

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

### 1.1 PRODUCT IDENTIFIER

**Product name:**

**Catalog number:**

<i>SeraSpot</i> <sup>®</sup> ANA IgG	
<i>SeraSpot</i> <sup>®</sup> ANA-17 IgG-S6	SP-002-17 G-S6
<i>SeraSpot</i> <sup>®</sup> ANA-17 IgG-S12	SP-002-17 G-S12
<i>SeraSpot</i> <sup>®</sup> ANA-17 IgG-S24	SP-002-17 G-S24
<i>SeraSpot</i> <sup>®</sup> ANA-12 IgG-S6	SP-002-12 G-S6
<i>SeraSpot</i> <sup>®</sup> ANA-12 IgG-S12	SP-002-12 G-S12
<i>SeraSpot</i> <sup>®</sup> ANA-12 IgG-S24	SP-002-12 G-S24
<i>SeraSpot</i> <sup>®</sup> Vaskulitis IgG	
<i>SeraSpot</i> <sup>®</sup> Vaskulitis-3 IgG-S6	SP-003-3 G-S6
<i>SeraSpot</i> <sup>®</sup> Vaskulitis-3 IgG-S12	SP-003-3 G-S12
<i>SeraSpot</i> <sup>®</sup> Vaskulitis-3 IgG-S24	SP-003-3 G-S24
<i>SeraSpot</i> <sup>®</sup> HepAk IgG	
<i>SeraSpot</i> <sup>®</sup> HepAk-7 IgG-S6	SP-004-7 G-S6
<i>SeraSpot</i> <sup>®</sup> HepAk-7 IgG-S12	SP-004-7 G-S12
<i>SeraSpot</i> <sup>®</sup> HepAk-7 IgG-S24	SP-004-7 G-S24
<i>SeraSpot</i> <sup>®</sup> Anti-Yersinia IgG	
<i>SeraSpot</i> <sup>®</sup> Anti-Yersinia-6 IgG-S6	SP-005-6 G-S6
<i>SeraSpot</i> <sup>®</sup> Anti-Yersinia-6 IgG-S12	SP-005-6 G-S12
<i>SeraSpot</i> <sup>®</sup> Anti-Yersinia-6 IgG-S24	SP-005-6 G-S24
<i>SeraSpot</i> <sup>®</sup> Anti-Yersinia IgA	
<i>SeraSpot</i> <sup>®</sup> Anti-Yersinia-6 IgA-S6	SP-005-6 A-S6
<i>SeraSpot</i> <sup>®</sup> Anti-Yersinia-6 IgA-S12	SP-005-6 A-S12
<i>SeraSpot</i> <sup>®</sup> Anti-Yersinia-6 IgA-S24	SP-005-6 A-S24
<i>SeraSpot</i> <sup>®</sup> Anti-Borrelia IgG	
<i>SeraSpot</i> <sup>®</sup> Anti-Borrelia-10 IgG-S6	SP-006-10 G-S6
<i>SeraSpot</i> <sup>®</sup> Anti-Borrelia-10 IgG-S12	SP-006-10 G-S12
<i>SeraSpot</i> <sup>®</sup> Anti-Borrelia-10 IgG-S24	SP-006-10 G-S24
<i>SeraSpot</i> <sup>®</sup> Anti-Borrelia IgM	
<i>SeraSpot</i> <sup>®</sup> Anti-Borrelia-10 IgM-S6	SP-006-10 M-S6
<i>SeraSpot</i> <sup>®</sup> Anti-Borrelia-10 IgM-S12	SP-006-10 M-S12
<i>SeraSpot</i> <sup>®</sup> Anti-Borrelia-10 IgM-S24	SP-006-10 M-S24
<i>SeraSpot</i> <sup>®</sup> Anti-Helicobacter IgG	
<i>SeraSpot</i> <sup>®</sup> Anti-Helicobacter-6 IgG-S6	SP-007-6 G-S6
<i>SeraSpot</i> <sup>®</sup> Anti-Helicobacter-6 IgG-S12	SP-007-6 G-S12
<i>SeraSpot</i> <sup>®</sup> Anti-Helicobacter-6 IgG-S24	SP-007-6 G-S24
<i>SeraSpot</i> <sup>®</sup> Anti- Helicobacter IgA	
<i>SeraSpot</i> <sup>®</sup> Anti-Helicobacter-6 IgA-S6	SP-007-6 A-S6
<i>SeraSpot</i> <sup>®</sup> Anti-Helicobacter-6 IgA-S12	SP-007-6 A -S12
<i>SeraSpot</i> <sup>®</sup> Anti-Helicobacter-6 IgA-S24	SP-007-6 A -S24
<i>SeraSpot</i> <sup>®</sup> Anti-Treponema IgG	
<i>SeraSpot</i> <sup>®</sup> Anti-Treponema-4 IgG-S6	SP-010-4 G-S6
<i>SeraSpot</i> <sup>®</sup> Anti-Treponema-4 IgG-S12	SP-010-4 G-S12
<i>SeraSpot</i> <sup>®</sup> Anti-Treponema-4 IgG-S24	SP-010-4 G-S24
<i>SeraSpot</i> <sup>®</sup> Anti-Treponema IgM	
<i>SeraSpot</i> <sup>®</sup> Anti-Treponema-4 IgM-S6	SP-010-4 M-S6
<i>SeraSpot</i> <sup>®</sup> Anti-Treponema-4 IgM-S12	SP-010-4 M-S12
<i>SeraSpot</i> <sup>®</sup> Anti-Treponema-4 IgM-S24	SP-010-4 M-S24
<i>SeraSpot</i> <sup>®</sup> Anti-Parvovirus IgG	
<i>SeraSpot</i> <sup>®</sup> Anti-Parvovirus-6 IgG-S6	SP-012-6 G-S6
<i>SeraSpot</i> <sup>®</sup> Anti-Parvovirus-6 IgG-S12	SP-012-6 G-S12
<i>SeraSpot</i> <sup>®</sup> Anti-Parvovirus-6 IgG-S24	SP-012-6 G-S24
<i>SeraSpot</i> <sup>®</sup> Anti- Parvovirus IgM	
<i>SeraSpot</i> <sup>®</sup> Anti-Parvovirus-5 IgM-S6	SP-012-5 M-S6
<i>SeraSpot</i> <sup>®</sup> Anti-Parvovirus-5 IgM-S12	SP-012-5 M-S12
<i>SeraSpot</i> <sup>®</sup> Anti-Parvovirus-5 IgM-S24	SP-012-5 M-S24

SeraSpot® Anti-EBV IgG		
SeraSpot® Anti-EBV-4 IgG-S6		SP-013-4 G-S6
SeraSpot® Anti-EBV-4 IgG-S12		SP-013-4 G-S12
SeraSpot® Anti-EBV-4 IgG-S24		SP-013-4 G-S24
SeraSpot® Anti-EBV IgM		
SeraSpot® Anti-EBV-3 IgM-S6		SP-013-3 M-S6
SeraSpot® Anti-EBV-3 IgM-S12		SP-013-3 M-S12
SeraSpot® Anti-EBV-3 IgM-S24		SP-013-3 M-S24

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

Array based *in-vitro* diagnostics for immunological determination of pathogen specific and autoantibodies in human medicine.

Relevant identified use PROC15: Laboratory chemical

Reserved for industrial and professional use.

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

Seramun Diagnostica GmbH

Spreehagener Straße 1

15754 Heidesee

GERMANY

Phone: +49 33767-791-10

Fax: +49 33767-791 99

E-mail: info@seramun.com

## 1.4 EMERGENCY TELEPHONE NUMBER

Phone: +49 33767-791-10 available only during office hours.

## 2. HAZARDS IDENTIFICATION

### 2.1 CLASSIFICATION OF THE SUBSTANCE OR MIXTURE

According the EU-edict (EC) 1272/2008 modified by (EC) 2016/1179 the conjugate solutions are classified as reproductive toxic (Repr. 1B, H360D).

Because of the preservative it may be dangerous for water organisms.

### 2.2 LABEL ELEMENTS

Applicable for the conjugate solutions:



Pictogram

Signal word

Hazard class

Hazard Statement(s)

Precautionary Statement(s)

Danger!

reproductive toxicity Repr. 1B

H360D: May damage the unborn child.

P280: Wear protective gloves/protective clothing/eye protection/face protection

**Note:** According the EU-edict (EC) 1272/2008, article 1, 5 (d) the labelling shall not apply to IVD as defined in the Directive 98/79/EC.

### 2.3 OTHER HAZARDS

Chemicals bear specific risks. That is why these are only handled by qualified staff in compliance with health and safety regulations.

None of the components is listed as PBT or vPvB relevant.

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

#### 3.1 SUBSTANCES

All products are mixtures.


#### 3.2 MIXTURES

Wash buffer: TRIS-buffer with inorganic salts and preservatives  
Concentrations of dangerous components according to (EC) 1272/2008 are below the limits of concentration mentioned in the law.

Sample dilution buffer: Casein containing buffer with inorganic salts and preservative  
Concentrations of dangerous components according to (EC) 1272/2008 are below the limits of concentration mentioned in the law.

Conjugate solution: TRIS-buffer, bovine serum albumin, inorganic salts, supplements and preservatives, as active substances IgG (goat or sheep) and horseradish peroxidase (EC1.11.1.7).  
The bovine serum albumin (BSA) is derived from bovine blood collected at USDA licensed establishment


Dangerous components according to (EC) 1272/2008:

REACH Register-number	EINECS	CAS-No.	name	percentage	symbol	H-statements
01-2119472430-46-XXXX	212-828-1	872-50-4	N-Methyl-2-pyrrolidone	< 2.0	 Danger!	H315, H319, H360D, H335

Substrate solution: aqueous solution of TMB, hydrogen peroxide, containing citrate and preservative  
Concentrations of dangerous components according to (EC) 1272/2008 are below the limits of concentration mentioned in the law

Alcohol swabs cellulose soaked with 70% isopropyl alcohol

Dangerous components according to (EC) 1272/2008:

REACH Register-number	EINECS	CAS-No.	name	percentage	symbol	H-statements
not available	200-661-7	67-63-0	Isopropyl alcohol	70	 Danger!	H225, H319, H336

The full text of H-statements is in article 16.

### 4. FIRST AID MEASURES

#### 4.1 DESCRIPTION OF FIRST AID MEASURES

General advice

Consult a physician. Show this safety data sheet to the doctor in attendance.

If inhaled

If breathed in, move the concerned person into fresh air. In case of apnoea, give artificial respiration.

Consult a physician.

In case of skin contact

Wash off with plenty of water. Consult a physician.

dry skin by caused by the Alcohol swabs: cream

In case of eye contact

Rinse the opened eye for several minutes with running water, if necessary remove contact lenses. Consult an ophthalmologist.

If swallowed

Never give anything by mouth to an unconscious person.

Rinse mouth with water, drink about 300 ml water, consult a physician.

#### **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**

No data available

## **5. FIREFIGHTING MEASURES**

### **5.1 EXTINGUISHING MEDIA**

Suitable extinguishing media

Use water spray, alcohol resistant foam, solid extinguishing agent or carbon dioxide.

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

The only flammable components are the alcohol swabs. Because of the small amount (< 0.5 g per sachet) no danger is caused. The further components are inflammable; extinguishing measures should therefore be prepared for an environmental fire.

In case of fire toxic vapors, e.g. nitric oxide and carbon monoxide, can be released.

### **5.3 ADVICE FOR FIREFIGHTERS**

Wear breath protective mask and protective clothes if necessary during fire fighting.

## **6. ACCIDENTAL RELEASE MEASURES**

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

Use personal protective equipment. Avoid breathing vapor/mist/gas. Care for appropriate ventilation.

### **6.2 ENVIRONMENTAL PRECAUTIONS**

Keep away from drains. Avoid contamination of water or soil.

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

Suck up with inert absorbance material and dispose as hazardous waste. Keep in a suitable, closed container.

### **6.4 REFERENCE TO OTHER SECTIONS**

For disposal considerations see chapter 13.

## **7. HANDLING AND STORAGE**

### **7.1 PRECAUTIONS FOR SAFE HANDLING**

No smoking, eating, drinking, chewing gum or storage of food or beverages in the working laboratories. Wash hands after work. Remove safety clothing before entering a refreshment room.

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

Store tightly closed on a cool dry place. Reseal opened bottles carefully and store in an upright position.

Recommended storage temperature: 2-8°C

Storage classification: 12 (non flammable liquids)

segregate from: class1 (explosives)

class 4.1A (flammable solids)

class 4.3 (dangerous when wet)

class 6.2 (infectious)  
class 7 (radioactive)

Further information:  
Store separated from foodstuffs.  
Protect from unauthorized access.

### 7.3 SPECIFIC END USE(S)

Use only in accordance to the manual.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### 8.1 CONTROL PARAMETERS

EINECS	name	limit value according to MAK (TRGS 900)	limit value according to BGW (TRGS 903)
212-828-1	N-Methyl-2-pyrrolidone	82 mg/m <sup>3</sup>	150 mg/l urine at the end of a shift, parameter: 5-Hydroxy-N-Methyl-2-pyrrolidone
200-661-7	isopropyl alcohol	500 mg/m <sup>3</sup>	not listed

If the products are used according to the instructions, no air pollution is to be expected.

### 8.2 EXPOSURE CONTROLS

Consider the usual good hygiene and safety practice by handling chemicals.  
Pregnant women should strictly avoid inhalation or skin contact.

#### Personal protective equipment

**Eye/face protection:** Safety glasses with side shields conforming to EN 166 (EC), NIOSH (US)

**Skin protection:** protective gloves of nitril rubber (thickness min. 0.28 mm, AQL1,5) or nature latex (thickness min. 0.22 mm, AQL 1,5), satisfying the norm EN 374.

**Body protection:** impermeable protective clothing, the kind of protective equipment has to be selected depending from concentration and amount of dangerous substance at the specific workplace.

**Respiratory protection:** not required, if handled according to the intended use. In case of a divergent risk assessment use a full-face respirator with multi-purpose combination respirator cartridge Type ABEK (EN 14387).

**Environmental exposure controls:** Keep away from drains, water or soil.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

component	description	colour	odour
<b>Sample dilution buffer</b>	liquid product	colourless	odourless
<b>Wash buffer</b>	liquid product	colourless	odourless
<b>Conjugate Solution</b>	liquid product	IgG: red IgA: violet IgM: green	odourless
<b>Substrate Solution</b>	liquid product	colourless to pale yellow	characteristic
<b>Alcohol swabs</b>	gel	colourless (white)	alcoholic

component	pH-value	boiling point	Flash point	Explosive properties

<b>Sample dilution buffer</b>	6.2 – 6.4	101 °C	not applicable	non
<b>Wash buffer</b>	7.3 – 7.5	102 °C	not applicable	non
<b>Conjugate Solution</b>	7.3 – 7.5	102 °C	not applicable	non
<b>Substrate Solution</b>	4.9 – 5.1	102 °C	not applicable	non
<b>Alcohol swabs</b>	not applicable	82 °C	12 °C	lower explosion limit: 2.0 vol% upper explosion limit: 14 vol%

<b>component</b>	<b>Oxidising properties</b>	<b>Vapour pressure</b>	<b>relative density</b>
<b>Sample dilution buffer</b>	non	not measured	1.11 g/ml
<b>Wash buffer</b>	non	not measured	1.11 g/ml
<b>Conjugate Solution</b>	non	not measured	1.043 g/ml
<b>Substrate Solution</b>	non	not measured	1.013 g/ml
<b>Alcohol swabs</b>	non	43 hPa (20°C)	0.79 g/ml

<b>component</b>	<b>solubility</b>	<b>Water solubility</b>	<b>Viscosity</b>
<b>Sample dilution buffer</b>	complete soluble/miscible in protic solvents	complete soluble/miscible	not measured
<b>Wash buffer</b>	complete soluble/miscible in protic solvents	complete soluble/miscible	not measured
<b>Conjugate Solution</b>	complete soluble/miscible in protic solvents	complete soluble/miscible	not measured
<b>Substrate Solution</b>	complete soluble/miscible in protic solvents	complete soluble/miscible	not measured
<b>Alcohol swabs</b>	complete soluble/miscible in protic solvents	complete soluble/miscible	not measured

## 9.2 OTHER INFORMATION

No further dangerous properties known.

## 10. STABILITY AND REACTIVITY

### 10.1 REACTIVITY

No data available.

### 10.2 CHEMICAL STABILITY

Store at 2 – 8°C.

### 10.3 POSSIBILITY OF HAZARDOUS REACTIONS

If the products are used according to the instructions, no hazardous reactions are to be expected.

### 10.4 CONDITIONS TO AVOID

Light, heat, moisture (will not cause a dangerous reaction, but destroys the quality of the products).

Sources of ignition (naked flame, sparks) (alcohol swabs are flammable).

For storage conditions see chapter 7.2.

### 10.5 INCOMPATIBLE MATERIALS

Oxidizing agents, metals (will not cause a dangerous reaction, but destroys the quality of the products).

### 10.6 HAZARDOUS DECOMPOSITION PRODUCTS

Dangerous decomposition products are not known.

## 11. TOXICOLOGICAL INFORMATION

### 11.1 INFORMATION ON TOXICOLOGICAL EFFECTS

(a) acute toxicity

Component	valuation	value	species
N-Methyl-2-pyrrolidone	LD <sub>50</sub> (oral)	3,598 mg/kg	rat
	LC <sub>50</sub> (inhalativ)	>5.1 mg/l	rat
isopropyl alcohol	LD <sub>50</sub> (oral)	~ 5,000 mg/kg	rat

(b) skin corrosion/irritation

Component	valuation	value	species
N-Methyl-2-pyrrolidone	LD <sub>50</sub> (dermal)	8,000 mg/kg	rabbit
isopropyl alcohol	LD <sub>50</sub> (dermal)	> 10 g/kg	rabbit

Risk of skin resorption (conjugate solution).

(c) serious eye damage/irritation

No information available

(d) respiratory or skin sensitization

No information available

(e) germ cell mutagenicity

No information available

(f) carcinogenicity

No information available

(g) reproductive toxicity

May damage the unborn child: N-Methyl-2-pyrrolidone (Repr. 1B)

(h) STOT-single exposure

May cause respiratory irritation.

(i) STOT-repeated exposure

No specific target organ toxicant, repeated exposure

(j) aspiration hazard

No information available

### 11.2 FURTHER TOXICOLOGICAL INFORMATION

Quantitative data on the toxicity of the mixtures are not available.

Calculation of ATE according to (EC) 1272/2008, Appendix I: see section 15.1.

Hazardous properties cannot be excluded but are unlikely when the products are handled appropriately.

Further data:

Handle in accordance with good industrial hygiene and safety practice.

## 12. ECOLOGICAL INFORMATION

### 12.1 TOXICITY

N-Methyl-2-pyrrolidone:

Spezies	Art	Wert
bluegill ( <i>Lepomis macrochirus</i> )	LC <sub>50</sub> (mg/l/96h)	832
gold orfe ( <i>Leuciscus idus</i> )	LC <sub>50</sub> (mg/l/96h)	> 500
green alga ( <i>Desmodesmus subspicatus</i> )	IC <sub>50</sub> (mg/l/72h)	> 500
invertebrates ( <i>Daphnia magna</i> )	EC <sub>50</sub> (mg/l/48h)	4,897

Isopropyl alcohol:

Spezies	Art	Wert
gold orfe ( <i>Leuciscus idus</i> )	LC <sub>50</sub> (mg/l/96h)	9,640
algae	IC <sub>50</sub> (mg/l/72h)	> 1,000
invertebrates ( <i>Daphnia magna</i> )	EC <sub>50</sub> (mg/l/48h)	>13,000

### 12.2 PERSISTENCE AND DEGRADABILITY

Biological degradability:



<u>substance</u>	<u>Value</u>
N-Methyl-2-pyrrolidone easily biologically degradable	> 90%/20d

#### **12.3 BIOACCUMULATIVE POTENTIAL**

Distribution: log P(o/w):  $\leq 4$  (for N-Methyl-2-pyrrolidone)  
There is no Bioaccumulation expected

#### **12.4 MOBILITY IN SOIL**

No data available.

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

None of the components is listed as PBT or vPvB relevant.

#### **12.6 OTHER ADVERSE EFFECTS**

Herbicide and nematicide effects known.

Keep away from drains. Avoid contamination of water or soil.

If used appropriately, no ecological problems are to be expected.

### **13. DISPOSAL CONSIDERATIONS**

#### **13.1 WASTE TREATMENT METHODS**

Products:

Disposal should be made in accordance with national and local regulations and laws.

Packaging:

Emptied packaging can be given to local recycling or waste disposal.

### **14. TRANSPORT INFORMATION**

#### **14.1 UN NUMBER**

ADR/RID: -

IMDG: -

IATA: -

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

ADR/RID: No dangerous goods

IMDG: No dangerous goods

IATA: No dangerous goods

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

ADR/RID: -

IMDG: -

IATA: -

#### **14.4 PACKING GROUP**

ADR/RID: -

IMDG: -

IATA: -

#### **14.5 ENVIRONMENTAL HAZARDS**

ADR/RID: No

IMDG: Marine pollutant no

IATA: No

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

According special regulation ADR 216 /IATA A46: shrink-wrapped swabs are not restricted.

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

These products will be shipped only in approved card boxes.

### **15. REGULATORY INFORMATION**



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

This This safety data sheet meets the requirements of the Regulation (EC) 453/2010 to amending Regulation (EC) 1907/2006 and (EC)2016/1179 modifying (EC) 1272/2008.

The calculated toxicity (ATE) of the mixtures according (EC) 1272/2008, Annex I:

Wash Buffer	910,000	mg/kg body weight	no classification
Sample dilution Buffer	12,200,000	mg/kg body weight	no classification
Conjugate Solution	164,000	mg/kg body weight	no classification
Substrate Solution	595,000	mg/kg body weight	no classification

According (EC) 1272/2008, Annex I: no classification not hazardous to water.

calculated L(E)C50 of the mixtures:

Wash Buffer	21,000	mg/l	no classification (> 100 mg/l)
Sample dilution Buffer	775	mg/l	no classification (> 100 mg/l)
Conjugate Solution	527	mg/l	no classification (> 100 mg/l)
Substrate Solution	66,000	mg/l	no classification (> 100 mg/l)

Water endangering class according to VwVwS (Germany): Water endangering class 1

**Employment limitations:**

Reference is made to the restrictions of employment specified in the Youth Employment Act and the Maternity Protection Act.

**Other regulations, limitations and prohibitive regulations:**

Substance of very high concern (SVHC) according EG 1907/2006 (REACH), Article 57: N-Methyl-2-pyrrolidone (CAS 872-50-4)

**15.2 CHEMICAL SAFETY ASSESSMENT**

No data available.

**16. OTHER INFORMATION**

Fully text to the H-Sentences mentioned in heading 3:

H225	Highly flammable liquid and vapour.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H336	May cause drowsiness or dizziness.
H360D	May damage the unborn child.

Categories of the Acute Toxicity (ATE) according EC 1272/2008:

Category 1	0 < ATE ≤ 5	(oral in mg/kg body weight)
Category 2	5 < ATE ≤ 50	(oral in mg/kg body weight)
Category 3	50 < ATE ≤ 300	(oral in mg/kg body weight)
Category 4	300 < ATE ≤ 2,000	(oral in mg/kg body weight)

Further information:

The information stated above is based on our actual knowledge and is intended to describe our products concerning safety recommendations. The information does not assure product properties and is therefore no basis for legal action.

The REACH registration numbers in heading 3 is not available as the substances or its use is exempted from registration according to article 2 REACH Regulation EC 1907/2006, or the annual tonnage does not require a registration, or is envisaged for a later registration deadline.

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Changes with respect to the previous version:

- Changes in the article 1:

elimination of the articles:

*SeraSpot*<sup>®</sup> ANA IgG

<i>SeraSpot</i> <sup>®</sup> ANA-13 IgG-S6	SP-002-13 G-S6
<i>SeraSpot</i> <sup>®</sup> ANA-13 IgG-S12	SP-002-13 G-S12
<i>SeraSpot</i> <sup>®</sup> ANA-13 IgG-S24	SP-002-13 G-S24

Addition of the articles:

*SeraSpot*<sup>®</sup> Anti-Helicobacter IgG

<i>SeraSpot</i> <sup>®</sup> Anti-Helicobacter-6 IgG-S6	SP-007-6 G-S6
<i>SeraSpot</i> <sup>®</sup> Anti-Helicobacter-6 IgG-S12	SP-007-6 G-S12
<i>SeraSpot</i> <sup>®</sup> Anti-Helicobacter-6 IgG-S24	SP-007-6 G-S24

*SeraSpot*<sup>®</sup> Anti- Helicobacter IgA

<i>SeraSpot</i> <sup>®</sup> Anti-Helicobacter-6 IgA-S6	SP-007-6 A-S6
<i>SeraSpot</i> <sup>®</sup> Anti-Helicobacter-6 IgA-S12	SP-007-6 A -S12
<i>SeraSpot</i> <sup>®</sup> Anti-Helicobacter-6 IgA-S24	SP-007-6 A -S24

*SeraSpot*<sup>®</sup> Anti-Parvovirus IgG

<i>SeraSpot</i> <sup>®</sup> Anti-Parvovirus-6 IgG-S6	SP-012-6 G-S6
<i>SeraSpot</i> <sup>®</sup> Anti-Parvovirus-6 IgG-S12	SP-012-6 G-S12
<i>SeraSpot</i> <sup>®</sup> Anti-Parvovirus-6 IgG-S24	SP-012-6 G-S24

*SeraSpot*<sup>®</sup> Anti- Parvovirus IgM

<i>SeraSpot</i> <sup>®</sup> Anti-Parvovirus-5 IgM-S6	SP-012-5 M-S6
<i>SeraSpot</i> <sup>®</sup> Anti-Parvovirus-5 IgM-S12	SP-012-5 M-S12
<i>SeraSpot</i> <sup>®</sup> Anti-Parvovirus-5 IgM-S24	SP-012-5 M-S24

*SeraSpot*<sup>®</sup> Anti-EBV IgG

<i>SeraSpot</i> <sup>®</sup> Anti-EBV-4 IgG-S6	SP-013-4 G-S6
<i>SeraSpot</i> <sup>®</sup> Anti-EBV-4 IgG-S12	SP-013-4 G-S12
<i>SeraSpot</i> <sup>®</sup> Anti-EBV-4 IgG-S24	SP-013-4 G-S24

*SeraSpot*<sup>®</sup> Anti-EBV IgM

<i>SeraSpot</i> <sup>®</sup> Anti-EBV-3 IgM-S6	SP-013-3 M-S6
<i>SeraSpot</i> <sup>®</sup> Anti-EBV-3 IgM-S12	SP-013-3 M-S12
<i>SeraSpot</i> <sup>®</sup> Anti-EBV-3 IgM-S24	SP-013-3 M-S24

- article 9; completion of data for the alcohol swabs
- Changes in the articles 2 and 15 due to the regulation (EC) 2016/1179 modifying (EC) 1272/2008