



# HighPrep™ DTR (CE/IVD) Safety Data Sheet

According to Federal Register/ Vol. 77, No. 58/ Monday, March 26, 2012/ Rules and Regulations According to Regulation (EC) No. 1907/2006

# Section 1: Identification of the Substance/Mixture and of the Company/Undertaking

#### 1.1 Product Identifier

**Product Name:** HighPrep<sup>™</sup> DTR (CE/IVD)

Product Number: DT-70001, DT-70005, DT-70050, DT-70250, DT-70500

#### 1.2 Intended Use for the Product:

Use of the substance/mixture: For in vitro diagnostic use

#### 1.3 Name, Address, and Telephone of the Responsible Party

# Manufacturer/Supplier:

MagBio Genomics, Inc. 944 Clopper Road Gaithersburg, MD 20879 USA (301) 302-0144

#### **EU Importer:**

MagBio Genomics Europe GmbH Nelkenstrasse 5 76703 Kraichtal Germany +49 7250 33 13 403

#### **Emergency telephone number:**

US: In case of medical emergency, call 911. Contact your local Poison Control Center.

Europe: Chemtrec Emergency Tel No. (001) 703-527-3887

# **Section 2: Hazards Identification**

#### 2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

#### 2.2 Label Elements

#### Labelling according to Regulation (EC) No 1272/2008

Pictogram N/A Signal Word N/A Warning N/A

Hazard statement(s)nonePrecautionary statement(s)noneSupplemental Hazard Statementsnone

# 2.3 Other hazards

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This substance/mixture contains no components considered to be either persistent, bio-accumulative and toxic (PBT), or very persistent and very bio accumulative (vPvB) at levels of 0.1% or higher.

# **Section 3: Composition/information on ingredients**

Hazardous Ingredients		Hazard Classification of Pure Ingredients	
Chemical Name	% by weight	EU 1272/2008 CLP/GHS	GHS
N/A	N/A	N/A	N/A

#### **Description of hazard Class and hazard statements**

There are no ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

# **Section 4: First aid measures**

#### 4.1 Description of first aid measures

First Aid Measures General: Wear protective gloves/protective clothing/eye protection/face protection.

**First Aid Measures after Inhalation:** If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

**First Aid Measures after Skin Contact:** In case of skin contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes. If pain or irritation occurs, obtain medical attention.

**First Aid Measures after Eye Contact:** If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occurs, obtain medical attention.

**First Aid Measures after Ingestion:** If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

#### 4.2 Most Important Symptoms and Effects, both acute and delayed

The known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11.

# 4.3 Indication of any medical attention and special treatment needed

If medical advice is needed, have product container or label at hand.

#### **Section 5: Firefighting Measures**

#### 5.1 Extinguishing media

Suitable extinguishing media: Use water spray, alcohol-resistant foam, dry chemical, or carbon dioxide.

# 5.2 Special Hazards arising from the substance or mixture

Flammability: Not flammable or combustible

Hazardous Combustion Products: No combustion products posing significant hazards are expected from this product.

#### 5.3 Advice for Firefighters

**Protection during firefighting:** Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

# **Section 6: Accidental release measures**

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

General Measures: Use good laboratory procedures, avoid eye and skin contact

# 6.2 Environmental Precautions

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Contain spill to prevent migration

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

Absorb spilled material with an appropriate inert, non-flammable absorbent and dispose of according to local regulations.

#### 6.4 Reference to other sections

See heading 8, Exposure Controls and Personnel Protection

# **Section 7: Handling and Storage**

# 7.1 Precautions for safe handling

Use good laboratory procedures, avoid eye and skin contact.

# 7.2 Conditions for safe storage, including any incompatibilities

**Storage conditions:** Keep away from incompatible materials. To maintain efficacy, store according to the instructions on product labeling.

#### 7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated.

# Section 8: Exposure controls/ personal protection

8.1 Exposure Lim	nits
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**US OSHA** None established

**ACGIH** 

Sodium Azide 0.29 mg/m3 Ceiling (as Sodium azide); 0.11 ppm Ceiling (as Hydrazoic acid vapor)

CAS # 26628-22-8

**DFG MAK** 

Sodium Azide 0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)

CAS # 26628-22-8

**Ireland** 

Sodium Azide 0.1 mg/m3 TWA; 0.3 mg/m3 STEL; Potential for cutaneous absorption

CAS # 26628-22-8

**IOELVs** 

Sodium Azide Possibility of significant uptake through the skin; 0.3mg/m3STEL; 0.1mg/m3 TWA

CAS # 26628-22-8

NIOSH None established

**Japan** None established

# Sweden (AFS 2015:7 and amendments)

Sodium Azide 0.1 mg/m3 TLV; 0.3 mg/m3 Binding STE

CAS # 26628-22-8

**8.2 Exposure Controls** This product does not contain any substances with occupational exposure limit values.

**8.3** Respiratory Protection Where risk assessment shows air-purifying respirators are

appropriate use a full-face respirator with multi-purpose

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combination (US) or type ABEK (EN 14387) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

**8.4** Hand Protection Use gloves when handling this product. Inspect gloves prior to

use for any visible damage. Use proper glove removal technique to prevent contact with skin. Dispose of gloves in accordance with applicable laws. Wash and dry hands after use. The selected protective gloves must satisfy the specifications of Regulation (EU)2016/425 and the standard EN 374 derived

from it.

**8.5** Eye Protection Safety glasses with side-shields conforming to EN166 Use

equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN

166(EU).

**8.6 Skin and Body Protection** Wear appropriate laboratory attire when handling this product

such as gloves, long pants, closed-toe shoes, and laboratory

coat.

**8.7 Hygiene Measures** Avoid contact with eyes, skin, and clothing. Wash hands

thoroughly after using this product.







# **Section 9: Physical and Chemical Properties**

#### 9.1 Information on basic physical and chemical properties

Physical State Liquid

**Color** Clear, with brown precipitate

**Odor** Odorless

**Odor Threshold** No data available No data available рΗ Relative evaporation rate No data available No data available **Melting Point Freezing Point** No data available **Boiling Point** No data available **Flash Point** No data available **Auto-ignition temperature** No data available **Decomposition Temperature** No data available No data available Flammability (Solid, Gas) **Vapor Pressure** No data available Relative vapor density at 20°C No data available **Relative Density** No data available Density No data available Solubility No data available

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Log PowNo data availableLog KowNo data availableViscosity, kinematicNo data availableViscosity, dynamicNo data availableExplosive propertiesNo data available

# Section 10: Stability and reactivity

- **10.1 Reactivity:** No data available
- 10.2 Chemical Stability: Stable under recommended storage conditions
- 10.3 Possibility of Hazardous Reactions: No data available
- 10.4 Conditions to Avoid: No data available10.5 Incompatible Materials: None known
- 10.6 Hazardous Decomposition Products: In the event of fire: see section 5

# **Section 11: Toxicological Information**

# 11.1 Information on Toxicological Effects Toxicity Data for Hazardous Ingredients

Sodium Azide Dermal LD50 Rabbit 20 mg/kg; Oral LD50 Rat 27 mg/kg

CAS # 26628-22-8

**Acute Toxicity:** 

Skin Corrosion/Irritation: No data available Serious Eye Damage/Irritation: No data available Respiratory or Skin Sensation: No data available Germ Cell Mutagenicity: No data available

Carcinogenicity:

IARC: No component of this product that is present at levels greater than or equal to 0.1% is identified as

probable, possible or confirmed human carcinogen by IARC.

Reproductive Toxicity: No data available

Specific Target Organ Toxicity (Single Exposure) No data available Specific Target Organ Toxicity (Repeated Exposure) No data available

Aspiration hazard: No data available

**Potential Health Effects** 

Inhalation: n/a Ingestion: n/a Skin: n/a Eyes: n/a

# **Section 12: Ecological Information**

#### **12.1 Ecotoxicity**: no data available

**Fresh Water Species** 

Sodium Azide 96 h LC50 Oncorhynchus mykiss: 0.8 mg/L; 96 h LC50 Lepomis macrochirus: 0.7 mg/L; 96 h LC50

Pimephales promelas: 5.46 mg/L [flow-through]

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MicrotoxNo data available.Water FleaNo data available.Fresh Water AlgaeNo data available.

- 12.2 Persistence and Degradability: No data available.
- **12.3 Bio accumulative Potential:** No data available.
- **12.4 Mobility in Soil**: No data available.
- **12.5** Other Adverse Effects: No data available.
- **12.6 Results of PBT and vPvB assessment:** This substance/mixture contains no components considered to be either persistent, bio accumulative and toxic (PBT), or very persistent and very bio accumulative (vPvB) at levels of 0.1% or higher.
- **12.7 Other adverse effects:** This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

# **Section 13: Disposal Considerations**

- **13.1 Product Disposal:** Disposal should be in accordance with applicable regional, national, and local laws and regulations. Refer to Section 7: Handling and Storage and Section 8: Exposure Control/Personal Protection for additional handling information and protection of employees. Offer surplus and non-recyclable solutions to a licensed disposal company. Waste material must be disposed of in accordance with the Directive on waste 2008/98/EC as well as other national and local regulations. Leave chemicals in original containers. No mixing with other waste. Handle uncleaned containers like the product itself. Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76). To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.
- **13.2** Contaminated Packaging: Disposal must be made according to official regulations.

# **Section 14: Transport Information**

14.1 UN number

ADR/RID: - IMDG: - IATA: -

14.2 UN proper shipping name

ADR/RID: Not dangerous goods IMDG: Not dangerous goods IATA: Not dangerous goods

14.3 Transport hazard class(es)

ADR/RID: - IMDG: - IATA: -

14.4 Packaging group

ADR/RID: - IMDG: - IATA: -

14.5 Environmental hazards

ADR/RID: no IMDG Marine pollutant: no IATA: no

# **Section 15: Regulatory Information**

**EU Regulations** This SDS complies with EC Regulations 1907/2006 (REACH) and amendments. REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization - No ingredients listed.

SARA 302 Components: This material does not contain any components with a section 302 EHS TPQ.

**SARA 313 Components**: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

SARA 311/312 Hazards: Acute Health Hazard

**Massachusetts Right To Know Components**: No components are subject to the Massachusetts Right to Know Act. **Pennsylvania Right To Know Components**: Sodium Azide (CAS-No. 26628-22-8)

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New Jersey Right To Know Components: Sodium Azide (CAS-No. 26628-22-8)

# **Section 16: Other Information**

Magbio Genomics, Inc. does not make any representations, guaranties, or warranties as to the accuracy of the information provided and is intended only to describe the product for the purposes of health, safety, and environmental requirement. It is expressly understood and agreed that MagBio Genomics, Inc. shall in no way be deemed or held to be obligated, liable, or accountable upon or under any guaranties or warranties, express or implied, statutory, by operation of law, or otherwise, in any manner or form, including any implied warranty of merchantability or fitness for a particular purpose, that in any way relates to or arises out of the information provided in this Safety Data Sheet.