



SAFETY DATA SHEET

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

amended by Regulation (EU) 2020/878 Date of Issue:

13/10/2023

Revision date: 13/10/2023

Version: 6

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

1.1. Product identifier

Product form : Solid, Article

Trade Name : Determine HBsAg 2, Test Device

Reference No. : 7D2922 / 7D2923, 7D2942 / 7D2943, 7D2946 / 7D2947,

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

1.2.1. Relevant identified uses

Use of the substance/mixture : In vitro diagnostic reagent. For professional use only.

1.2.2. Uses Advised Against

Restrictions on use : -

1.3. Details of the supplier of the safety data sheet

Manufacturer

Ballybrit, Galway, Ireland, H91 VK7E

Abbott Diagnostics Medical Co., Ltd.

357 Matsuhidai, Matsudo-shi, Chiba

Europe: EME.TechSupport@abbott.com

270-2214, Japan Telephone:

Middle East: EME.TechSupport@abbott.com

+81 47 311 5750 E-Mail

(competent person):

Asia Pacific: AP.TechSupport@abbott.com

Africa: arcis.techsupport@abbott.com

Importer

Russia & CIS: arcis.techsupport@abbott.com

Abbott Rapid Dx International
Limited

Latin America: LA.TechSupport@abbott.com

Parkmore East Business Park,

1.4. Emergency telephone number

Emergency number : Europe: + (44) 161 483 9032

Middle East: +(965) 2202 2828

Asia Pacific: + (61) 7 3363 7711

Africa: + (27) 10 500 9700



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Russia & CIS: +(7) 499 403 9512

Latin America: +(57) 601 482 4033

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 [CLP]

Not classified as hazardous.

Adverse physicochemical, human health and environmental effects

Not applicable.

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard Pictogram(s) (CLP) : Not applicable

Signal Word(s) (CLP) : Not applicable.

Hazard Statement(s) (CLP) : Not applicable.

Precautionary Statement(s) (CLP) : Not applicable.

Precautionary Statement(s) (CLP) : Not applicable.

EUH-statements

2.3. Other hazards

Other hazards which do not result in : Not applicable.
classification



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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

Not applicable.

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No 1272/2008 [CLP]
Not applicable.	Not applicable.	Not applicable.	Not applicable.

Specific concentration limits:

Name	Product identifier	Specific concentration limits
Not applicable.	Not applicable.	Not applicable.

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

First-aid measures after inhalation : Supply fresh air; consult doctor in case of complaint.

First-aid measures after skin : Wash skin with soap and water. contact

First-aid measures after eye contact : Rinse cautiously with water for several minutes. Consult a doctor in case of complaint.

First-aid measures after ingestion : Wash out mouth with water. Consult a doctor.

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



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Symptoms/effects : None anticipated.

4.3. Indication of any immediate medical attention and special treatment needed

None.

SECTION 5: FIREFIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing media : CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

5.2. Special hazards arising from the substance or mixture

Fire hazard : Combustible but not readily ignited.

Hazardous decomposition products : Hazardous fumes, Carbon oxides (CO_x). in case of fire

5.3. Advice for fire-fighters

Firefighting instructions : Use fire-extinguishing methods suitable to surrounding conditions.

Protection during firefighting : 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

6.1.1. For non-emergency personnel

Emergency procedures : Refer to Section 8 for protective measures when handling the spillage.

6.1.2. For emergency responders

Protective Equipment : Refer to Section 8 for protective measures when handling the spillage.



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6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Collect material and dispose of as waste according to Section 13.
Other information : Not applicable.

6.4. Reference to other sections

8, 13

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

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 materials of human origin will not transmit infectious agents.
Avoid contact with the eyes, skin and mucous membranes.
Keep out of the reach of children.
Specimens should be handled as potentially infectious materials. Refer to Directive 2000/54/EC for information on handling biohazardous materials.

Hygiene Measures : Wash hands before breaks and after work.
Clean work areas with hypochlorite or other disinfecting agent.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in the original container at 2 to 30°C.
Incompatible materials : No data.

7.3. Specific end use(s)

In vitro diagnostic medical device.



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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

EU - Indicative Occupational Exposure Limit Value (IOELV)	
IOELV (8hr TWA)	-
IOELV STEL	-
Remark	-
Austria - Occupational Exposure Limits	
MAK (OEL TWA)	-
MAK (OEL STEL)	-
OEL chemical category	-
Belgium - Occupational Exposure Limits	
OEL chemical category	-
Bulgaria - Occupational Exposure Limits	
OEL TWA	-
OEL STEL	-
Croatia - Occupational Exposure Limits	



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GVI (OEL TWA) [1]	-
KGVI (OEL STEL)	-
OEL chemical category	-

Cyprus - Occupational Exposure Limits

OEL TWA	-
OEL STEL	-
OEL chemical category	-

Czech Republic - Occupational Exposure Limits

PEL (OEL TWA)	-
OEL chemical category	-

Denmark - Occupational Exposure Limits

OEL TWA [1]	-
OEL chemical category	-

Estonia - Occupational Exposure Limits

OEL TWA	-
OEL STEL	-
OEL chemical category	-



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Finland - Occupational Exposure Limits

HTP (OEL TWA) [1]	-
HTP (OEL STEL)	-
OEL chemical category	-

France - Occupational Exposure Limits

VME (OEL TWA)	-
VLE (OEL C/STEL)	-

OEL chemical category	-
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Germany - Occupational Exposure Limits (TRGS 900)

AGW (OEL TWA) [1]	-
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Gibraltar - Occupational Exposure Limits

OEL TWA	-
OEL STEL	-
OEL chemical category	-

Greece - Occupational Exposure Limits

OEL TWA	-
OEL TWA [ppm]	-



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OEL STEL	-
OEL STEL [ppm]	-
Hungary - Occupational Exposure Limits	
AK (OEL TWA)	-
CK (OEL STEL)	-
Ireland - Occupational Exposure Limits	
OEL TWA [1]	-
OEL STEL	-
OEL chemical category	-
Italy - Occupational Exposure Limits	
OEL TWA	-

OEL STEL	-
OEL chemical category	-
Latvia - Occupational Exposure Limits	
OEL TWA	-
OEL chemical category	-
Lithuania - Occupational Exposure Limits	



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IPRV (OEL TWA)	-
TPRV (OEL STEL)	-
OEL chemical category	-
Luxembourg - Occupational Exposure Limits	
OEL TWA	-
OEL STEL	-
OEL chemical category	-
Malta - Occupational Exposure Limits	
OEL TWA	-
OEL STEL	-
OEL chemical category	-
Netherlands - Occupational Exposure Limits	
TGG-8u (OEL TWA)	-
TGG-15min (OEL STEL)	-
MAC chemical category	-



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Poland - Occupational Exposure Limits

NDS (OEL TWA)

-

NDSch (OEL STEL)

-

Portugal - Occupational Exposure Limits

OEL TWA

-

OEL STEL

-

OEL C

-

OEL C [ppm]

-

OEL chemical category

-

Romania - Occupational Exposure Limits

OEL TWA

-

OEL STEL

-

OEL chemical category

-

Slovak Republic - Occupational Exposure Limits



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NPHV (OEL TWA) [1]	-
NPHV (OEL C)	-
OEL chemical category	-
Slovenia - Occupational Exposure Limits	
OEL TWA	-
OEL STEL	-
OEL chemical category	--

Spain - Occupational Exposure Limits	
VLA-ED (OEL TWA) [1]	-
VLA-EC (OEL STEL)	-
OEL chemical category	-
Sweden - Occupational Exposure Limits	
NGV (OEL TWA)	-
KTV (OEL STEL)	-
United Kingdom - Occupational Exposure Limits	
WEL TWA (OEL TWA) [1]	-
WEL STEL (OEL STEL)	-



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WEL chemical category	-
Norway - Occupational Exposure Limits	
Grenseverdi (OEL TWA) [1]	-
Korttidsverdi (OEL STEL)	-
Switzerland - Occupational Exposure Limits	
MAK (OEL TWA) [1]	-
KZGW (OEL STEL)	-
USA - ACGIH - Occupational Exposure Limits	
ACGIH OEL C	-
ACGIH OEL C [ppm]	-
ACGIH chemical category	-

8.1.2. Recommended monitoring method

Not applicable.

8.1.3. Air contaminants formed

Not applicable.

8.1.4. DNEL and PNEC

Not applicable.



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8.1.5. Control banding

Not applicable.

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Not relevant for this material.

8.2.2. Personal protection equipment

8.2.2.1. Eye and face protection

Eye Protection:

Safety glasses recommended. (EN166)

8.2.2.2. Skin protection

Skin and body protection:

Laboratory coat.

Hand protection:

Disposable gloves. (EN374).

8.2.2.3. Respiratory protection

Respiratory protection:

Not normally required.

8.2.2.4. Thermal hazards

Not applicable.

8.2.3. Environmental exposure controls

Environmental exposure controls:

No special measures are required.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES



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9.1. Information on basic physical and chemical properties

Physical state	: Solid.
Colour	: White.
Appearance	: Laminated test strip consisting of solid support materials impregnated with dried chemical / biochemical reagents.
Odour	: Odourless.
Odour threshold	: Not applicable.
Melting Point (°C)	: Not determined.
Freezing Point (°C)	: Not applicable.
Boiling Point (°C)	: Not determined.
Flammability	: Not flammable.
Explosive properties	: Not explosive.
Oxidising properties	: Not oxidising.
Explosive limits	: Not applicable.
Lower explosion limit	: Not applicable.
Upper explosion limit	: Not applicable.
Flash point	: Not applicable.
Auto-ignition temperature	: Not determined.
Decomposition Temperature	: Not determined.
pH	: Not determined.
Viscosity, kinematic	: Not applicable.
Solubility(ies)	: Not determined.



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Partition coefficient: n-: Not applicable.
octanol/water (log value)



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Vapour pressure	Not applicable.
Vapour pressure at 50 °C	: Not applicable.
Density (g/ml)	: Not determined.
Relative density	: Not determined.
Relative vapour density at 20 °C	: Not applicable.
Particle characteristics	: Not applicable.

9.2. Other information

9.2.1. Information with regard to physical hazard classes

Not applicable.

9.2.2. Other safety characteristics

No information 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 products

None known.

SECTION 11: TOXICOLOGICAL INFORMATION



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11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (Oral)	: Based upon the available data, the classification criteria are not met.
Acute toxicity (Dermal)	: Based upon the available data, the classification criteria are not met.
Acute toxicity (Inhalation)	: Based upon the available data, the classification criteria are not met.

LD50 oral rat	Not relevant for this material.

LD50 oral rat	
LD50 Dermal Rabbit	Not relevant for this material.

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 or skin sensitization	: Based upon the available data, the classification criteria are not met.



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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.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Adverse health effects caused by : No information available. endocrine disrupting properties

11.2.2. Other information

Not applicable.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - general : The product does not contain significant quantities of ingredients that are environmentally toxic.

Hazardous to the aquatic : Not classified. environment, Short Term (acute)

Hazardous to the aquatic : Not classified.
environment, Long Term (Chronic)



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LC50 - Fish [1]	Not relevant for this material.
LC50 - Fish [2]	Not relevant for this material.

12.2. Persistence and degradability

The product is likely to persist in the environment.

12.3. Bioaccumulative potential

	None anticipated.

12.4. Mobility in soil

The product is predicted to have low mobility in soil.

12.5. Results of PBT and vPvB assessment

	Not applicable.

12.6. Endocrine disrupting properties



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Adverse effects on the environment : Decomposition products (of Triton X-405): 4-tert-octylphenol caused by endocrine disrupting properties

12.7. Other adverse effects

Not applicable.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste treatment methods : Used devices and other contaminated materials should be disposed of as potentially biohazardous waste. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Contaminated 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

In accordance with: ADR / IMDG / IATA / ADN / RID

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
-	-	--		-
14.2. UN proper shipping name				
-	-	-	-	-
14.3. Transport hazard class(es)				



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:				
Not classified as dangerous for transport.	Not classified as dangerous for transport.	Not classified as dangerous for transport.	Not classified as dangerous for transport.	Not classified as dangerous for transport.
14.4. Packing group				
-	-	-	--	
14.5. Environmental hazards				
-	-	-	-	-
14.6. Special precautions for user				

Overland transport

Not applicable.

Transport by sea

Not applicable.

Air transport

Not applicable.

Inland waterway transport

Not applicable.

Rail transport

Not applicable.



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14.7. Maritime transport in bulk according to IMO instruments

Not applicable.

SECTION 15. REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

15.1.1. EU-Regulations

REACH Annex XVII (Restriction List)

Not applicable.

REACH Annex XIV (Authorisation List)

4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated – Triton X-405

REACH Candidate List (SVHC)

4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated – Triton X-405

PIC Regulation (Prior Informed Consent)

Not applicable.

POP Regulation (Persistent Organic Pollutants)

Not applicable.

Ozone Regulation (1005/2009)

Not applicable.

Explosives Precursors Regulation (2019/1148)

Not applicable.



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Drug Precursors Regulation (273/2004)

Not applicable.

15.2. Chemical Safety Assessment

Not applicable.

SECTION 16: OTHER INFORMATION

Indication of changes:

Update in accordance with Regulation (EU) 2020/878.

Full text of H- and EUH-statements:

-	-
-	-



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Abbreviations and acronyms:

STOT	Specific Target Organ Toxicity

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Data sources : Raw material safety data sheets.

Training advice : No special requirements.

Other information : Not applicable.

Safety Data Sheet (SDS), EU

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.