CONSIDERATIONS**

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**Waste Disposal**

Treatment, storage, transportation, and disposal must be in accordance with applicable Federal, State/Provincial, and Local regulations.

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**13. TRANSPORTATION INFORMATION**

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**Shipping Information**

The known properties of this material do not constitute a hazard, as defined by the U.S. Department of Transportation.

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14. OTHER INFORMATION

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**NFPA, NPCA-HMIS**

## NFPA Rating

Health:	0
Flammability:	0
Reactivity:	0

## NPCA-HMIS Rating

Health:	0
Flammability:	0
Reactivity:	0

**Additional Information**

HESPAN is a Registered Trademark of B. Braun Medical Inc.

## References:

Physicians' Desk Reference, 49<sup>th</sup> Edition, 1995.

Poison Control Monograph from the DuPont Merck Pharmaceutical Company, 1992.

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The data in this Material Safety Data Sheet relates only to the specific material designated herein and does not relate to use in combination with any other material or in any process.

Responsibility for MSDS: Safety Assessment Section

Address: B. Braun Medical Inc.  
2525 McGaw Avenue  
P.O. Box 19791  
Irvine, CA 92623-9791

Telephone: (949) 660-2082



# Safety Data Sheet

## HESPAN®

SDS Revision Date:

05/12/2015

### 1. Identification

#### 1.1. Product identifier

**Product Identity** HESPAN®

**Alternate Names** HESPAN®

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

**Intended use** See Technical Data Sheet.

**Application Method** See Technical Data Sheet.

#### 1.3. Details of the supplier of the safety data sheet

**Company Name** B. Braun Medical Inc.  
2525 McGaw Ave  
Irvine, CA 92614

**Emergency** (800) 854-6851

**Customer Service: B. Braun Medical Inc.** (949) 660-2000

### 2. Hazard(s) identification

#### 2.1. Classification of the substance or mixture

No applicable GHS categories.

#### 2.2. Label elements

Using the Toxicity Data listed in section 11 and 12 the product is labeled as follows.

No applicable GHS categories.

#### **[Prevention]:**

No GHS prevention statements

#### **[Response]:**

No GHS response statements

#### **[Storage]:**

No GHS storage statements

#### **[Disposal]:**

No GHS disposal statements

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### 3. Composition/information on ingredients

This product contains the following substances that present a hazard within the meaning of the relevant State and Federal Hazardous Substances regulations.

Ingredient/Chemical Designations	Weight %	GHS Classification	Notes
Starch, 2-hydroxyethyl ether CAS Number: 0009005-27-0	75 - 100	Not Classified	[1]
Sodium chloride CAS Number: 0007647-14-5	10 - 25	Not Classified	[1]

In accordance with paragraph (i) of §1910.1200, the specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret.

[1] Substance classified with a health or environmental hazard.

[2] Substance with a workplace exposure limit.

[3] PBT-substance or vPvB-substance.

\*The full texts of the phrases are shown in Section 16.

This SDS and its hazards pertain to the drug component only - the diluent is a nonhazardous mixture of dextrose and water.

### 4. First aid measures

#### 4.1. Description of first aid measures

##### General

HESPAN is indicated in the treatment of hypovolemia when plasma volume expansion is desired. It is not a substitute for blood or plasma and is not inherently biologically active. Adverse effects from the occupational handling and use of HESPAN is very unlikely. If ingested and patient is conscious, induction of emesis may be indicated. Gastric lavage may be indicated if the patient is unconscious.

##### Inhalation

Remove to fresh air, keep patient warm and at rest. If breathing is irregular or stopped, give artificial respiration. If unconscious place in the recovery position and obtain immediate medical attention. Give nothing by mouth.

##### Eyes

Irrigate copiously with clean water for at least 15 minutes, holding the eyelids apart and seek medical attention.

##### Skin

Remove contaminated clothing. Wash skin thoroughly with soap and water or use a recognized skin cleanser.

##### Ingestion

If swallowed, immediately give two glasses of water and induce vomiting. Never give anything to an unconscious person. Call a physician.

#### 4.2. Most important symptoms and effects, both acute and delayed

##### Overview

No hazards expected.

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### 5. Fire-fighting measures

#### 5.1. Extinguishing media

Water spray, dry chemical, carbon dioxide or foams as appropriate for surrounding fire and materials.

#### 5.2. Special hazards arising from the substance or mixture

Hazardous decomposition: No hazardous decomposition data available.

#### 5.3. Advice for fire-fighters

This material is assumed to be combustible. As with all dry powders, it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity.

As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

ERG Guide No. ----

### 6. Accidental release measures

#### 6.1. Personal precautions, protective equipment and emergency procedures

Put on appropriate personal protective equipment (see section 8).

#### 6.2. Environmental precautions

Do not allow spills to enter drains or waterways.

Use good personal hygiene practices. Wash hands before eating, drinking, smoking or using toilet. Promptly remove soiled clothing and wash thoroughly before reuse.

#### 6.3. Methods and material for containment and cleaning up

Soak up with sawdust, sand, oil dry or other absorbent material.

### 7. Handling and storage

#### 7.1. Precautions for safe handling

See section 2 for further details. - [Prevention]:

#### 7.2. Conditions for safe storage, including any incompatibilities

Do not store or consume food, drink, or tobacco in areas where they may become contaminated with this material. Avoid excessive heat. Protect from freezing. Recommended storage at room temperature 25 deg C (77 deg F); however, brief exposure up to 40 deg C (104 deg F) does not adversely affect the product.

Exposure to prolonged adverse storage conditions may result in a change to a turbid deep brown or the formation of a crystalline precipitate.

Incompatible materials: No data available.

See section 2 for further details. - [Storage]:

#### 7.3. Specific end use(s)

No data available.

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### 8. Exposure controls and personal protection

#### 8.1. Control parameters

##### Exposure

CAS No.	Ingredient	Source	Value
0007647-14-5	Sodium chloride	OSHA	No Established Limit
		ACGIH	No Established Limit
		NIOSH	No Established Limit
		Supplier	No Established Limit
0009005-27-0	Starch, 2-hydroxyethyl ether	OSHA	No Established Limit
		ACGIH	No Established Limit
		NIOSH	No Established Limit
		Supplier	No Established Limit

#### Carcinogen Data

CAS No.	Ingredient	Source	Value
0007647-14-5	Sodium chloride	OSHA	Select Carcinogen: No
		NTP	Known: No; Suspected: No
		IARC	Group 1: No; Group 2a: No; Group 2b: No; Group 3: No; Group 4: No;
0009005-27-0	Starch, 2-hydroxyethyl ether	OSHA	Select Carcinogen: No
		NTP	Known: No; Suspected: No
		IARC	Group 1: No; Group 2a: No; Group 2b: No; Group 3: No; Group 4: No;

#### 8.2. Exposure controls

##### Respiratory

Wear an appropriate NIOSH/MSHA approved air purifying respirator or positive pressure air supplied respirator in situations where a respirator is judged appropriate.

##### Eyes

Wear safety glasses. Wear full face protection, when judged that the possibility exists for eye and face contact due to spraying/splashing of solutions.

##### Skin

Wear impervious clothing made from Neoprene or Tyvek, such as gloves, apron, boots, jumpsuit, or whole bodysuit, as appropriate. Rubber (use non-latex gloves if possible).

##### Engineering Controls

Provide adequate ventilation. Where reasonably practicable this should be achieved by the use of local exhaust ventilation and good general extraction. If these are not sufficient to maintain concentrations of particulates and any vapor below occupational exposure limits suitable respiratory protection must be worn.

##### Other Work Practices

No special ventilation required. Use good personal hygiene practices. Wash hands before eating, drinking, smoking or using toilet. Promptly remove soiled clothing and wash thoroughly before reuse.

See section 2 for further details. - [Prevention]:

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### 9. Physical and chemical properties

Appearance	Clear, Pale Yellow to Amber Liquid
Odor	Unknown
Odor threshold	Not Measured
pH	3.5-7.0
Melting point / freezing point	Not Measured
Initial boiling point and boiling range	Not Measured
Flash Point	Not Measured
Evaporation rate (Ether = 1)	Not Measured
Flammability (solid, gas)	Not Applicable
Upper/lower flammability or explosive limits	<b>Lower Explosive Limit:</b> Not Measured <b>Upper Explosive Limit:</b> Not Measured
Vapor pressure (Pa)	Not Measured
Vapor Density	Not Measured
Specific Gravity	Not Measured
Solubility in Water	Miscible
Partition coefficient n-octanol/water (Log Kow)	Not Measured
Auto-ignition temperature	Not Measured
Decomposition temperature	Not Measured
Viscosity (cSt)	Not Measured
% Volatile	93.1%

#### 9.2. Other information

No other relevant information.

### 10. Stability and reactivity

#### 10.1. Reactivity

Hazardous Polymerization will not occur.

#### 10.2. Chemical stability

Stable under normal circumstances.

#### 10.3. Possibility of hazardous reactions

No data available.

#### 10.4. Conditions to avoid

Avoid exposure to light and heat.

#### 10.5. Incompatible materials

No data available.

#### 10.6. Hazardous decomposition products

No hazardous decomposition data available.

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### 11. Toxicological information

#### Acute toxicity

Ingredient	Oral LD50, mg/kg	Skin LD50, mg/kg	Inhalation Vapor LC50, mg/L/4hr	Inhalation Dust/Mist LC50, mg/L/4hr	Inhalation Gas LC50, ppm
Starch, 2-hydroxyethyl ether - (9005-27-0)	No data available	No data available	No data available	No data available	No data available
Sodium chloride - (7647-14-5)	3,550.00, Rat - Category: 5	10,000.00, Rabbit - Category: NA	No data available	No data available	No data available

Note: When no route specific LD50 data is available for an acute toxin, the converted acute toxicity point estimate was used in the calculation of the product's ATE (Acute Toxicity Estimate).

Classification	Category	Hazard Description
Acute toxicity (oral)	---	Not Applicable
Acute toxicity (dermal)	---	Not Applicable
Acute toxicity (inhalation)	---	Not Applicable
Skin corrosion/irritation	---	Not Applicable
Serious eye damage/irritation	---	Not Applicable
Respiratory sensitization	---	Not Applicable
Skin sensitization	---	Not Applicable
Germ cell mutagenicity	---	Not Applicable
Carcinogenicity	---	Not Applicable
Reproductive toxicity	---	Not Applicable
STOT-single exposure	---	Not Applicable
STOT-repeated exposure	---	Not Applicable
Aspiration hazard	---	Not Applicable

### 12. Ecological information

#### 12.1. Toxicity

No additional information provided for this product. See Section 3 for chemical specific data.

#### Aquatic Ecotoxicity

Ingredient	96 hr LC50 fish, mg/l	48 hr EC50 crustacea, mg/l	ErC50 algae, mg/l
Starch, 2-hydroxyethyl ether - (9005-27-0)	Not Available	Not Available	Not Available

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Sodium chloride - (7647-14-5)

1,100.00, Freshwater Fish

3,310.00, Daphnia magna

Not Available

### 12.2. Persistence and degradability

There is no data available on the preparation itself.

### 12.3. Bioaccumulative potential

Not Measured

### 12.4. Mobility in soil

No data available.

### 12.5. Results of PBT and vPvB assessment

This product contains no PBT/vPvB chemicals.

### 12.6. Other adverse effects

No data available.

## 13. Disposal considerations

### 13.1. Waste treatment methods

Observe all federal, state and local regulations when disposing of this substance.

## 14. Transport information

	DOT (Domestic Surface Transportation)	IMO / IMDG (Ocean Transportation)	ICAO/IATA
14.1. UN number	Not Applicable	Not Regulated	Not Regulated
14.2. UN proper shipping name	Not Regulated	Not Regulated	Not Regulated
14.3. Transport hazard class(es)	DOT Hazard Class: Not Applicable	IMDG: Not Applicable Sub Class: Not Applicable	Air Class: Not Applicable
14.4. Packing group	Not Applicable	Not Applicable	Not Applicable
14.5. Environmental hazards			
IMDG	Marine Pollutant: No		
14.6. Special precautions for user	No further information		

## 15. Regulatory information

### Regulatory Overview

The regulatory data in Section 15 is not intended to be all-inclusive, only selected regulations are represented.

### Toxic Substance Control Act (TSCA)

All components of this material are either listed or exempt from listing on the TSCA Inventory.

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**WHMIS Classification** Not Regulated

**US EPA Tier II Hazards**

**Fire:** No

**Sudden Release of Pressure:** No

**Reactive:** No

**Immediate (Acute):** No

**Delayed (Chronic):** No

**EPCRA 311/312 Chemicals and RQs:**

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

**EPCRA 302 Extremely Hazardous:**

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

**EPCRA 313 Toxic Chemicals:**

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

**Proposition 65 - Carcinogens (>0.0%):**

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

**Proposition 65 - Developmental Toxins (>0.0%):**

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

**Proposition 65 - Female Repro Toxins (>0.0%):**

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

**Proposition 65 - Male Repro Toxins (>0.0%):**

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

**New Jersey RTK Substances (>1%) :**

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

**Pennsylvania RTK Substances (>1%) :**

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

## 16. Other information

The information provided in this SDS is intended to be used in the handling of this material in the work place. This SDS is not a substitute for the direction for use of product literature that may accompany the finished product. All information contained in this SDS has been assembled from other published documents and are assumed to be accurate. In the event of an adverse incident associated with this material, this SDS is not intended to be a substitute for consultation with appropriately qualified personnel.

The full text of the phrases appearing in section 3 is: Not applicable

**This is the first version in the GHS SDS format. Listings of changes from previous versions in other formats are not applicable.**

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