



SAFETY DATA SHEET

According to Regulation (EC) No. 1907/2006 (REACH), Annex II

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

- 1.1 Product identifier**
Trade name Alere Determine™ HIV-1/2 Ag/Ab Combo, Chase Buffer
- 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 Alere Scarborough, Inc.
10 Southgate Road
Scarborough, ME 04074 - United States
Telephone T +1 (207) 730-5750
E-Mail (competent person) ts.scr@alere.com
- 1.4 Emergency telephone number**
Emergency Phone No. T +1 (207) 730-5750

SECTION 2: HAZARDS IDENTIFICATION

- 2.1 Classification of the substance or mixture**
OSHA Hazard Communication Standard 29 CFR 1910.1200 (HazCom 2012) / GHS Not classified as hazardous.
- 2.2 Label elements** No measures required.
- 2.3 Other hazards** None anticipated.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

- 3.2 Mixtures**
Description: In vitro diagnostic reagent. Aqueous solution.
Dangerous components: The product does not contain reportable quantities of hazardous ingredients.

SECTION 4: FIRST AID MEASURES



- 4.1 Description of first aid measures**
Inhalation Supply fresh air; consult doctor in case of complaint.
Skin Contact Wash skin with soap and water. Remove soiled clothing.
Eye Contact Rinse cautiously with water for several minutes. Consult a doctor in case of complaint.
Ingestion Wash out mouth with water. Consult a doctor in case of complaint.
- 4.2 Most important symptoms and effects, both acute and delayed** None.
- 4.3 Indication of the immediate medical attention** None.

SAFETY DATA SHEET

According to Regulation (EC) No. 1907/2006 (REACH), Annex II

and special treatment needed

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: Phosphorous oxides (P _x O _y) |
| 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

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|--|---|
| 6.1 Personal precautions, protective equipment and emergency procedures | Refer to Section 8 for protective measures when handling the spillage. |
| 6.2 Environmental precautions | Do not allow the undiluted product to enter sewers/surface or ground water. |
| 6.3 Methods and material for containment and cleaning up | Adsorb spillages onto sand, earth or any suitable adsorbent material. Dispose of contaminated material as waste according to Section 13. Rinse off area with water. |
| 6.4 Reference to other sections | 8, 13 |

SECTION 7: HANDLING AND STORAGE

- | | |
|---|---|
| 7.1 Precautions for safe handling | Avoid contact with the eyes, skin and mucous membranes. Keep out of reach of children. Wash hands before breaks and after work. |
| 7.2 Conditions for safe storage, including any incompatibilities | Store in the original container at 2 to 30°C. |
| 7.3 Specific end use(s) | Use as per instructions for use. |

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

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|---|--|
| 8.1 Control parameters | |
| 8.1.1 Occupational Exposure Limits | The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace. |
| 8.2 Exposure controls | |
| 8.2.1 Appropriate engineering controls | Not relevant for this material. |
| 8.2.2 Personal protection equipment | |
| Eye/face protection | Not normally required. |
| 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. |



SAFETY DATA SHEET

According to Regulation (EC) No. 1907/2006 (REACH), Annex II

Respiratory protection

Not normally required.

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	Colourless.
Odour	No odour.
Odour Threshold (ppm)	Not applicable.
pH (Value)	7.4
Melting Point (°C) / Freezing Point (°C)	Similar to water, approximately 0°C.
Boiling point/boiling range (°C):	Similar to water, approximately 100°C.
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)	Similar to water, approximately 23 hPa.
Vapour Density (Air=1)	Not determined.
Density (g/ml)	1.01
Solubility (Water)	Completely miscible with water.Soluble.
Solubility (Other)	Not determined.
Partition Coefficient (n-Octanol/water)	Not determined.
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	None known. Hazardous polymerisation will not occur.
10.4 Conditions to avoid	None
10.5 Incompatible materials	None known.
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.
Irritation	Based upon the available data, the classification criteria are not met.
Corrosivity	Based upon the available data, the classification criteria are not met.
Sensitisation	Based upon the available data, the classification criteria are not met.



SAFETY DATA SHEET

According to Regulation (EC) No. 1907/2006 (REACH), Annex II

Repeated dose toxicity	No data
Carcinogenicity	Based upon the available data, the classification criteria are not met.
Mutagenicity	No data
Toxicity for reproduction	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

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	Contains inorganic phosphate
12.3 Bioaccumulative potential	None anticipated.
12.4 Mobility in soil	The product is predicted to have high 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:	Chemical residues and remains should be routinely handled as special waste. This must be disposed of 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. 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



SAFETY DATA SHEET

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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
Section 355 (extremely hazardous substances): None of the ingredients is listed.
Section 313 (specific toxic chemical listings): None of the ingredients is listed..

15.2 Chemical Safety Assessment Not applicable.

SECTION 16: OTHER INFORMATION

LEGEND

STOT Specific Target Organ Toxicity

References:

Raw material safety data sheets.

Additional Information

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