



SAFETY DATA SHEET

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

- 1.1 Product identifier**
Trade name Determine™ HIV-1/2 Ag/Ab Combo Controls, HIV-1 Control & HIV-2 Control
Reference No. 7D2628
- 1.2 Relevant identified uses of the substance or mixture and uses advised against**
Identified use(s) In vitro diagnostic reagent. For professional use only.
- 1.3 Details of the supplier of the safety data sheet**
Company Identification Abbott Diagnostics Scarborough, Inc.
10 Southgate Road
Scarborough, ME 04074 - United States
Telephone T +1 (207) 730-5750
E-Mail (competent person) ts.scr@abbott.com
- 1.4 Emergency telephone number**
Emergency Phone No. T +1 (800) 424-9300

SECTION 2: HAZARDS IDENTIFICATION

- 2.1 Classification of the substance or mixture**
Regulation (EC) No. 1272/2008 (CLP) Not classified as hazardous.
- 2.2 Label elements** No measures required.
- 2.3 Other hazards** Contains materials of human origin.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

- 3.2 Mixtures**
Description: In vitro diagnostic reagent. Aqueous preparation containing the hazardous components listed below.
- Dangerous components

Hazardous ingredient(s)	CAS No.	GHS Classification and Hazard Statement(s)	%W/W
Sodium azide	26628-22-8	Acute Tox. 2; H300 Acute Tox. 1; H310 STOT RE 2; H373 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 EUH032	< 0.1

- 3.3 Additional Information** For full text of H phrases see section 16.
Contains materials of human origin.
Biological materials of human origin contained in this product were tested for Anti-HCV, and HBs Ag on a single donor basis using FDA approved methods and were found to be nonreactive. Additionally the plasma was heat treated.

SECTION 4: FIRST AID MEASURES



- | | |
|--|---|
| 4.1 Description of first aid measures
Inhalation
Skin Contact
Eye Contact

Ingestion | Supply fresh air; consult doctor in case of complaint.
Wash skin with soap and water. Remove soiled clothing.
Rinse cautiously with water for several minutes. Consult a doctor in case of complaint.
Wash out mouth with water. Consult a doctor. |
| 4.2 Most important symptoms and effects, both acute and delayed | None. |
| 4.3 Indication of the immediate medical attention and special treatment needed | None. |

SECTION 5: FIRE-FIGHTING MEASURES

- | | |
|--|---|
| 5.1 Extinguishing media
Suitable Extinguishing Media | CO ₂ , powder or water spray. Fight larger fires with water spray or alcohol resistant foam. |
| 5.2 Special hazards arising from the substance or mixture | In case of fire, the following can be released: Carbon oxides (CO _x), nitrogen oxides (NO _x). |
| 5.3 Advice for fire-fighters | Use fire-extinguishing methods suitable to surrounding conditions.
Wear full protective suit and self-contained breathing apparatus (SCBA) when extinguishing fires. |

SECTION 6: ACCIDENTAL RELEASE MEASURES

- | | |
|--|--|
| 6.1 Personal precautions, protective equipment and emergency procedures | Isolate spillage and clean up immediately.
Refer to Section 8 for protective measures when handling the spillage. |
| 6.2 Environmental precautions | Avoid release to the environment. |
| 6.3 Methods and material for containment and cleaning up | Absorb with liquid-binding material (paper towelling, sand, diatomite, acid binders, universal binders, sawdust). Dispose of contaminated material as waste according to Section 13.
Swab down area with Chlorox or other disinfecting agent. |
| 6.4 Reference to other sections | 8, 13 |

SECTION 7: HANDLING AND STORAGE

- | | |
|--|---|
| 7.1 Precautions for safe handling | This product should be handled as a potentially infectious material, as no known test method / inactivation procedure can offer complete assurance that products derived from human blood will not transmit infectious agents.
Refer to US regulation 29 CFR 1910.1030 for information on handling biohazardous materials.
Avoid contact with the eyes, skin and mucous membranes.
Keep out of reach of children.
Wash hands before breaks and after work.
Clean work areas with hypochlorite or other disinfecting agent. |
|--|---|

SAFETY DATA SHEET

- 7.2 **Conditions for safe storage, including any incompatibilities** Store in the original container at 2 to 8°C.
- 7.3 **Specific end use(s)** Use as per instructions for use.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

8.1.1 Occupational Exposure Limits

SUBSTANCE.	CAS No.	LTEL (8 hr TWA ppm)	LTEL (8 hr TWA mg/m ³)	STEL (ppm)	STEL (mg/m ³)	Note:
Sodium azide	26628-22-8			0.11 (HN ₃)	0.29 (NaN ₃)	ACGIH TLV

Sk - Can be absorbed through skin.

8.2 Exposure controls

8.2.1 **Appropriate engineering controls** Not relevant for this material.

8.2.2 Personal protection equipment

Eye/face protection Safety glasses recommended.



Hand protection

Disposable gloves.



Material of gloves:

Latex / natural rubber, Nitrile rubber.

Penetration time of glove material:

Gloves resistance is not critical when the product is handled according to the instructions for use.

Body protection

Laboratory coat.

Respiratory protection

Face mask - recommended.

8.2.3 Environmental Exposure Controls

No special measures are required.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance	Liquid
Colour	Pale yellow.
Odour	No odour.
Odour Threshold (ppm)	Not applicable.
pH (Value)	7.5
Melting Point (°C) / Freezing Point (°C)	Not determined.
Boiling point/boiling range (°C):	Not determined.
Flash Point (°C)	Not applicable.
Evaporation rate (BA = 1)	Not determined.
Flammability (solid, gas)	Not applicable.
Explosive limit ranges	Not applicable.
Vapour Pressure (mm Hg)	Not determined.
Vapour Density (Air=1)	Not applicable.
Density (g/ml)	Not determined.
Solubility (Water)	Soluble.

SAFETY DATA SHEET

	Solubility (Other)	Not determined.
	Partition Coefficient (n-Octanol/water)	Not applicable.
	Auto Ignition Temperature (°C)	Not determined.
	Decomposition Temperature (°C)	Not determined.
	Viscosity (mPa.s)	Not determined.
	Explosive properties	Not explosive.
	Oxidising properties	Not oxidising.
9.2	Other information	Not available.

SECTION 10: STABILITY AND REACTIVITY

10.1	Reactivity	None known.
10.2	Chemical stability	The product is stable in accordance with the recommended storage conditions.
10.3	Possibility of hazardous reactions	Contact with acids may liberate trace amounts of toxic gas (hydrazoic acid). Hazardous polymerisation will not occur.
10.4	Conditions to avoid	None
10.5	Incompatible materials	Concentrated acids, heavy metals, metallic salts.
10.6	Hazardous Decomposition Product(s)	None known.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

11.1.2 Mixtures

Acute toxicity	Based upon the available data, the classification criteria are not met.
Skin corrosion/irritation	Based upon the available data, the classification criteria are not met.
Serious eye damage/irritation	Based upon the available data, the classification criteria are not met.
Respiratory/skin sensitization	Based upon the available data, the classification criteria are not met.
Germ cell mutagenicity	Based upon the available data, the classification criteria are not met.
Carcinogenicity	Based upon the available data, the classification criteria are not met.
Reproductive toxicity	Based upon the available data, the classification criteria are not met.
STOT-single exposure	Based upon the available data, the classification criteria are not met.
STOT-repeated exposure	Based upon the available data, the classification criteria are not met.
Aspiration hazard	Based upon the available data, the classification criteria are not met.

Health Effects and Symptoms

Skin Contact	No significant harmful effects anticipated.
Eye Contact	No significant harmful effects anticipated.
Ingestion	No significant harmful effects anticipated.

11.2	Other information	Not applicable.
-------------	--------------------------	-----------------



SAFETY DATA SHEET

SECTION 12: ECOLOGICAL INFORMATION

12.1	Toxicity	The product does not contain significant quantities of ingredients that are environmentally toxic.
12.2	Persistence and degradability	The product is unlikely to persist in the environment.
12.3	Bioaccumulative potential	None anticipated.
12.4	Mobility in soil	The product is predicted to have moderate mobility in soil.
12.5	Results of PBT and vPvB assessment	Not applicable.
12.6	Other adverse effects	Not applicable.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1	Waste treatment methods	
	Product:	Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.
	Packaging:	Disposal should be in accordance with local, state or national legislation. Contaminated packaging must be disposed of in the same manner as the product. Non-contaminated packaging materials may be recycled. Contact your local service providers for further information.

SECTION 14: TRANSPORT INFORMATION

14.1	UN number	Not applicable
14.2	UN Proper Shipping Name	Not applicable
14.3	Transport hazard class(es)	Not classified as dangerous for transport.
14.4	Packing Group	Not applicable
14.5	Environmental hazards	Not applicable
14.6	Special precautions for user	Not applicable
14.7	Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable

SECTION 15: REGULATORY INFORMATION

15.1	Safety, health and environmental regulations/legislation specific for the substance or mixture	OSHA Hazard Communication Standard 29 CFR 1910.1200 Consumer Product Safety Regulations 16 CFR 1600 IVD Product Labelling 21 CFR 809
	Carcinogen listings	
	IARC:	None of the ingredients is listed.
	NTP:	None of the ingredients is listed.
	ACGIH:	None of the ingredients is listed.
	OSHA:	None of the ingredients is listed.
	EPA:	None of the ingredients is listed.
	Californian Proposition 65	
	Chemicals known to cause cancer:	None of the ingredients is listed.
	Chemicals known to cause reproductive toxicity:	None of the ingredients is listed.
	SARA	



SAFETY DATA SHEET

Section 355 (extremely hazardous substances): Sodium azide.
Section 313 (specific toxic chemical listings): Sodium azide.

15.2 **Chemical Safety Assessment** Not applicable.

SECTION 16: OTHER INFORMATION

LEGEND

STOT Specific Target Organ Toxicity

Classification code(s):

Acute Tox. 1 Acute toxicity, Category 1
Acute Tox. 2 Acute toxicity, Category 2
STOT RE 2 Specific Target Organ Toxicity, repeat exposure, Category 2
Aquatic Acute 1 Hazardous to the aquatic environment, Acute, Category 1
Aquatic Chronic 1 Hazardous to the aquatic environment, Chronic, Category 1

Hazard statement(s)

H300: Fatal if swallowed.
H310: Fatal in contact with skin.
H373: May cause damage to organs through prolonged or repeated exposure.
H400: Very toxic to aquatic life.
H410: Very toxic to aquatic life with long lasting effects.

Additional Information

Prepared by: Dr. J. J. Tobin, ChemHaz Solutions, Email: info@chemhazsolutions.com

To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.