

Material Safety Data Sheet for Rapid Test kits
According to EC 1907/2006 (REACH), Annex II

Document Name: Rapid Test: MHCV-MD-MHIV-MC-AHP-AD Rev. 3 Effective date: 2016-06-13 CCN: 16/768

1. IDENTIFICATION OF SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

IDENTIFICATION OF THE PRODUCTS AND SUBSTANCE OR PREPARATION

Component	Product Name / Package Content					
	MP Diagnostics MULTISURE HCV Antibody Assay	MP Diagnostics MULTISURE HIV Rapid Test	MP Diagnostics MULTISURE Dengue Ag/Ab Rapid Test	MP Diagnostics MULTISURE HCV Confirmatory Test	MP Diagnostics ASSURE® H. pylori Rapid Test	MP Diagnostics ASSURE® Dengue IgA Rapid Test
Test device	20 test devices	20 test devices	20 test devices	20 test devices	20 test devices	20 test devices
Sample Applicator	20 pieces	20 pieces	20 pieces	20 pieces	20 pieces	20 pieces
Chase Buffer	1 bottle x 5ml	1 bottle x 5ml	1 bottle x 5ml	1 bottle x 5ml	1 bottle x 5ml	1 bottle x 5ml

USE OF THE SUBSTANCE/PREPARATION

The **Rapid Test** kits are qualitative immunochromatographic assay test devices for the rapid *in vitro* detection of specific antibodies and/or antigens in human whole blood, plasma or serum. It is intended for professional use as a rapid assay for the presence of specific disease antibodies and/or in patient samples.

COMPANY/UNDERTAKING IDENTIFICATION

Manufacturer : MP Biomedicals Asia Pacific Pte. Ltd.
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www.mpbio.com

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Eschwege, Germany
Tel: (+49) 5651 921 204
Fax.: (+49) 5651 921 181
Email: diagnostics@mpbio.com

Contact Person : Jan Gassmann

EMERGENCY TELEPHONE/CONTACT

European emergency number: 112

United Kingdom of Great Britain and Northern Ireland
National Poisons Information Service (Birmingham Unit)
City Hospital
Dudley Rd
Birmingham

Telephone number: +44 121 507 4123
Emergency telephone number: 844 892 0111
Fax: +44 121 507 55 88 **E-mail:** mail@npis.org

National Poisons Information Service Edinburgh
Scottish Poisons Information Bureau
Royal Infirmary
51 Little France Crescent
Edinburgh

Telephone number: +44 131 242 1383
Emergency telephone number: 844 892 0111
Fax: +44 131 242 13 87 **E-mail:** spib@luht.scot.nhs.uk

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Ireland

Poisons Information Centre of Ireland
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Emergency number: 999

Telephone number: +353 1 809 25 66
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+353 1 837 9964 (medical professionals)
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Fax: +353 1 836 84 76 **E-mail:** npicdublin@beaumont.ie

The Netherlands

National Poisons Information Centre, The Netherlands
University Medical Centre Utrecht
Postbus 85500
Utrecht

Telephone number: +31 88 755 85 61
Emergency telephone number: +31 30 274 88 88
Fax: +31 30 254 15 11 **E-mail:** nvic@umcutrecht.nl

Malta

Mater Dei Hospital
Msida MSD 2090
MALTA

Telephone number: 2545-0000
Fax: 2545 4154 **E-mail:** mdh@gov.mt

Australia

NSW Poisons Information Centre
Childrens Hospital Westmead
Hawkesbury Road
Sydney

Telephone number: +61 2 9845 3969
Emergency telephone number: 131126 (national calls)
Fax: +61 2 9845 3597 **E-mail:** www.poisonsinfo.nsw.gov.au


South Africa

Tygerberg Poison Information Centre
Division of Pharmacology, Department of Medicine
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Tygerberg

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Fax: +27 21 938 91 22 **E-mail:** caw@sun.ac.za

2. HAZARDS IDENTIFICATION

The product is not classified as hazardous pursuant to the provisions set forth in EC Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). However, since the product contains hazardous substances in concentrations such as to be declared in section no. 3, it requires a safety data sheet with appropriate information, compliant to EC Regulation 1907/2006 and subsequent amendments

Kit Component	Hazard Classification (EC Directive 1272/2008)			
	Signal Word	Hazard Symbols/Pictograms	Hazard Statements	Precautionary Statements
Test device	Not applicable	Not applicable	Not applicable	Not applicable
Sample Applicator	Not applicable	Not applicable	Not applicable	Not applicable
Chase Buffer	Warning		Health hazards: • H319 Supplementary Hazard EUH210	Prevention: P264, P280 Response: P305+P351+P338 P337+P313

Refer to section 16 for complete texts of hazard and precautionary statements.

Other hazards:

Not known

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3. COMPOSITION/INFORMATION OF INGREDIENTS

Kit Component	Hazardous component	EC No.	CAS No.	Hazardous classification (EC Directive 1272/2008) as pure substance	Composition Concentration (%)	Concentration Limit (%)
Chase Buffer	Sodium Azide (NaN ₃)	247-852-1	26628-22-8	Health Hazard • Acute Tox. 2; H300 Environmental Hazard • Aquatic Acute 1; H400 • Aquatic Chronic 1; H410 Supplementary Hazard • EUH032	≤0.1 %	0.1%
	p-tertiary-Octylphenoxy polyethyl alcohol (Triton X – 100)	Not available	9036-19-5	Health Hazard • Acute Tox. 4; H302 • Eye Irrit. 1; H318 Environmental Hazard • Aquatic Chronic 3; H412	1 %	0.1%

4. FIRST AID MEASURES

General information:

If signs of infection occur, seek medical attention. Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the incident.

Kit Component	Inhalation	Ingestion	Skin Contact	Eye Contact
Test Device	Only in case of fire, supply fresh air; consult doctor.	Not applicable	Not applicable	Not applicable
Sample Applicator	Not applicable	Not applicable	Not applicable	Not applicable
Chase buffer	Supply fresh air. If required, provide artificial respiration. Consult doctor if symptoms persist.	Seek medical treatment.	Wash well with soap and water. Rinse with water.	Rinse opened eye for several minutes under running water. Get medical attention if irritation persists.

Advise for physicians:

No special treatment. Treat symptomatically. In case of ingestion or inhalation of larger amounts, consult toxicologist.

Special treatment:

No data available

5. FIRE-FIGHTING MEASURES

• **Suitable extinguishing agents:**

- CO₂, extinguishing powder or water jet. Fight larger fires with water jet or alcohol-resistant foam.

• **Protective equipment :**

- Test Device / Chase buffer - Put on breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Kit Component	Personal Precaution	Environmental Precaution	Methods for Cleaning/collecting
Test Device	See "Exposure Controls and Personal Protection"	No Special measures required.	Collect mechanically

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Kit Component	Personal Precaution	Environmental Precaution	Methods for Cleaning/collecting
Sample Applicator	No Special measures required.		
Chase buffer	See "Exposure Controls and Personal Protection"	No Special measures required.	Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders and sawdust). Dispose of contaminated material as waste according to section on "Disposal Considerations"

7. HANDLING AND STORAGE

Kit Component	Handling	Storage
Test Device	<ul style="list-style-type: none"> No special precautions necessary if used correctly. No special measures required against explosions and fires. Keep away from alkalis, amines, strong acids, self-igniting and fire risk materials 	<ul style="list-style-type: none"> Refer to the package insert or product label for additional information on storage conditions. Keep away from sources of ignition. Take precautionary measures against static discharges. Avoid frictional heat, impact and shocks. Information about storage in one common storage facility: Not required. Store in cool place. (2 - 28°C). Protect from heat and direct sunlight.
Chase buffer	<ul style="list-style-type: none"> No special precautions necessary if used correctly. No special measures required against explosions and fires. 	<ul style="list-style-type: none"> Refer to the package insert or product label for additional information on storage conditions. Information about storage in one common storage facility: Not required. Store in cool place. (2 - 28°C). Protect from heat and direct sunlight.
Sample applicator	<ul style="list-style-type: none"> Information for safe handling: No special precautions necessary if used correctly. Information about protection against explosions and fires: No special measures required. 	<ul style="list-style-type: none"> Refer to the package insert or product label for additional information on storage conditions. Information about storage in one common storage facility: Not required. Store in cool place. (2 - 28°C). Protect from heat and direct sunlight.

8. EXPOSURE CONTROL/PERSONAL PROTECTION

General protective and hygienic measures:

- Engineering measures should be taken before personal protection equipment is necessary.
- It is recommended that human sourced materials should be handled according to good laboratory practices and safe handling procedures.
- Keep away from foodstuffs, beverages and food. Wash hands during breaks and at the end of the work. Avoid contact with the skin.

Personal protective equipment:

- Respiratory protection
Not necessary, if room is well ventilated.
- Hand protection
The gloves serve to protect the user against splashes. For safety reasons they should be changed immediately after wetting. Since the product is in fact a preparation out of several substances, no specific information can be given on the permeation breakthrough time. The choice of suitable gloves depends not only on the material, but also on other quality features and must, therefore, be checked with the respective manufacturer. As far as we know, disposable gloves, among other things out of nitriles, are suitable. Nevertheless, this recommendation is not intended to replace a suitability test, which is essential and must be carried out under the respective conditions of use.
- Eye protection
Safety glasses recommended.
- Skin protection
Laboratory coat and apron recommended.

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9. PHYSICAL AND CHEMICAL PROPERTIES

	Test Device	Sample Applicator	Chase buffer
Physical State	Solid	Solid	Fluid
Colour	White	Colourless	Colourless
Odour	Odourless	Odourless	Odourless
pH value at 25 ± 3°C	Not applicable	Not applicable	pH 8.0 ± 0.1
Ignition temperature	180°C	Not applicable	Not applicable
Flammability	Nitrocellulose membrane	Product is not self-igniting	Product is not self-igniting
Solubility in / Miscibility with water	Insoluble	Insoluble	Fully miscible

10. STABILITY AND REACTIVITY

Kit Component	Thermal decomposition / conditions to be avoided	Dangerous reactions	Dangerous products of decomposition
Test Device	<ul style="list-style-type: none"> Toxic fumes of carbon dioxide, carbon monoxide and sulfur oxides Keep away from heat, flames, sparks and other sources of ignition 	<ul style="list-style-type: none"> Incompatible to acids, alcohols, amines, bases, ketones, oxidising materials. 	<ul style="list-style-type: none"> Toxic fumes of carbon dioxide, carbon monoxide and sulfur oxides. Thermal decomposition products : oxides of carbon
Sample applicator	<ul style="list-style-type: none"> Toxic fumes of carbon dioxide, carbon monoxide and sulfur oxides 	<ul style="list-style-type: none"> Not known 	<ul style="list-style-type: none"> Toxic fumes of carbon dioxide, carbon monoxide and sulfur oxides.
Chase buffer	<ul style="list-style-type: none"> Toxic fumes of carbon dioxide, carbon monoxide and sulfur oxides 	Contact with acid liberates very toxic gas and may also form explosive compounds when in contact with heavy metals e.g. lead or copper.	<ul style="list-style-type: none"> Toxic fumes of carbon dioxide, carbon monoxide and sulfur oxides.

11. TOXICOLOGICAL INFORMATION

Kit Component	Hazardous composition	Inhalation	Ingestion	Skin Contact	Eye Contact
Test Device	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Sample applicator	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Chase buffer	Sodium Azide (NaN ₃) at ≤0.1 %	Not known	Not known	Not known	Not known
	p-tertiary-Octylphenoxy polyethyl alcohol (Triton X – 100)	Not known	Not known	Not known	Not known

Acute toxicity:

LD/LC50 values that are relevant for classification			
Sodium Azide (NaN ₃)	Oral	LD50	27 mg/kg (rat)
p-tertiary-Octylphenoxy polyethyl alcohol (Triton X – 100)	Oral	LD50	1800 mg/kg Rat
p-tertiary-Octylphenoxy polyethyl alcohol (Triton X – 100)	Dermal	LD50	8000 mg/kg Rabbit

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12. ECOLOGICAL INFORMATION

Kit Component	Hazardous composition	Aquatic toxicity
Test Device	Not applicable	Poor biodegradability in soil and water
Sample applicator	Not applicable	Poor biodegradability in soil and water
Chase buffer	Sodium Azide (NaN ₃) at ≤0.1 %	Not known
	p-tertiary-Octylphenoxy polyethyl alcohol (Triton X – 100)	LC50 (96h). 8,9 mg/l Pimephales promelas EC50 (48h). 26 mg/l Daphnia

13. DISPOSAL CONSIDERATIONS

General notes:

In general, laboratory waste is under the special supervision of the authorities. Refer to applicable local regulations.

European waste catalogue:

Please consult the responsible regulatory body for the assignment of disposal codes according to European Waste Catalogue.

Following waste disposal key number is possible: 18 01 06: chemicals consisting of or containing dangerous substances. 18 01 07: chemicals other than those mentioned in 18 01 06

Unclean packaging:

There are no uniform EC-regulations for the disposal of packaging as waste.

Recommendation:

Non contaminated packaging can be used for recycling. For disposal of contaminated packaging, please refer to applicable local regulations.

Nitrocellulose membrane (Small quantities) - moisten with water and dispose of.

14. TRANSPORT INFORMATION

	Land transport	Sea transport	Air transport
ADR/RID	Not Restricted	Not applicable	Not applicable
UN-No.	Not Restricted	Not applicable	Not applicable
IMDG Class	Not applicable	Not Restricted	Not applicable
Marine pollutant	Not applicable	Not Restricted	Not applicable
ICAO/IATA Class	Not applicable	Not applicable	Not Restricted
Name	Not Restricted	Not Restricted	Not Restricted

15. REGULATORY INFORMATION

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

EU	Restriction pursuant to Annex XVII to EC Regulation 1907/2006	Point 3
	Seveso category	None
	Candidate List (art. 59 Regulation 1907/2006)	p-tertiary-octylphenoxy polyethyl alcohol
	authorization (Annex XIV REACH)	None
Rotterdam Convention - annex III		N/A
Stockholm Convention		N/A

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	This procedure derives from S19g para. 5 of the German "Water Law" (Wasserhaushaltsgesetz, WHG) dated 1 March 2010, in conjunction with the administrative directive governing substances hazardous to water.	
Germany	Water Hazard Class	WGK 2 - hazardous to water

Chemical safety assessment:

No chemical safety assessment has been processed for the mixture and the substances it contains.

16. OTHER INFORMATION

Abbreviations and acronyms:

Acute Tox. 2	Acute toxicity, category 2
Acute Tox. 4	Acute toxicity, category 4
Skin Sens. 1	Skin sensitization, category 1
Eye Irrit. 1	Eye irritation, category 1
Aquatic Acute 1	Hazardous to the aquatic environment, acute category 1
Aquatic Chronic 1	Hazardous to the aquatic environment, chronic category 1
Aquatic Chronic 3	Hazardous to the aquatic environment, chronic category 3

Relevant hazard statements:

H300	Fatal if swallowed
H302	Harmful if swallowed
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects
H412	Harmful to aquatic life with long lasting effects
EUH032	Contact with acids liberates very toxic gas

Relevant precautionary statements (prevention):

P264	Wash ... thoroughly after handling
P270	Do not eat, drink or smoke when using this product
P273	Avoid release to the environment.
P280	Wear protective gloves/protective clothing/eye protection/face protection.

Relevant precautionary statements (response):

P301+P310	IF SWALLOWED: Immediately call a POISON CENTER/doctor
P301+P312	IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
P301+P330+P331	IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing.
P310	Immediately call a POISON CENTER/doctor
P321	Specific treatment (see ... on this label)
P330	Rinse mouth.
P391	Collect spillage.

Relevant precautionary statements (storage):

P403+P233	Store in a well-ventilated place. Keep container tightly closed.
P405	Store locked up.

Relevant precautionary statements (disposal):

P501	Dispose of content/container in accordance with local/regional/national/international regulation.
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Legends:

ADR	European Agreement concerning the carriage of Dangerous goods by Road
CAS	NUMBER:Chemical Abstract Service Number
CE NUMBER	Identifier in ESIS (European archive of existing substances)
CLP	Classification, Labelling and Packaging (EC Regulation 1272/2008)
GHS	Globally Harmonized System of classification and labeling of chemicals
IATA	International Air Transport Association
ICAO	International Civil Aviation Organization
IMDG	International Maritime Code for dangerous goods
IMO	International Maritime Organization
LC50	Lethal Concentration 50%
LD50	Lethal dose 50%
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals (EC Regulation 1907/2006)
RID	Regulation concerning the international transport of dangerous goods by train
UN No.	United Nations Number

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Indication of changes:

Description	Date
SDS for compliance with EU Directive 1272/2008	2015-11-11
To include the hazard symbol for chase buffer	2016-05-20
Change of EC Rep	2016-05-24
To include MP Diagnostics MULTISURE HCV Confirmatory Test	2016-06-09

The information supplied in this data sheet represents the data and best information available at the date of preparation. It is provided with the aim of allowing proper and safe use, storage, transport and disposal of the product. It is not to be considered as warranty or specification of product quality. It is related to the materials specifically indicated and does not apply if these are used in combination with other materials or during processes not specifically indicated in the text of this Safety Data Sheet