

# SAFETY DATA SHEET



Revision date: 13-May-2019

Version: 1.0

## 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

### Product Identifier

**Material Name:** HYDRAVOL IV™

**Trade Name:** HYDRAVOL IV™

**Generic Name:** 6% hydroxyethyl starch 130/0.4 in 0.9% Sodium Chloride Injection

**Chemical Family:** Mixture

### Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

**Intended Use:** Veterinary product

**Restrictions on Use:** Not for human use

### Details of the Supplier of the Safety Data Sheet

Vedco, Inc.  
St. Joseph, MO 64507 USA  
Telephone: (816) 238-8840  
FAX: (888) 708-3326

## 2. HAZARDS IDENTIFICATION

**Appearance:** Colorless to slightly yellow liquid

### Classification of the Substance or Mixture

**GHS - Classification** Not classified as hazardous

### Label Elements

**Signal Word:** Not Classified

**Hazard Statements:** Non-hazardous in accordance with international standards for workplace safety.

### Other Hazards

**Short Term:** Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions. Signs and symptoms might include skin rash, itching, redness or swelling. Respiratory reactions may be characterized by rhinitis, sneezing, scratchy throat, oral mucosal edema, laryngeal mucosal edema, coughing, shortness of breath, wheezing, and chest pain. Asthma like reactions occur with acute exposures in sensitized patients. If an allergic reaction occurs, the worker should be removed to the nearest emergency room and the appropriate therapy instituted. May cause eye irritation; May cause slight irritation (based on components) .

## SAFETY DATA SHEET

Material Name: HYDRAVOL IV™  
Revision date: 13-May-2019

Version: 1.0

### Known Clinical Effects:

Products containing hydroxyethyl starch may lead to anaphylactoid reactions (hypersensitivity, mild influenza-like symptoms, bradycardia, tachycardia, bronchospasm, non-cardiac pulmonary edema). In the event of an intolerance reaction, handling or contact should be discontinued immediately and the appropriate emergency medical treatment initiated. Prolonged contact with high doses of hydroxyethyl starch may cause pruritus (itching) which is an undesirable effect observed with all hydroxyethyl starches.

### Australian Hazard Classification (NOHSC):

Non-Hazardous Substance. Non-Dangerous Goods.

### Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Sodium chloride	7647-14-5	231-598-3	Not Listed	0.9

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Hydroxyethyl starch	9005-27-0	Not Listed	Not Listed	6
Water for injection	7732-18-5	231-791-2	Not Listed	90 - 95

### Additional Information:

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

## 4. FIRST AID MEASURES

### Description of First Aid Measures

#### Eye Contact:

Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

#### Skin Contact:

Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

#### Ingestion:

Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

#### Inhalation:

Remove to fresh air and keep patient at rest. Seek medical attention immediately.

### Most Important Symptoms and Effects, Both Acute and Delayed

#### Symptoms and Effects of Exposure:

For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

#### Medical Conditions

#### Aggravated by Exposure:

Individuals with a known history of hypersensitivity to this material or other materials in its chemical class and individuals with impaired kidney function are more susceptible to toxicity in cases of overexposure. Individuals with cardiac conditions may be more susceptible to toxicity in cases of overexposure.

### Indication of the Immediate Medical Attention and Special Treatment Needed

## SAFETY DATA SHEET

Material Name: HYDRAVOL IV™  
Revision date: 13-May-2019

Version: 1.0

Notes to Physician: None

### 5. FIRE-FIGHTING MEASURES

**Extinguishing Media:** Extinguish fires with CO<sub>2</sub>, extinguishing powder, foam, or water.

**Special Hazards Arising from the Substance or Mixture**

**Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.

**Fire / Explosion Hazards:** Not flammable.

**Advice for Fire-Fighters**

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

**Additional Information:** This product is a nonflammable aqueous solution.

### 6. ACCIDENTAL RELEASE MEASURES

**Personal Precautions, Protective Equipment and Emergency Procedures**

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

**Environmental Precautions**

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

**Methods and Material for Containment and Cleaning Up**

**Measures for Cleaning / Collecting:** Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

**Additional Consideration for Large Spills:** Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

### 7. HANDLING AND STORAGE

**Precautions for Safe Handling**

When handling, use appropriate personal protective equipment (see Section 8). Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Avoid accidental injection. Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided.

**Conditions for Safe Storage, Including any Incompatibilities**

**Storage Conditions:** Keep in a dry, cool and well-ventilated place. Keep away from direct sunlight. Protect from freezing.

**Specific end use(s):** Veterinary product indicated for the treatment and prophylaxis of hypovolemia. It is not a substitute for red blood cells or coagulation factors in plasma.

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Control Parameters**

Refer to available public information for specific member state Occupational Exposure Limits.

**Sodium chloride**

Latvia OEL - TWA	5 mg/m <sup>3</sup>
Lithuania OEL - TWA	5 mg/m <sup>3</sup>

**Exposure Controls**

## SAFETY DATA SHEET

Material Name: HYDRAVOL IV™  
Revision date: 13-May-2019

Version: 1.0

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<b>Engineering Controls:</b>	Engineering controls should be used as the primary means to control exposures.
<b>Personal Protective Equipment:</b>	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
<b>Hands:</b>	Wear impervious gloves if skin contact is possible.
<b>Eyes:</b>	Safety glasses or goggles
<b>Skin:</b>	Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.
<b>Respiratory protection:</b>	Whenever air contamination (mist or aerosol) is generated, respiratory protection is recommended as a precaution to minimize exposure. If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b>	Liquid	<b>Color:</b>	Colorless to light yellow
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture
<b>Solvent Solubility:</b>	No data available		
<b>Water Solubility:</b>	Soluble		
<b>pH:</b>	7.2 - 7.8		
<b>Melting/Freezing Point (°C):</b>	No data available		
<b>Boiling Point (°C):</b>	No data available.		
<b>Partition Coefficient: (Method, pH, Endpoint, Value)</b>			
No data available			
<b>Decomposition Temperature (°C):</b>	No data available.		
<b>Evaporation Rate (Gram/s):</b>	No data available		
<b>Vapor Pressure (kPa):</b>	No data available		
<b>Vapor Density (g/ml):</b>	No data available		
<b>Relative Density:</b>	No data available		
<b>Viscosity:</b>	No data available		
<b>Flammability:</b>			
<b>Autoignition Temperature (Solid) (°C):</b>		No data available	
<b>Flammability (Solids):</b>		No data available	
<b>Flash Point (Liquid) (°C):</b>		No data available	
<b>Upper Explosive Limits (Liquid) (% by Vol.):</b>		No data available	
<b>Lower Explosive Limits (Liquid) (% by Vol.):</b>		No data available	

### 10. STABILITY AND REACTIVITY

<b>Reactivity:</b>	No data available
<b>Chemical Stability:</b>	Stable under normal conditions of use.
<b>Possibility of Hazardous Reactions</b>	
<b>Oxidizing Properties:</b>	No data available
<b>Conditions to Avoid:</b>	Fine particles (such as dust and mists) may fuel fires/explosions.
<b>Incompatible Materials:</b>	As a precautionary measure, keep away from strong oxidizers
<b>Hazardous Decomposition Products:</b>	No data available

## SAFETY DATA SHEET

Material Name: HYDRAVOL IV™

Revision date: 13-May-2019

Version: 1.0

### 11. TOXICOLOGICAL INFORMATION

#### Information on Toxicological Effects

##### General Information:

The information in this section describes the potential hazards of the individual ingredients and the formulation. Toxicological properties of the formulation have not been fully investigated. Routes of exposure: eye contact , skin contact

##### Acute Toxicity: (Species, Route, End Point, Dose)

###### Sodium chloride

Rat Oral LD50 3000 mg/kg

Mouse Oral LD50 4000 mg/kg

###### Hydroxyethyl starch

Rat Oral LD50 > 50 g/kg

##### Inhalation Acute Toxicity

Allergic reactions might occur based on effects of the individual components.

##### Irritation / Sensitization: (Study Type, Species, Severity)

###### Sodium chloride

Eye Irritation Rabbit Moderate

Skin Irritation Rabbit Mild

##### Irritation / Sensitization Comments:

May cause eye irritation based on components.

##### Skin Irritation / Sensitization

May cause mild skin irritation. based on components. May cause allergic reactions in susceptible individuals.

##### Carcinogen Status:

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

##### Product Level Toxicity Data

##### Reproductive & Development Toxicity Comments:

In reproduction studies in rats and rabbits, an analogous product had no teratogenic properties. Embryolethal effects were observed in rabbits at 5 g/kg body weight/day. In rats, bolus injection of this dose during pregnancy and lactation reduced body weight of offspring and induced developmental delays. All adverse effects were seen exclusively at maternal toxic doses due to fluid overload.

##### Genetic Toxicity

###### Study Type

Bacterial Mutagenicity (Ames)

*In Vitro* Mammalian Cell Mutagenicity

*In Vitro* Chromosome Aberration

*In Vivo* Cytogenetics

###### Cell Type / Organism

*Salmonella*

Not reported

Human Lymphocytes

Rat

###### Result

Negative

Negative

Negative

Negative

##### Genetic Toxicity Comments:

The genetic toxicity studies noted above were conducted on an analogous product.

## SAFETY DATA SHEET

Material Name: HYDRAVOL IV™  
Revision date: 13-May-2019

Version: 1.0

### 12. ECOLOGICAL INFORMATION

<b>Environmental Overview:</b>	Environmental properties have not been investigated. Releases to the environment should be avoided.
<b>Toxicity:</b>	No data available
<b>Persistence and Degradability:</b>	No data available
<b>Bio-accumulative Potential:</b>	No data available
<b>Mobility in Soil:</b>	No data available

### 13. DISPOSAL CONSIDERATIONS

<b>Waste Treatment Methods:</b>	Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.
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### 14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

### 15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

**Canada - WHMIS: Classifications**

**WHMIS hazard class:**

Non-controlled

This product has been classified in accordance with the hazard criteria of the CPR and the SDS contains all of the information required by the CPR.

**Sodium chloride**

CERCLA/SARA 313 Emission reporting  
California Proposition 65

Not Listed  
Not Listed

## SAFETY DATA SHEET

Material Name: HYDRAVOL IV™  
Revision date: 13-May-2019

Version: 1.0

### 15. REGULATORY INFORMATION

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-598-3

#### Hydroxyethyl starch

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

#### Water for injection

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

### 16. OTHER INFORMATION

**Data Sources:** The data contained in this SDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

**Prepared by:** VEDCO Inc.

VEDCO Inc. believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

**End of Safety Data Sheet**

Manufactured for:



Vedco, Inc.  
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For a copy of the Safety Data Sheet (SDS) or to report adverse reactions call Vedco, Inc.  
Customer service at 1(888) 708-3326.  
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**CAUTION: Federal Law (U.S.) restricts this drug to use by or on the order of a licensed veterinarian.**