

# **Standards; Positive Control; Cut-off Control; Control; Control Low, Control High, Additional Control; Performance Control; Negative Control (anti-TG, anti TPO, RF IgM); Antigen Solution lyophilized (Dengue Virus IgM $\mu$ -capture)**

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## **1. IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING**

### **1.1 PRODUCT IDENTIFIER**

**Product name:** Standards; Positive Control; Cut-off Control; Control; Control Low, Control High, Additional Control; Performance Control; Negative Control (anti-TG, anti TPO, RF IgM); Antigen Solution lyophilized (Dengue Virus IgM  $\mu$ -capture)  
for all products listed in the annex

### **1.2 RELEVANT IDENTIFIED USES OF THE SUBSTANCE OR MIXTURE AND USES ADVISED AGAINST**

Reagent for in-vitro diagnostics in human samples.

For professional use only.

### **1.3 DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET**

NovaTec Immundiagnostica GmbH  
Waldstrasse 23 A6  
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responsible for this SDS: +49 (0)6074-4876-0

### **1.4 EMERGENCY TELEPHONE NUMBER**

Phone: +49 (0)6074-4876-0 available only during office hours

## **2. HAZARDS IDENTIFICATION**

### **2.1 CLASSIFICATION OF THE SUBSTANCE OR MIXTURE**

**Classification according to EC regulation 1272/2008 (CLP)**

This mixture is classified as not hazardous.

**Classification according to Directive 67/548/EEC or 1999/45/EC**

This preparation is classified as not hazardous.

### **2.2 LABEL ELEMENTS**

**Labelling (CLP)**

Hazard statements:- -not applicable

Safety precautions:- -not applicable

**Labelling (67/548/EEC or 1999/45/EC)**

R phrase(s): not applicable

S phrase(s): not applicable

### **2.3 OTHER HAZARDS**

No risks worthy of mention.

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### **3. INFORMATION ON INGREDIENTS**

**3.1 SUBSTANCES:** -not applicable

**3.2 MIXTURES**

Chemical characterization: Aqueous solution of additives

Additional information: Contains 5-bromo-5-nitro-1,3-dioxane and 2-Methyl-2H-isothiazol-3-one

### **4. FIRST AID MEASURES**

**4.1 DESCRIPTION OF FIRST AID MEASURES**

After inhalation: Provide fresh air. Seek medical treatment in case of troubles.

In case of skin contact: Remove residues with water. Change contaminated clothing. In case of skin reactions, consult a physician.

After eye contact: Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids apart. In case of troubles or persistent symptoms, consult an ophthalmologist.

After swallowing: Rinse mouth and drink large quantities of water. Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice.

**4.2 MOST IMPORTANT SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED**

No data available

**4.3 INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED**

Treat symptomatically.

### **5. FIREFIGHTING MEASURES**

**5.1 EXTINGUISHING MEDIA**

Suitable extinguishing media:

Product is non-combustible. Extinguishing materials should therefore be selected according to surroundings.

**5.2 SPECIAL HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE**

Fires in the immediate vicinity may cause the development of dangerous vapours.

Can be released in case of fire: Nitrogen oxides (NO<sub>x</sub>), Carbon monoxide and carbon dioxide.

**5.3 ADVICE FOR FIRE-FIGHTERS**

Special protective equipment for firefighters:

In case of surrounding fires: Wear self-contained breathing apparatus.

Additional information:

Do not allow fire water to penetrate into surface or ground water.

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## 6. ACCIDENTAL RELEASE MEASURES

### 6.1 PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES

Avoid contact with skin and eyes. Provide adequate ventilation. Wear personal protection equipment.

### 6.2 ENVIRONMENTAL PRECAUTIONS

Do not allow to penetrate into soil, waterbodies or drains.

### 6.3 METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP

Soak up with absorbent materials such as sand, siliceous earth, acid- or universal binder. Store in special closed containers and dispose of according to ordinance. Wash spill area with plenty of water.

### 6.4 REFERENCE TO OTHER SECTIONS

Refer additionally to chapters 8 and 13.

## 7. HANDLING AND STORAGE

### 7.1 PRECAUTIONS FOR SAFE HANDLING

Advices on safe handling:

Avoid contact with skin and eyes. Provide adequate ventilation, and local exhaust as needed.

Keep all containers, equipment and working place clean.

### 7.2 CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES

Requirements for storerooms and containers:

Store container tightly closed in a dry and cool place.

Storage class:

12 Non-combustible liquids

### 7.3 SPECIFIC END USE(S)

No information available.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### 8.1 CONTROL PARAMETERS

Occupational exposure limit values:

CAS No.	Designation	Type	Limit value
2682-20-4	2-Methyl-2H-isothiazol-3-one	Germany: DFG long term	0,2 mg/m <sup>3</sup> Inhalable fraction (Mixture of 5-Chlor-2-methyl-2H-isothiazol-3-one and 2-Methyl-2H-isothiazol-3-one (3:1))

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## 8.2 EXPOSURE CONTROLS

Provide good ventilation and/or an exhaust system in the work area.

### Occupational exposure controls

**Respiratory protection:** Respiratory protection must be worn whenever the WEL levels have been exceeded. Use filter type A (= against vapours of organic substances) according to EN 14387.

**Hand protection:** Protective gloves according to EN 374.  
Glove material: Nitrile rubber.  
Breakthrough time: > 480 min.  
Observe glove manufacturer's instructions concerning penetrability and breakthrough time.

**Eye protection:** Tightly sealed goggles according to EN 166.

**Body protection:** Wear suitable protective clothing.

**General protection and hygiene measures:**  
Change contaminated clothing.  
Wash hands before breaks and after work.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

Physical state:	liquid
Colour:	yellow
Odour:	odourless
Odour threshold	no data available
pH value:	6.3-7.5
Melting point/melting range:	no data available
Boiling temperature/boiling range:	no data available
Flash point/flash point range:	no data available
Vapourisation rate:	no data available
Flammability:	no data available
Explosive properties:	no data available
Explosion limits:	no data available
Vapour pressure:	no data available
Vapour density:	no data available
Density:	no data available
Solubility:	no data available
Partition coefficient n-octanol/water:	no data available
Autoflammability:	no data available
Thermal decomposition:	no data available
Viscosity, dynamic:	no data available
Explosive properties:	no data available
Oxidizing characteristics:	no data available

### 9.2 OTHER INFORMATION

No data available

## 10. STABILITY AND REACTIVITY

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### 10.1 REACTIVITY

refer to 10.3

### 10.2 CHEMICAL STABILITY

Product is stable under normal storage conditions.

### 10.3 POSSIBILITY OF HAZARDOUS REACTIONS

No hazardous reactions known.

### 10.4 CONDITIONS TO AVOID

Protect from excessive heat.

### 10.5 INCOMPATIBLE MATERIALS

No data available

### 10.6 HAZARDOUS DECOMPOSITION PRODUCTS

Fires in the immediate vicinity may cause the development of dangerous vapours.

Can be released in case of fire: Nitrogen oxides (NO<sub>x</sub>), Carbon monoxide and carbon dioxide.

Thermal decomposition: no data available

## 11. TOXICOLOGICAL INFORMATION

### 11.1 INFORMATION ON TOXICOLOGICAL EFFECTS

<b>Toxicological effects:</b>	Acute toxicity (oral):	Lack of data.
	Acute toxicity (dermal):	Lack of data.
	Acute toxicity (inhalative):	Lack of data.
	Skin corrosion/irritation:	Lack of data.
	Eye damage/irritation:	Lack of data.
	Sensitisation to the respiratory tract:	Lack of data.
	Skin sensitisation:	Lack of data.
	Germ cell mutagenicity/Genotoxicity:	Lack of data.
	Carcinogenicity:	Lack of data.
	Reproductive toxicity:	Lack of data.
	Effects on or via lactation:	Lack of data.
	Specific target organ toxicity (single exposure):	Lack of data.
	Specific target organ toxicity (repeated exposure):	Lack of data.
	Aspiration hazard:	Lack of data.

### General remarks:

Component	valuation	value	species
2-Methyl-2H-isothiazol-3-one	LD <sub>50</sub> (oral)	285 mg/kg	rat
5-bromo-5-nitro-1,3-dioxane	LD <sub>50</sub> (oral)	455 mg/kg	rat
	LD <sub>50</sub> (oral)	590 mg/kg	mouse

## 12. ECOLOGICAL INFORMATION

### 12.1 TOXICITY

Water Hazard Class: 1 = slightly hazardous to water

### 12.2 PERSISTENCE AND DEGRADABILITY

Further details: No data available

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### **12.3 BIOACCUMULATIVE POTENTIAL**

Partition coefficient n-octanol/water: no data available

### **12.4 MOBILITY IN SOIL**

No data available.

### **12.5 RESULTS OF PBT AND VPVB ASSESSMENT**

No data available.

### **12.6 OTHER ADVERSE EFFECTS**

General information: Do not allow to enter into ground-water, surface water or drains.

## **13. DISPOSAL CONSIDERATIONS**

### **13.1 WASTE TREATMENT METHODS**

#### **Product:**

Waste key number: 16 05 06\* = Laboratory chemicals consisting of or containing dangerous substances including mixtures of laboratory chemicals.

\* = Evidence for disposal must be provided.

Recommendation:— Special waste. Dispose of waste according to applicable legislation.

#### **Contaminated Packaging:**

Waste key number:— 15 01 02 = Plastic packaging.

Recommendation:— Dispose of waste according to applicable legislation.  
Non-contaminated packages may be recycled.

## **14. TRANSPORT INFORMATION**

### **14.1 UN NUMBER**

not applicable

### **14.2 UN PROPER SHIPPING NAME**

Not restricted

### **14.3 TRANSPORT HAZARD CLASS(ES)**

not applicable

### **14.4 PACKING GROUP**

not applicable

### **14.5 ENVIRONMENTAL HAZARDS**

Marine pollutant - IMDG: No

### **14.6 SPECIAL PRECAUTIONS FOR USER**

No dangerous good in sense of these transport regulations.

### **14.7 TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL73/78 AND THE IBC CODE**

No data available

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## 15. REGULATORY INFORMATION

### 15.1 SAFETY, HEALTH AND ENVIRONMENTAL REGULATIONS/LEGISLATION SPECIFIC FOR THE SUBSTANCE OR MIXTURE

#### National regulations - Germany

Storage class:- 12 Non-combustible liquids

Water Hazard Class:- 1 = slightly hazardous to water

### 15.2 CHEMICAL SAFETY ASSESSMENT

No data available.

## 16. OTHER INFORMATION

### Further information

For abbreviations and acronyms, see: ECHA Guidance on information requirements and chemical safety assessment, chapter R.20 (Table of terms and abbreviations).

The information in this data sheet has been established to our best knowledge and was up-to-date at time of revision. It does not represent a guarantee for the properties of the product described in terms of the legal warranty regulations.

History: updated annex

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### Annex

Product code	Product name
ADVA0010	Adenovirus IgA
ADVG0010	Adenovirus IgG
ADVM0010	Adenovirus IgM
ASCG0020	Ascaris lumbricoides IgG
BOPA0030	Bordetella pertussis IgA
BOPG0030	Bordetella pertussis IgG
BOPM0030	Bordetella pertussis IgM
BPTA0610	Bordetella pertussis toxin (PT) IgA
BPTG0610	Bordetella pertussis toxin (PT) IgG
BORG0040	Borrelia burgdorferi IgG
BORM0040	Borrelia burgdorferi IgM
BORG0320	Lyme Borrelia IgG
BRUG0050	Brucella IgG
BRUM0050	Brucella IgM
CANA0060	Candida albicans IgA
CANG0060	Candida albicans IgG
CANM0060	Candida albicans IgM
CCVG0630	Crimean-Congo Hemorrhagic Fever Virus (CCHVF) IgG
CCVM0630	Crimean-Congo Hemorrhagic Fever Virus (CCHVF) IgM
CHAG0560	Chagas (Trypanosoma cruzi) IgG
TRYP0570	Chagas
CHIG0590	Chikungunya Virus IgG capture
CHIM0590	Chikungunya Virus IgM $\mu$ -capture
CHLA0070	Chlamydia trachomatis IgA
CHLG0070	Chlamydia trachomatis IgG
CHLM0070	Chlamydia trachomatis IgM
CHLA0510	Chlamydia pneumoniae IgA
CHLG0510	Chlamydia pneumoniae IgG
CHLM0510	Chlamydia pneumoniae IgM
CORG0090	Corynebacterium diphtheriae toxin IgG
CORG5009	Corynebacterium diphtheriae toxin 5S IgG
PCORG009	Corynebacterium diphtheriae toxin 5S IgG plus
COX1G0600	Coxiella burnetii (Q-Fever) Phase 1 IgG
COX2G0600	Coxiella burnetii (Q-Fever) Phase 2 IgG
COX2M0600	Coxiella burnetii (Q-Fever) Phase 2 IgM
CMVG0110	Cytomegalovirus (CMV) IgG
CMVM0110	Cytomegalovirus (CMV) IgM
DENG0120	Dengue Virus IgG
DENM0120	Dengue Virus IgM
DVM0640	Dengue Virus IgM $\mu$ -capture
ECHG0130	Echinococcus IgG
ENTG0140	Entamoeba histolytica IgG
EBVG0150	Epstein-Barr Virus (VCA) IgG
EBVM0150	Epstein-Barr Virus (VCA) IgM
EBVG0580	Epstein-Barr Virus (EBNA) IgG
HELA0220	Helicobacter pylori IgA
HELG0220	Helicobacter pylori IgG



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Product code	Product name
PHELA022	Helicobacter pylori IgA plus
PHELG022	Helicobacter pylori IgG plus
HSVG0250	Herpes simplex Virus 1+2 (HSV) IgG
HSVM0250	Herpes simplex Virus 1+2 (HSV) IgM
HSV1G0500	Herpes simplex Virus 1 (HSV 1) IgG
HSV1M0500	Herpes simplex Virus 1 (HSV 1) IgM
HSV2G0540	Herpes simplex Virus 2 (HSV 2) IgG
HSV2M0540	Herpes simplex Virus 2 (HSV 2) IgM
INFA0290	Influenza Virus A IgA
INFG0290	Influenza Virus A IgG
INFM0290	Influenza Virus A IgM
INFA0300	Influenza Virus B IgA
INFG0300	Influenza Virus B IgG
INFM0300	Influenza Virus B IgM
LEGG0650	Legionella pneumophila IgG
LEGM0650	Legionella pneumophila IgM
LEIG0310	Leishmania infantum IgG
LEPG0660	Leptospira IgG
LEPM0660	Leptospira IgM
MAL0620	Malaria
MEAG0330	Measles Virus IgG
MEAM0330	Measles Virus IgM
MUMG0340	Mumps Virus IgG
MUMM0340	Mumps Virus IgM
MYCA0350	Mycoplasma pneumoniae IgA
MYCG0350	Mycoplasma pneumoniae IgG
MYCM0350	Mycoplasma pneumoniae IgM
PAIA0360	Parainfluenza Virus 1,2,3 IgA
PAIG0360	Parainfluenza Virus 1,2,3 IgG
PARG0370	Parvovirus B19 IgG
PARM0370	Parvovirus B19 IgM
RSVA0380	Respiratory syncytial Virus IgA
RSVG0380	Respiratory syncytial Virus IgG
RSVM0380	Respiratory syncytial Virus IgM
RUBG0400	Rubella Virus IgG
RUBM0400	Rubella Virus IgM $\mu$ -capture
SCHG0410	Schistosoma mansoni IgG
TAEG0420	Taenia solium IgG
TETG0430	Clostridium tetani toxin IgG
TETG5043	Clostridium tetani toxin 5S IgG
PTETG043	Clostridium tetani toxin 5S IgG plus
TICG0440	TBE / FSME IgG
PTICG044	TBE / FSME IgG plus
TICM0440	TBE / FSME IgM
TOCG0450	Toxocara canis IgG
TOXA0460	Toxoplasma gondii IgA
TOXG0460	Toxoplasma gondii IgG
TOXGA460	Toxoplasma gondii IgG Avidity Test
TOXM0460	Toxoplasma gondii IgM $\mu$ -capture

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Product code	Product name
TREG0470	Treponema pallidum
TRIG0480	Trichinella spiralis IgG
VZVA0490	Varicella-Zoster Virus (VZV) IgA
VZVG0490	Varicella-Zoster Virus (VZV) IgG
VZVM0490	Varicella-Zoster Virus (VZV) IgM
ATG1010	Anti-TG
ATPO1020	Anti-TPO
TSH1030	TSH
RFM3010	Rheumatoid Factor IgM