

**Safety Data Sheet**

According to Regulation (EG) Nr. 1907/2006

Revision Date: 29.11.2022

Version: 004

replaced Version: 10.11.2020

**ALPCO GAD65 ELISA**

**Product identifier**

Product name: GAD65 ELISA

Product number: 35-GADHU-E01

<i>Article Name</i>	<i>Symbol</i>	<i>Appendix</i>
Break apart microtiter test strips	MP	(1)
Calibrator A – F	CAL	(2)
Cut-off Calibrator	CO-CAL	(2)
Positive Control	CON +	(2)
Negative Control	CON –	(2)
Sample Buffer, 5x conc.	SB 5x	(3)
Wash Buffer, 50x conc.	WASHB 50x	(4)
Anti-Human IgG Conjugate	CONJ	(5)
Substrate	SUB	(6)
Stop Solution	STOP	(7)
Reconstitution Buffer	RB	(8)
...		
GAD65-Biotin	GAD65-Biotin	(9)
...		

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Changes to the prior version:

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# SAFETY DATA SHEET

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

**Revision date:** 25 Nov 2022

**Print date:** 25 Nov 2022

**Version:** 2

Page 1/7

## Break apart microtiter test strips

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

**Trade name/designation:**

Break apart microtiter test strips

**Other means of identification:**

MP

**Article No.:**

3xxx

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

**Use of the substance/mixture:**

This assay and its reagents are not for personal or veterinary use. The reagents should not be used for any purpose other than the intended purpose.

#### 1.3. Details of the supplier of the safety data sheet

**Manufacturer:**

ALPCO  
26-G Keewaydin Drive  
Salem, NH 03079 USA  
Email: ts@alpc.com  
P: (800) 592-5726

#### 1.4. Emergency telephone number

Dial 911 in the United States. If outside of the United States, dial local emergency number.

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

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

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

**Additional information:**

The mixture contains material of human or animal origin and is therefore classified as potentially infectious.

#### 2.2. Label elements

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

According to EC directives or the corresponding national regulations the product does not have to be labelled.

**Hazard statements:** none

**Supplemental hazard information:** none

**Precautionary statements:** none

**Special rules for supplemental label elements for certain mixtures:**

1,6 % percent of the mixture consists of ingredient(s) of unknown acute toxicity (dermal).

2,9 % percent of the mixture consists of ingredient(s) of unknown acute toxicity (inhalative).

#### 2.3. Other hazards

**Adverse physicochemical effects:**

This product does not contain a substance that has endocrine disrupting properties with respect to humans as no components meets the criteria.

# SAFETY DATA SHEET

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

**Revision date:** 25 Nov 2022

**Print date:** 25 Nov 2022

**Version:** 2

Page 2/7

## Break apart microtiter test strips

### SECTION 3: Composition/information on ingredients

#### 3.2. Mixtures

No data available

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

##### General information:

In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible). Remove victim out of the danger area. Remove contaminated, saturated clothing. If unconscious but breathing normally, place in recovery position and seek medical advice. Do not leave affected person unattended.

##### Following inhalation:

Provide fresh air.

##### Following ingestion:

Rinse mouth. Let 1 glass of water be drunken in little sips (dilution effect). Get medical advice/attention if you feel unwell.

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

No known symptoms to date.

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

Treat symptomatically.

### SECTION 5: Firefighting measures

#### 5.1. Extinguishing media

##### Suitable extinguishing media:

Co-ordinate fire-fighting measures to the fire surroundings.

#### 5.2. Special hazards arising from the substance or mixture

The product itself does not burn.

##### Hazardous combustion products:

In case of fire: Gases/vapours, toxic

#### 5.3. Advice for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing.

#### 5.4. Additional information

Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

### SECTION 6: Accidental release measures

#### 6.1. Personal precautions, protective equipment and emergency procedures

##### 6.1.1. For non-emergency personnel

###### Personal precautions:

Remove persons to safety. Avoid breathing dust/fume/gas/mist/vapours/spray.

###### Protective equipment:

Wear protective gloves/protective clothing/eye protection/face protection.

##### 6.1.2. For emergency responders

###### Personal protection equipment:

Personal protection equipment: see section 8

#### 6.2. Environmental precautions

Do not allow to enter into surface water or drains.

#### 6.3. Methods and material for containment and cleaning up

##### For containment:

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents).

# SAFETY DATA SHEET

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

**Revision date:** 25 Nov 2022

**Print date:** 25 Nov 2022

**Version:** 2

Page 3/7

## Break apart microtiter test strips

### 6.4. Reference to other sections

Safe handling: see section 7 Personal protection equipment: see section 8 Disposal: see section 13

### 6.5. Additional information

Use appropriate container to avoid environmental contamination.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

#### Protective measures

#### Advices on safe handling:

Wear personal protection equipment (refer to section 8).

#### Fire prevent measures:

No special measures are necessary.

#### Advices on general occupational hygiene

When using do not eat, drink, smoke, sniff. Avoid contact with skin, eyes and clothes.

### 7.2. Conditions for safe storage, including any incompatibilities

#### Technical measures and storage conditions:

Keep container tightly closed in a cool, well-ventilated place.

#### Further information on storage conditions:

+2°C - +8°C.

### 7.3. Specific end use(s)

No data available

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

No data available

### 8.2. Exposure controls

#### 8.2.1. Appropriate engineering controls

No data available

#### 8.2.2. Personal protection equipment

##### Eye/face protection:

Eye glasses with side protection EN 166

##### Skin protection:

Tested protective gloves must be worn EN ISO 374 Suitable material: Breakthrough time: min In the case of wanting to use the gloves again, clean them before taking off and air them well. Breakthrough times and swelling properties of the material must be taken into consideration.

#### 8.2.3. Environmental exposure controls

No data available

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

#### Appearance

**Physical state:** solid:

**Colour:** whitish

**Odour:** not determined

### 9.2. Other information

No data available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

The product itself does not burn. not relevant

# SAFETY DATA SHEET

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

**Revision date:** 25 Nov 2022

**Print date:** 25 Nov 2022

**Version:** 2

Page 4/7

## Break apart microtiter test strips

### 10.2. Chemical stability

Recommended storage temperature: 2-8°C

### 10.3. Possibility of hazardous reactions

No. Product becomes unusable.

### 10.4. Conditions to avoid

Licht, Hitze, Feuchtigkeit (Es folgt keine gefährliche Reaktion, das Produkt wird unbrauchbar).

### 10.5. Incompatible materials

No data available

### 10.6. Hazardous decomposition products

In case of fire: Gases/vapours, toxic

## SECTION 11: Toxicological information

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

#### Acute oral toxicity:

Based on available data, the classification criteria are not met.

#### Acute dermal toxicity:

Based on available data, the classification criteria are not met.

#### Acute inhalation toxicity:

Based on available data, the classification criteria are not met.

#### Skin corrosion/irritation:

Based on available data, the classification criteria are not met.

#### Serious eye damage/irritation:

Based on available data, the classification criteria are not met.

#### Respiratory or skin sensitisation:

Based on available data, the classification criteria are not met.

#### Germ cell mutagenicity:

Based on available data, the classification criteria are not met.

#### Carcinogenicity:

Based on available data, the classification criteria are not met.

#### Reproductive toxicity:

Based on available data, the classification criteria are not met.

#### STOT-single exposure:

Based on available data, the classification criteria are not met.

#### STOT-repeated exposure:

Based on available data, the classification criteria are not met.

#### Aspiration hazard:

Based on available data, the classification criteria are not met.

#### Additional information:

No data available

### 11.2. Information on other hazards

No data available

## SECTION 12: Ecological information

### 12.1. Toxicity

No data available

### 12.2. Persistence and degradability

No data available

### 12.3. Bioaccumulative potential

No data available

### 12.4. Mobility in soil

No data available

# SAFETY DATA SHEET

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

Revision date: 25 Nov 2022

Print date: 25 Nov 2022

Version: 2

Page 5/7

## Break apart microtiter test strips

### 12.5. Results of PBT and vPvB assessment

No data available

### 12.6. Endocrine disrupting properties

No data available

### 12.7. Other adverse effects

No data available

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

#### 13.1.1. Product/Packaging disposal

#### Waste codes/waste designations according to EWC/AVV

##### Waste code product

18 02 03	wastes whose collection and disposal is not subject to special requirements in order to prevent infection
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#### Waste treatment options

##### Appropriate disposal / Product:

Consult the appropriate local waste disposal expert about waste disposal.

## SECTION 14: Transport information

Land transport (ADR/RID)	Inland waterway craft (ADN)	Sea transport (IMDG)	Air transport (ICAO-TI / IATA-DGR)
<b>14.1. UN number or ID number</b>			
No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.
<b>14.2. UN proper shipping name</b>			
No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.
<b>14.3. Transport hazard class(es)</b>			
not relevant	not relevant	not relevant	not relevant
<b>14.4. Packing group</b>			
not relevant	not relevant	not relevant	not relevant
<b>14.5. Environmental hazards</b>			
not relevant	not relevant	not relevant	not relevant
<b>14.6. Special precautions for user</b>			
not relevant	not relevant	not relevant	not relevant

### 14.7. Maritime transport in bulk according to IMO instruments

No data available

## SECTION 15: Regulatory information

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

No data available

### 15.2. Chemical Safety Assessment

No data available

## SECTION 16: Other information

### 16.1. Indication of changes

Revision according to REACH Regulation (EC) No. 1907/2006, last amended by Regulation (EU) 2020/878

# SAFETY DATA SHEET

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

**Revision date:** 25 Nov 2022

**Print date:** 25 Nov 2022

**Version:** 2

Page 6/7

## Break apart microtiter test strips

### 16.2. Abbreviations and acronyms

°C centigrade

ABEK Gases and vapors from organic compounds with a boiling point >65°C (A), inorganic gases and vapors, except carbon monoxide (B), sulfur dioxide and other acidic gases and vapors (E) and ammonia and organic ammonia derivatives (K)

ADR European Agreement concerning the International Carriage of Dangerous Goods by Road ( Accord européen relatif au transport international des marchandises dangereuses par route)

AwSV Ordinance on systems for handling water-polluting substances

CO carbon monoxide

CO<sub>2</sub> carbon dioxide

EC/EU European Community/European Union

EN European standard

IATA International Air Transport Association

IBC bulk packaging (Intermediate Bulk Container)

IgA Immunoglobuline A

IgG Immunoglobulin G

IgM Immunoglobuline M

IMDG International Maritime Code for Dangerous Goods

IVD in vitro diagnostics

MARPOL International Convention for the Prevention of Marine Pollution

NIOSH National Institute for Occupational Safety and Health

PBT Persistent (P), Bioaccumulative (B), Toxic (T)

RID Regulations for the International Carriage of Dangerous Goods by Rail (Règlement concernant le transport international ferroviaire de marchandises Dangereuse)

UN United Nations

vPvB very Persistent (vP), very Bioaccumulative (vB)

### 16.3. Key literature references and sources for data

No data available

### 16.4. Classification for mixtures and used evaluation method according to regulation (EC) No 1272/2008 [CLP]

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

### 16.5. Relevant R-, H- and EUH-phrases (Number and full text)

No data available

### 16.6. Training advice

No data available

# SAFETY DATA SHEET

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

**Revision date:** 25 Nov 2022

**Print date:** 25 Nov 2022

**Version:** 2

Page 7/7

## Break apart microtiter test strips

### 16.7. Additional information

The information is based on the current state of our knowledge.

# SAFETY DATA SHEET

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

Revision date: 27 Oct 2022

Print date: 28 Nov 2022

Version: 1 Page 1/9

## Calibrators A-F (CAL), Cut-off Calibrator (CO-CAL), Positive Control (CON +), Negative Control (CON -)

### SECTION 1: Identification of the substance/mixture and of the company/ undertaking

#### 1.1. Product identifier

Trade name/designation:

Calibrators A-F (CAL), Cut-off Calibrator (CO-CAL), Positive Control (CON +) Negative Control (CON -)

Article No.:

3xxx

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against Use of the substance/mixture:

This enzyme immunoassay (in vitro diagnostic tool or component) is not intended for anything other than the detection and semi-quantitative determination of human IgA / IgG / IgM antibodies against specific antigens in autoimmune diagnostics. This assay and its reagents are not for personal or veterinary use. The reagents should not be used for any purpose other than the intended purpose.

#### 1.3. Details of the supplier of the safety data sheet

Manufacturer:

ALPCO  
26-G Keewaydin Drive  
Salem, NH 03079 USA  
Phone: (800) 592-5726  
Email: ts@alpco.com

#### 1.4. Emergency telephone number

Dial 911 in the United States. If outside the United States, dial local emergency number.

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

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

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

#### 2.2. Label elements

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

According to EC directives or the corresponding national regulations the product does not have to be labelled.

Hazard statements: none

Supplemental hazard information: none

Precautionary statements: none

Special rules for supplemental label elements for certain mixtures:

1,5 % percent of the mixture consists of ingredient(s) of unknown acute toxicity (dermal).

3,2 % percent of the mixture consists of ingredient(s) of unknown acute toxicity (inhalative).

# SAFETY DATA SHEET

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

Revision date: 27 Oct 2022

Print date: 28 Nov 2022

Version: 1 Page 2/9

## Calibrators A-F (CAL) Cut-off Calibrator (CO-CAL), Positive Control (CON +), Negative Control (CON -)

### 2.3. Other hazards

#### Adverse environmental effects:

This mixture does not contain any substances presenting a health or environmental hazard within the means of Regulation (EC) No. 1272/2008, assigned a Community workplace exposure limit, classified as PBT/vPvB or included in the Candidate List.



#### Other adverse effects:

The mixture contains material of human or animal origin and is therefore classified as potentially infectious.

## SECTION 3: Composition/information on ingredients

### 3.2. Mixtures

#### Hazardous ingredients / Hazardous impurities / Stabilisers:

Product identifiers	Substance name Classification according to Regulation (EC) No 1272/2008 [CLP]	Concentration
	<b>ProClin® 300</b> Acute Tox. 4 (H302), Aquatic Acute 1 (H400), Aquatic Chronic 1 (H410), Skin Corr. 1C (H314), Skin Sens. 1 (H317)  <b>Danger</b>	0 - < 0.1 weight-%
<b>CAS No.:</b> 108-95-2 <b>EC No.:</b> 203-632-7 <b>Index No.:</b> 604-001-00-2	<b>phenol</b> Acute Tox. 3 (H301, H331, H311), Aquatic Chronic 2 (H411), Eye Dam. 1 (H318), Muta. 2 (H341), STOT RE 2 (H373), Skin Corr. 1B (H314)  <b>Danger</b> <b>Specific concentration limit (SCL)</b> Skin Corr. 1B; H314: $C \geq 3\%$ Skin Irrit. 2; H315: $1\% \leq C < 3\%$ Eye Dam. 1; H318: $C \geq 3\%$ Eye Irrit. 2; H319: $1\% \leq C < 3\%$	0 - < 0.007 weight-%

Full text of H- and EUH-phrases: see section 16.

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

#### General information:

In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible). Remove victim out of the danger area. Remove contaminated, saturated clothing. If unconscious but breathing normally, place in recovery position and seek medical advice. Do not leave affected person unattended.

#### Following inhalation:

Provide fresh air.

#### Following ingestion:

Rinse mouth. Let 1 glass of water be drunken in little sips (dilution effect). Get medical advice/attention if you feel unwell.

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

No known symptoms to date.

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

Treat symptomatically.

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

#### Suitable extinguishing media:

Co-ordinate fire-fighting measures to the fire surroundings.

### 5.2. Special hazards arising from the substance or mixture

The product itself does not burn.

# SAFETY DATA SHEET

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

Revision date: 27 Oct 2022

Print date: 28 Nov 2022

Page: 3/9  
Version: 1

## Calibrators A-F (CAL), Cut-off Calibrator (CO-CAL), Positive Control (CON +), Negative Control (CON -)

### Hazardous combustion products:

In case of fire: Gases/vapours, toxic

### 5.3. Advice for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing.

### 5.4. Additional information

Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

#### 6.1.1. For non-emergency personnel

##### Personal precautions:

Remove persons to safety. Avoid breathing dust/fume/gas/mist/vapours/spray.

##### Protective equipment:

Wear protective gloves/protective clothing/eye protection/face protection.

#### 6.1.2. For emergency responders

##### Personal protection equipment:

Personal protection equipment: see section 8

### 6.2. Environmental precautions

Do not allow to enter into surface water or drains.

### 6.3. Methods and material for containment and cleaning up

##### For containment:

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents).

### 6.4. Reference to other sections

Safe handling: see section 7 Personal protection equipment: see section 8 Disposal: see section 13

### 6.5. Additional information

Use appropriate container to avoid environmental contamination.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

#### Protective measures

##### Advices on safe handling:

Wear personal protection equipment (refer to section 8).

##### Fire prevent measures:

No special measures are necessary.

##### Advices on general occupational hygiene

When using do not eat, drink, smoke, sniff. Avoid contact with skin, eyes and clothes.

### 7.2. Conditions for safe storage, including any incompatibilities

#### Technical measures and storage conditions:

Keep container tightly closed in a cool, well-ventilated place.

#### Further information on storage conditions:

Recommended storage temperature: 2-8°C

### 7.3. Specific end use(s)

#### Recommendation:

Item 1.2 and the instructions for use must be observed.

# SAFETY DATA SHEET

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

Revision date: 27 Oct 2022

Print date: 28 Nov 2022

Page: 4/9

Version: 1

## Calibrators A-F (CAL)®, Cut-off Calibrator (CO-CAL) Positive Control (CON +), Negative Control (CON -)

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

##### 8.1.1. Occupational exposure limit values

Limit value type (country of origin)	Substance name	① Long-term occupational exposure limit value ② Short-term occupational exposure limit value ③ Instantaneous value ④ Monitoring and observation processes ⑤ Remark
WEL (GB)	phenol CAS No.: 108-95-2 EC No.: 203-632-7	① 2 ppm (7.8 mg/m <sup>3</sup> ) ② 4 ppm (16 mg/m <sup>3</sup> ) ⑤ (may be absorbed through the skin)
TRGS 900 (DE)	phenol CAS No.: 108-95-2 EC No.: 203-632-7	① 2 ppm (8 mg/m <sup>3</sup> ) ② 4 ppm (16 mg/m <sup>3</sup> ) ⑤ (Aerosol und Dampf, kann über die Haut aufgenommen werden) EU, H, 11
ES	phenol CAS No.: 108-95-2 EC No.: 203-632-7	① 2 ppm (8 mg/m <sup>3</sup> ) ② 4 ppm (16 mg/m <sup>3</sup> ) ⑤ (puede ser absorbido a través dérmica) vía dérmica, VLB®, VLI
IOELV (EU)	phenol CAS No.: 108-95-2 EC No.: 203-632-7	① 2 ppm (8 mg/m <sup>3</sup> ) ② 4 ppm (16 mg/m <sup>3</sup> ) ⑤ (may be absorbed through the skin)
VRC (FR)	phenol CAS No.: 108-95-2 EC No.: 203-632-7	① 2 ppm (7.8 mg/m <sup>3</sup> ) ② 4 ppm (15.6 mg/m <sup>3</sup> ) ⑤ (peut être absorbé par la peau)
GR	phenol CAS No.: 108-95-2 EC No.: 203-632-7	① 2 ppm (8 mg/m <sup>3</sup> ) ② 4 ppm (16 mg/m <sup>3</sup> ) ⑤ (αναμένετε απορρόφηση από το δέρμα)
ACGIH (US)	phenol CAS No.: 108-95-2 EC No.: 203-632-7	① 5 ppm (19 mg/m <sup>3</sup> ) ⑤ (may be absorbed through the skin)

##### 8.1.2. Biological limit values

Limit value type (country of origin)	Substance name	Limit value	① Parameter ② Test material ③ Time of sampling: ④ Remark
TRGS 903 (DE)	phenol CAS No.: 108-95-2 EC No.: 203-632-7	120 mg/g Creatinin	① Phenol ② Urin ③ Expositionsende bzw. Schichtende
VLB (ES)	phenol CAS No.: 108-95-2 EC No.: 203-632-7	120 mg/g creatinina	① fenol ② orina ③ fin de exposición o fin de turno
ACGIH-BEI (US)	phenol CAS No.: 108-95-2 EC No.: 203-632-7	250 mg/g creatinine	① phenol ② urine ③ end of exposure or end of shift
BLV (EU)	phenol CAS No.: 108-95-2 EC No.: 203-632-7	120 mg/g creatinine	① phenol ② urine ③ no restriction

# SAFETY DATA SHEET

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

Revision date: 27 Oct 2022

Print date: 28 Nov 2022

Page: 5/9

Version: 1

## Calibrators A-F (CAL), Cut-off Calibrator (CO-CAL), Positive Control (CON +), Negative Control (CON -)

### 8.1.3. DNEL-/PNEC-values

No data available

### 8.2. Exposure controls

#### 8.2.1. Appropriate engineering controls

No data available

#### 8.2.2. Personal protection equipment

##### Eye/face protection:

Eye glasses with side protection EN 166

##### Skin protection:

Tested protective gloves must be worn EN ISO 374 Suitable material: Breakthrough time: min In the case of wanting to use the gloves again, clean them before taking off and air them well. Breakthrough times and swelling properties of the material must be taken into consideration.

#### 8.2.3. Environmental exposure controls

No data available

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

#### Appearance

**Physical state:** Liquid

**Colour:** yellow-orange

**Odour:** not determined

#### Safety relevant basis data

Parameter	Value	at °C	① Method ② Remark
pH	6.7 - 6.9	21 °C	
Melting point	<i>not determined</i>		
Freezing point	<i>not determined</i>		
Initial boiling point and boiling range	<i>not determined</i>		
Decomposition temperature	<i>not determined</i>		
Flash point	<i>not determined</i>		
Evaporation rate	<i>not determined</i>		
Auto-ignition temperature	<i>not determined</i>		
Upper/lower flammability or explosive limits	<i>not determined</i>		
Vapour pressure	<i>not determined</i>		
Vapour density	<i>not determined</i>		
Density	<i>not determined</i>		
Relative density	<i>not determined</i>		
Bulk density	<i>not determined</i>		
Water solubility	<i>not determined</i>		
Partition coefficient: n-octanol/water	<i>not determined</i>		
Dynamic viscosity	<i>not determined</i>		
Kinematic viscosity	<i>not determined</i>		

### 9.2. Other information

No data available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

The product itself does not burn. not relevant

# SAFETY DATA SHEET

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

Revision date: 27 Oct 2022

Print date: 28 Nov 2022

Page: 6/9

Version: 1

## Calibrators A-F (CAL), Cut-off Calibrator (CO-CAL), Positive Control (CON +) Negative Control (CON -)

### 10.2. Chemical stability

Light, heat, moisture (no dangerous reaction follows, the product becomes unusable).

### 10.3. Possibility of hazardous reactions

No known hazardous reactions.

### 10.4. Conditions to avoid

Light, heat, moisture (no dangerous reaction follows, the product becomes unusable).

### 10.5. Incompatible materials

No data available

### 10.6. Hazardous decomposition products

In case of fire: Gases/vapours, toxic

### Further information

Light, heat, moisture (no dangerous reaction follows, the product becomes unusable)

## SECTION 11: Toxicological information

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

phenol	CAS No.:	108-95-2	EC No.:	203-632-7
--------	----------	----------	---------	-----------

LD <sub>50</sub> oral:	317 mg/kg (Ratte)
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LD <sub>50</sub> dermal:	630 mg/kg (Kaninchen)
--------------------------	-----------------------

#### Acute oral toxicity:

Based on available data, the classification criteria are not met.

#### Acute dermal toxicity:

Based on available data, the classification criteria are not met.

#### Acute inhalation toxicity:

Based on available data, the classification criteria are not met.

#### Skin corrosion/irritation:

Based on available data, the classification criteria are not met.

#### Serious eye damage/irritation:

Based on available data, the classification criteria are not met.

#### Respiratory or skin sensitisation:

Based on available data, the classification criteria are not met.

#### Germ cell mutagenicity:

Based on available data, the classification criteria are not met.

#### Carcinogenicity:

Based on available data, the classification criteria are not met.

#### Reproductive toxicity:

Based on available data, the classification criteria are not met.

#### STOT-single exposure:

Based on available data, the classification criteria are not met.

#### STOT-repeated exposure:

Based on available data, the classification criteria are not met.

#### Aspiration hazard:

Based on available data, the classification criteria are not met.

#### Additional information:

No data available

### 11.2. Information on other hazards

#### Endocrine disrupting properties:

This product does not contain a substance that has endocrine disrupting properties with respect to humans as no components meets the criteria.

# SAFETY DATA SHEET

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

Revision date: 27 Oct 2022

Print date: 28 Nov 2022

Page: 7/9

Version: 1

## Calibrators A-F (CAL), Cut-off Calibrator (CO-CAL), Positive Control (CON +), Negative Control (CON -)

### SECTION 12: Ecological information

#### 12.1. Toxicity

phenol CAS No.: 108-95-2 EC No.: 203-632-7

LC<sub>50</sub>: 8.9 mg/L 4 d (fish)

EC<sub>50</sub>: 3.1 mg/L 2 d

LC<sub>50</sub>: 21.93 mg/L (fish)

EC<sub>50</sub>: 10 mg/L

NOEC: 0.077 mg/L (fish)

#### 12.2. Persistence and degradability

phenol CAS No.: 108-95-2 EC No.: 203-632-7

Biodegradation: Yes, rapidly

#### 12.3. Bioaccumulative potential

phenol CAS No.: 108-95-2 EC No.: 203-632-7

Log K<sub>ow</sub>: 1.47

Bioconcentration factor (BCF): 17.5

#### 12.4. Mobility in soil

No data available

#### 12.5. Results of PBT and vPvB assessment

phenol CAS No.: 108-95-2 EC No.: 203-632-7

Results of PBT and vPvB assessment: This substance does not meet the PBT/vPvB criteria of REACH, Annex XIII.

#### 12.6. Endocrine disrupting properties

No data available

#### 12.7. Other adverse effects

No data available

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

##### 13.1.1. Product/Packaging disposal

Waste codes/waste designations according to EWC/AVV

Waste code product

18 02 03 wastes whose collection and disposal is not subject to special requirements in order to prevent infection

#### Waste treatment options

Appropriate disposal / Product:

Consult the appropriate local waste disposal expert about waste disposal.

### SECTION 14: Transport information

Land transport (ADR/RID)	Inland waterway craft (ADN)	Sea transport (IMDG)	Air transport (ICAO-TI / IATA-DGR)
--------------------------	-----------------------------	----------------------	------------------------------------

#### 14.1. UN number or ID number

No dangerous good in sense of these transport regulations.

No dangerous good in sense of these transport regulations.

No dangerous good in sense of these transport regulations.

No dangerous good in sense of these transport regulations.

#### 14.2. UN proper shipping name

No dangerous good in sense of these transport regulations.

No dangerous good in sense of these transport regulations.

No dangerous good in sense of these transport regulations.

No dangerous good in sense of these transport regulations.

# SAFETY DATA SHEET

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

Revision date: 27 Oct 2022

Print date: 28 Nov 2022

Page: 8/9  
Version: 1

## Calibrators A-F (CAL), Cut-off Calibrator (CO-CAL), Positive Control (CON +), Negative Control (CON -)

Land transport (ADR/RID)	Inland waterway craft (ADN)	Sea transport (IMDG)	Air transport (ICAO-TI / IATA-DGR)
<b>14.3. Transport hazard class(es)</b>			
not relevant	not relevant	not relevant	not relevant
<b>14.4. Packing group</b>			
not relevant	not relevant	not relevant	not relevant
<b>14.5. Environmental hazards</b>			
not relevant	not relevant	not relevant	not relevant
<b>14.6. Special precautions for user</b>			
not relevant	not relevant	not relevant	not relevant

### 14.7. Maritime transport in bulk according to IMO instruments

No data available

## SECTION 15: Regulatory information

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

#### 15.1.1. EU legislation

No data available

#### 15.1.2. National regulations

 [DE] National regulations

#### Water hazard class

WGK:

### 15.2. Chemical Safety Assessment

No data available

## SECTION 16: Other information

**16.1. Indication of changes** Revision according to REACH Regulation (EC) No. 1907/2006, last amended by Regulation (EU) 2020/878

### 16.2. Abbreviations and acronyms

°C centigrade

ABEK Gases and vapors from organic compounds with a boiling point >65°C (A), inorganic gases and vapors, except carbon monoxide (B), sulfur dioxide and other acidic gases and vapors (E) and ammonia and organic ammonia derivatives (K)

ADR European Agreement concerning the International Carriage of Dangerous Goods by Road ( Accord européen relatif au transport international des marchandises dangereuses par route)

AWSV Ordinance on systems for handling water-polluting substances

CO carbon monoxide

CO<sub>2</sub> carbon dioxide

EC/EU European Community/European Union

EN European standard

IATA International Air Transport Association

# SAFETY DATA SHEET

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

Revision date: 27 Oct 2022

Print date: 28 Nov 2022

Page: 9/9

Version: 1

## Calibrators A-F (CAL), Cut-off Calibrator (CO-CAL) Positive Control (CON +) Negative Control (CON -)

IBC bulk packaging (Intermediate Bulk Container)

IgA Immunoglobuline A

IgG Immunoglobulin G

IgM Immunoglobuline M

IMDG International Maritime Code for Dangerous Goods

IVD in vitro diagnostics

MARPOL International Convention for the Prevention of Marine Pollution

NIOSH National Institute for Occupational Safety and Health

PBT Persistent (P), Bioaccumulative (B), Toxic (T)

RID Regulations for the International Carriage of Dangerous Goods by Rail (Règlement concernant le transport international ferroviaire de marchandises Dangereuse)

UN United Nations

vPvB very Persistent (vP), very Bioaccumulative (vB)

### 16.3. Key literature references and sources for data

No data available

### 16.4. Classification for mixtures and used evaluation method according to regulation (EC) No 1272/2008 [CLP]

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

### 16.5. Relevant R-, H- and EUH-phrases (Number and full text)

Hazard statements	
H301	Toxic if swallowed.
H302	Harmful if swallowed.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H331	Toxic if inhaled.
H341	Suspected of causing genetic defects.
H373	May cause damage to organs through prolonged or repeated exposure.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H411	Toxic to aquatic life with long lasting effects.

### 16.6. Training advice

No data available

### 16.7. Additional information

The information is based on the current state of our knowledge.

# SAFETY DATA SHEET

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

**Revision date:** 28 Oct 2022

**Print date:** 28 Nov 2022

**Version:** 2

Page 1/8

## Sample Dilution Buffer 5x

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

**Trade name/designation:**

Sample Dilution Buffer 5x

**Other means of identification:**

SB 5x

**Article No.:**

3xxx

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

**Use of the substance/mixture:**

This enzyme immunoassay (in vitro diagnostic tool or component) is not intended for anything other than the detection and semi-quantitative determination of human IgA / IgG / IgM antibodies against specific antigens in autoimmune diagnostics. This assay and its reagents are not for personal or veterinary use. The reagents should not be used for any purpose other than the intended purpose.

#### 1.3. Details of the supplier of the safety data sheet

**Manufacturer:**

ALPCO  
26-G Keewaydin Drive  
Salem, NH 03079 USA  
Phone: (800) 592-5726  
email: ts@alpc.com

#### 1.4. Emergency telephone number

Dial 911 in the United States. If outside the United States, dial local emergency number.

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

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

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

#### 2.2. Label elements

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

According to EC directives or the corresponding national regulations the product does not have to be labelled.

**Hazard statements:** none

**Supplemental hazard information:** none

**Precautionary statements:** none

#### 2.3. Other hazards

**Adverse human health effects and symptoms:**

This product does not contain a substance that has endocrine disrupting properties with respect to humans as no components meets the criteria.

**Adverse environmental effects:**

This mixture does not contain any substances presenting a health or environmental hazard within the means of Regulation (EC) No. 1272/2008, assigned a Community workplace exposure limit, classified as PBT/vPvB or included in the Candidate List.

# SAFETY DATA SHEET

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

**Revision date:** 28 Oct 2022

**Print date:** 28 Nov 2022

**Version:** 2

Page 2/8

## Sample Dilution Buffer 5x


### Other adverse effects:

This mixture contains material of human or animal origin and is therefore considered as potentially infectious.

## SECTION 3: Composition/information on ingredients

### 3.2. Mixtures

#### Hazardous ingredients / Hazardous impurities / Stabilisers:

Product identifiers	Substance name Classification according to Regulation (EC) No 1272/2008 [CLP]	Concentration
<b>CAS No.:</b> 26628-22-8 <b>EC No.:</b> 247-852-1 <b>REACH No.:</b> 01-2119457019-37	<b>Natriumazid</b> Acute Tox. 1 (H310), Acute Tox. 2 (H300, H330), Aquatic Acute 1 (H400), Aquatic Chronic 1 (H410), STOT RE 2 (H373)  <b>Danger</b>	0.01 - ≤ 0.05 weight-%

Full text of H- and EUH-phrases: see section 16.

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

#### General information:

In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible). Remove victim out of the danger area. Remove contaminated, saturated clothing. If unconscious but breathing normally, place in recovery position and seek medical advice. Do not leave affected person unattended.

#### Following inhalation:

Provide fresh air.

#### Following ingestion:

Rinse mouth. Let 1 glass of water be drunken in little sips (dilution effect). Get medical advice/attention if you feel unwell.

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

No known symptoms to date.

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

Treat symptomatically.

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

#### Suitable extinguishing media:

Co-ordinate fire-fighting measures to the fire surroundings.

### 5.2. Special hazards arising from the substance or mixture

The product itself does not burn.

#### Hazardous combustion products:

In case of fire: Gases/vapours, toxic

### 5.3. Advice for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing.

### 5.4. Additional information

Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

#### 6.1.1. For non-emergency personnel

##### Personal precautions:

Remove persons to safety. Avoid breathing dust/fume/gas/mist/vapours/spray.

##### Protective equipment:

Wear protective gloves/protective clothing/eye protection/face protection.

# SAFETY DATA SHEET

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

Revision date: 28 Oct 2022

Print date: 28 Nov 2022

Version: 2

Page 3/8

## Sample Dilution Buffer 5x

### 6.1.2. For emergency responders

#### Personal protection equipment:

Personal protection equipment: see section 8

### 6.2. Environmental precautions

Do not allow to enter into surface water or drains.

### 6.3. Methods and material for containment and cleaning up

#### For containment:

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents).

### 6.4. Reference to other sections

Safe handling: see section 7 Personal protection equipment: see section 8 Disposal: see section 13

### 6.5. Additional information

Use appropriate container to avoid environmental contamination.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

#### Protective measures

#### Advices on safe handling:

Wear personal protection equipment (refer to section 8).

#### Fire prevent measures:

No special measures are necessary.

#### Advices on general occupational hygiene

When using do not eat, drink, smoke, sniff. Avoid contact with skin, eyes and clothes.

### 7.2. Conditions for safe storage, including any incompatibilities

#### Technical measures and storage conditions:

Keep container tightly closed in a cool, well-ventilated place.

#### Further information on storage conditions:

Recommended storage temperature: 2-8°C

### 7.3. Specific end use(s)

#### Recommendation:

Item 1.2 and the instructions for use must be observed.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### 8.1.1. Occupational exposure limit values

Limit value type (country of origin)	Substance name	① Long-term occupational exposure limit value ② Short-term occupational exposure limit value ③ Instantaneous value ④ Monitoring and observation processes ⑤ Remark
WEL (GB)	Natriumazid CAS No.: 26628-22-8 EC No.: 247-852-1	① 0.1 mg/m <sup>3</sup> ② 0.3 mg/m <sup>3</sup> ⑤ (may be absorbed through the skin)
ES	Natriumazid CAS No.: 26628-22-8 EC No.: 247-852-1	① 0.1 mg/m <sup>3</sup> ② 0.3 mg/m <sup>3</sup> ⑤ (puede ser absorbido a través dérmica) vía dérmica, VLI
VRC (FR)	Natriumazid CAS No.: 26628-22-8 EC No.: 247-852-1	① 0.1 mg/m <sup>3</sup> ② 0.3 mg/m <sup>3</sup> ⑤ (peut être absorbé par la peau)

# SAFETY DATA SHEET

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

Revision date: 28 Oct 2022

Print date: 28 Nov 2022

Version: 2

Page 4/8

## Sample Dilution Buffer 5x

Limit value type (country of origin)	Substance name	① Long-term occupational exposure limit value ② Short-term occupational exposure limit value ③ Instantaneous value ④ Monitoring and observation processes ⑤ Remark
ACGIH (US)	Natriumazid CAS No.: 26628-22-8 EC No.: 247-852-1	③ 0.29 mg/m <sup>3</sup> ⑤ (as Sodium azide)
GR	Natriumazid CAS No.: 26628-22-8 EC No.: 247-852-1	① 0.1 ppm (0.3 mg/m <sup>3</sup> ) ② 0.1 ppm (0.3 mg/m <sup>3</sup> )
ACGIH (US)	Natriumazid CAS No.: 26628-22-8 EC No.: 247-852-1	③ 0.11 ppm ⑤ (as Hydrazoic acid vapour)
IOELV (EU)	Natriumazid CAS No.: 26628-22-8 EC No.: 247-852-1	① 0.1 mg/m <sup>3</sup> ② 0.3 mg/m <sup>3</sup> ⑤ (may be absorbed through the skin)
TRGS 900 (DE)	Natriumazid CAS No.: 26628-22-8 EC No.: 247-852-1	① 0.2 mg/m <sup>3</sup> ② 0.4 mg/m <sup>3</sup> ⑤ (einatembare Fraktion) DFG, EU

### 8.1.2. Biological limit values

No data available

### 8.1.3. DNEL-/PNEC-values

No data available

## 8.2. Exposure controls

### 8.2.1. Appropriate engineering controls

No data available

### 8.2.2. Personal protection equipment

#### Eye/face protection:

Eye glasses with side protection EN 166

#### Skin protection:

Tested protective gloves must be worn EN ISO 374 Suitable material: Breakthrough time: min In the case of wanting to use the gloves again, clean them before taking off and air them well. Breakthrough times and swelling properties of the material must be taken into consideration.

### 8.2.3. Environmental exposure controls

No data available

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

#### Appearance

Physical state: Liquid

Colour: yellow

Odour: not determined

#### Safety relevant basis data

Parameter	Value	at °C	① Method ② Remark
pH	7.4 - 7.6	21 °C	
Melting point	<i>not determined</i>		
Freezing point	<i>not determined</i>		
Initial boiling point and boiling range	<i>not determined</i>		
Decomposition temperature	<i>not determined</i>		
Flash point	<i>not determined</i>		

# SAFETY DATA SHEET

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

Revision date: 28 Oct 2022

Print date: 28 Nov 2022

Version: 2

Page 5/8

## Sample Dilution Buffer 5x

Parameter	Value	at °C	① Method ② Remark
Evaporation rate	<i>not determined</i>		
Auto-ignition temperature	<i>not determined</i>		
Upper/lower flammability or explosive limits	<i>not determined</i>		
Vapour pressure	<i>not determined</i>		
Vapour density	<i>not determined</i>		
Density	<i>not determined</i>		
Relative density	<i>not determined</i>		
Bulk density	<i>not determined</i>		
Water solubility	<i>not determined</i>		
Partition coefficient: n-octanol/water	<i>not determined</i>		
Dynamic viscosity	<i>not determined</i>		
Kinematic viscosity	<i>not determined</i>		

### 9.2. Other information

No data available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

Light, heat, moisture (no dangerous reaction follows, the product becomes unusable).

### 10.2. Chemical stability

No data available

### 10.3. Possibility of hazardous reactions

No data available

### 10.4. Conditions to avoid

No data available

### 10.5. Incompatible materials

No data available

### 10.6. Hazardous decomposition products

In case of fire: Gases/vapours, toxic

### Further information

Light, heat, moisture (no dangerous reaction follows, the product becomes unusable)

## SECTION 11: Toxicological information

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

**Natriumazid** CAS No.: 26628-22-8 EC No.: 247-852-1

**LD<sub>50</sub> oral:** 27 mg/kg (Rat) TOXNET

**LD<sub>50</sub> dermal:** 20 mg/kg (Rat) TOXNET

#### Acute oral toxicity:

Based on available data, the classification criteria are not met.

#### Acute dermal toxicity:

Based on available data, the classification criteria are not met.

#### Acute inhalation toxicity:

Based on available data, the classification criteria are not met.

#### Skin corrosion/irritation:

Based on available data, the classification criteria are not met.

#### Serious eye damage/irritation:

Based on available data, the classification criteria are not met.

# SAFETY DATA SHEET

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

**Revision date:** 28 Oct 2022

**Print date:** 28 Nov 2022

**Version:** 2

Page 6/8

## Sample Dilution Buffer 5x

### **Respiratory or skin sensitisation:**

Based on available data, the classification criteria are not met.

### **Germ cell mutagenicity:**

Based on available data, the classification criteria are not met.

### **Carcinogenicity:**

Based on available data, the classification criteria are not met.

### **Reproductive toxicity:**

Based on available data, the classification criteria are not met.

### **STOT-single exposure:**

Based on available data, the classification criteria are not met.

### **STOT-repeated exposure:**

Based on available data, the classification criteria are not met.

### **Aspiration hazard:**

Based on available data, the classification criteria are not met.

### **Additional information:**

No data available

### **11.2. Information on other hazards**

No data available

## SECTION 12: Ecological information

### **12.1. Toxicity**

<b>Natriumazid</b> CAS No.: 26628-22-8 EC No.: 247-852-1
--

<b>LC<sub>50</sub>:</b> 2.75 mg/L 4 d (fish) ECHA
---

<b>EC<sub>50</sub>:</b> 0.35 mg/L 4 d (Algae/water plant) ECHA
--

### **12.2. Persistence and degradability**

No data available

### **12.3. Bioaccumulative potential**

No data available

### **12.4. Mobility in soil**

No data available

### **12.5. Results of PBT and vPvB assessment**

<b>Natriumazid</b> CAS No.: 26628-22-8 EC No.: 247-852-1
--

<b>Results of PBT and vPvB assessment:</b> This substance does not meet the PBT/vPvB criteria of REACH, Annex XIII.
---

### **12.6. Endocrine disrupting properties**

No data available

### **12.7. Other adverse effects**

No data available

## SECTION 13: Disposal considerations

### **13.1. Waste treatment methods**

#### **13.1.1. Product/Packaging disposal**

#### **Waste codes/waste designations according to EWC/AVV**

#### **Waste code product**

18 02 03	wastes whose collection and disposal is not subject to special requirements in order to prevent infection
----------	---

#### **Waste treatment options**

#### **Appropriate disposal / Product:**

Consult the appropriate local waste disposal expert about waste disposal.

#### **13.2. Additional information**

Do not allow to enter into surface water or drains.

# SAFETY DATA SHEET

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

Revision date: 28 Oct 2022

Print date: 28 Nov 2022

Version: 2

Page 7/8

## Sample Dilution Buffer 5x

### SECTION 14: Transport information

Land transport (ADR/RID)	Inland waterway craft (ADN)	Sea transport (IMDG)	Air transport (ICAO-TI / IATA-DGR)
<b>14.1. UN number or ID number</b>			
No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.
<b>14.2. UN proper shipping name</b>			
No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.
<b>14.3. Transport hazard class(es)</b>			
not relevant	not relevant	not relevant	not relevant
<b>14.4. Packing group</b>			
not relevant	not relevant	not relevant	not relevant
<b>14.5. Environmental hazards</b>			
not relevant	not relevant	not relevant	not relevant
<b>14.6. Special precautions for user</b>			
not relevant	not relevant	not relevant	not relevant

#### 14.7. Maritime transport in bulk according to IMO instruments

No data available

### SECTION 15: Regulatory information

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

##### 15.1.1. EU legislation

No data available

##### 15.1.2. National regulations

 [DE] National regulations

##### Water hazard class

###### WGK:

nwg - nicht wassergefährdend

#### 15.2. Chemical Safety Assessment

No data available

### SECTION 16: Other information

#### 16.1. Indication of changes

Revision according to REACH Regulation (EC) No. 1907/2006, last amended by Regulation (EU) 2020/878

#### 16.2. Abbreviations and acronyms

°C centigrade

ABEK Gases and vapors from organic compounds with a boiling point >65°C (A), inorganic gases and vapors, except carbon monoxide (B), sulfur dioxide and other acidic gases and vapors (E) and ammonia and organic ammonia derivatives (K)

ADR European Agreement concerning the International Carriage of Dangerous Goods by Road ( Accord européen relatif au transport international des marchandises dangereuses par route)

AwSV Ordinance on systems for handling water-polluting substances

CO carbon monoxide

# SAFETY DATA SHEET

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

**Revision date:** 28 Oct 2022

**Print date:** 28 Nov 2022

**Version:** 2

Page 8/8

## Sample Dilution Buffer 5x

CO2 carbon dioxide

EC/EU European Community/European Union

EN European standard

IATA International Air Transport Association

IBC bulk packaging (Intermediate Bulk Container)

IgA Immunoglobuline A

IgG Immunoglobulin G

IgM Immunoglobuline M

IMDG International Maritime Code for Dangerous Goods

IVD in vitro diagnostics

MARPOL International Convention for the Prevention of Marine Pollution

NIOSH National Institute for Occupational Safety and Health

PBT Persistent (P), Bioaccumulative (B), Toxic (T)

RID Regulations for the International Carriage of Dangerous Goods by Rail (Règlement concernant le transport international ferroviaire de marchandises Dangereuse)

UN United Nations

vPvB very Persistent (vP), very Bioaccumulative (vB)

### 16.3. Key literature references and sources for data

No data available

### 16.4. Classification for mixtures and used evaluation method according to regulation (EC) No 1272/2008 [CLP]

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

### 16.5. Relevant R-, H- and EUH-phrases (Number and full text)

Hazard statements	
H300	Fatal if swallowed.
H310	Fatal in contact with skin.
H330	Fatal if inhaled.
H373	May cause damage to organs through prolonged or repeated exposure.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

### 16.6. Training advice

No data available

### 16.7. Additional information

The information is based on the current state of our knowledge.

# SAFETY DATA SHEET

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

Revision date: 2 Nov 2022

Print date: 29 Nov 2022

Version: 2

Page 1/8

## wash buffer, 50x conc.

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

Trade name/designation:

wash buffer, 50x conc.

Other means of identification:

WASHB 50x

Article No.:

3xxx

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

Use of the substance/mixture:

This assay and its reagents are not for personal or veterinary use. The reagents should not be used for any purpose other than the intended purpose.

#### 1.3. Details of the supplier of the safety data sheet

Manufacturer:

ALPCO  
26-G Keewaydin Drive  
Salem, NH 03079 USA  
phone: (800) 592-5726  
email: ts@alpco.com

#### 1.4. Emergency telephone number

Dial 911 in the United States. If outside of the United States, dial local emergency number.

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

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

Hazard classes and hazard categories	Hazard statements	Classification procedure
Hazardous to the aquatic environment (Aquatic Chronic 3)	H412: Harmful to aquatic life with long lasting effects.	

#### 2.2. Label elements

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

According to EC directives or the corresponding national regulations the product does not have to be labelled.

Hazard statements for environmental hazards	
H412	Harmful to aquatic life with long lasting effects.
Supplemental hazard information	
EUH208	Contains ProClin ® 300. May produce an allergic reaction.
Precautionary statements Prevention	
P270	Do not eat, drink or smoke when using this product.
P273	Avoid release to the environment.
Precautionary statements Disposal	
P501	Dispose of contents/container to ....

# SAFETY DATA SHEET

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

**Revision date:** 2 Nov 2022

**Print date:** 29 Nov 2022

**Version:** 2

Page 2/8

## wash buffer, 50x conc.

### 2.3. Other hazards

#### Adverse human health effects and symptoms:

This product does not contain a substance that has endocrine disrupting properties with respect to humans as no components meets the criteria.

#### Adverse environmental effects:

This mixture does not contain any substances presenting a health or environmental hazard within the means of Regulation (EC) No. 1272/2008, assigned a Community workplace exposure limit, classified as PBT/vPvB or included in the Candidate List.




#### Other adverse effects:

The mixture contains material of human or animal origin and is therefore classified as potentially infectious.

## SECTION 3: Composition/information on ingredients

### 3.2. Mixtures

#### Hazardous ingredients / Hazardous impurities / Stabilisers:

Product identifiers	Substance name Classification according to Regulation (EC) No 1272/2008 [CLP]	Concentration
	<b>ProClin ® 300</b> Acute Tox. 4 (H302), Aquatic Acute 1 (H400), Aquatic Chronic 1 (H410), Skin Corr. 1B (H314), Skin Sens. 1 (H317)    <b>Danger</b>	0.1 - ≤ 0.5 weight-%

Full text of H- and EUH-phrases: see section 16.

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

#### General information:

In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible). Remove victim out of the danger area. Remove contaminated, saturated clothing. If unconscious but breathing normally, place in recovery position and seek medical advice. Do not leave affected person unattended.

#### Following inhalation:

Provide fresh air.

#### Following ingestion:

Rinse mouth. Let 1 glass of water be drunken in little sips (dilution effect). Get medical advice/attention if you feel unwell.

### 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.

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

#### Suitable extinguishing media:

Co-ordinate fire-fighting measures to the fire surroundings.

### 5.2. Special hazards arising from the substance or mixture

The product itself does not burn.

#### Hazardous combustion products:

In case of fire: Gases/vapours, toxic

### 5.3. Advice for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing.

### 5.4. Additional information

Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

# SAFETY DATA SHEET

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

**Revision date:** 2 Nov 2022

**Print date:** 29 Nov 2022

**Version:** 2

Page 3/8

## wash buffer, 50x conc.

### SECTION 6: Accidental release measures

#### 6.1. Personal precautions, protective equipment and emergency procedures

##### 6.1.1. For non-emergency personnel

**Personal precautions:**

Remove persons to safety.

**Protective equipment:**

Wear protective gloves/protective clothing/eye protection/face protection.

##### 6.1.2. For emergency responders

**Personal protection equipment:**

Personal protection equipment: see section 8

#### 6.2. Environmental precautions

Do not allow to enter into surface water or drains.

#### 6.3. Methods and material for containment and cleaning up

**For containment:**

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents).

#### 6.4. Reference to other sections

Safe handling: see section 7 Personal protection equipment: see section 8 Disposal: see section 13

#### 6.5. Additional information

Use appropriate container to avoid environmental contamination.

### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

**Protective measures**

**Advices on safe handling:**

Wear personal protection equipment (refer to section 8).

**Fire prevent measures:**

No special measures are necessary.

**Advices on general occupational hygiene**

When using do not eat, drink, smoke, sniff. Avoid contact with skin, eyes and clothes.

#### 7.2. Conditions for safe storage, including any incompatibilities

**Technical measures and storage conditions:**

Keep container tightly closed in a cool, well-ventilated place.

**Further information on storage conditions:**

Recommended storage temperature: 2-8°C

#### 7.3. Specific end use(s)

**Recommendation:**

Item 1.2 and the instructions for use must be observed.

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

No data available

#### 8.2. Exposure controls

##### 8.2.1. Appropriate engineering controls

No data available

##### 8.2.2. Personal protection equipment

**Eye/face protection:**

Eye glasses with side protection EN 166

# SAFETY DATA SHEET

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

Revision date: 2 Nov 2022

Print date: 29 Nov 2022

Version: 2

Page 4/8

## wash buffer, 50x conc.

### Skin protection:

Tested protective gloves must be worn EN ISO 374 Suitable material: Breakthrough time: min In the case of wanting to use the gloves again, clean them before taking off and air them well. Breakthrough times and swelling properties of the material must be taken into consideration.

### 8.2.3. Environmental exposure controls

No data available

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

#### Appearance

Physical state: Liquid

Colour: green

Odour: not determined

#### Safety relevant basis data

Parameter	Value	at °C	① Method ② Remark
pH	7.4 - 7.8	21 °C	
Melting point	<i>not determined</i>		
Freezing point	<i>not determined</i>		
Initial boiling point and boiling range	<i>not determined</i>		
Decomposition temperature	<i>not determined</i>		
Flash point	<i>not determined</i>		
Evaporation rate	<i>not determined</i>		
Auto-ignition temperature	<i>not determined</i>		
Upper/lower flammability or explosive limits	<i>not determined</i>		
Vapour pressure	<i>not determined</i>		
Vapour density	<i>not determined</i>		
Density	<i>not determined</i>		
Relative density	<i>not determined</i>		
Bulk density	<i>not determined</i>		
Water solubility	<i>not determined</i>		
Partition coefficient: n-octanol/water	<i>not determined</i>		
Dynamic viscosity	<i>not determined</i>		
Kinematic viscosity	<i>not determined</i>		

### 9.2. Other information

No data available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

The product itself does not burn.

### 10.2. Chemical stability

Light, heat, moisture (no dangerous reaction follows, the product becomes unusable).

### 10.3. Possibility of hazardous reactions

Light, heat, moisture (no dangerous reaction follows, the product becomes unusable).

### 10.4. Conditions to avoid

Light, heat, moisture (no dangerous reaction follows, the product becomes unusable).

### 10.5. Incompatible materials

No data available

### 10.6. Hazardous decomposition products

In case of fire: Gases/vapours, toxic

# SAFETY DATA SHEET

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

Revision date: 2 Nov 2022

Print date: 29 Nov 2022

Version: 2

Page 5/8

**wash buffer, 50x conc.**

## SECTION 11: Toxicological information

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

**ProClin ® 300**

**LD<sub>50</sub> oral:** 862 mg/kg (Ratte)

**LD<sub>50</sub> dermal:** 2,800 mg/kg (Kaninchen)

**Acute oral toxicity:**

Based on available data, the classification criteria are not met.

**Acute dermal toxicity:**

Based on available data, the classification criteria are not met.

**Acute inhalation toxicity:**

Based on available data, the classification criteria are not met.

**Skin corrosion/irritation:**

Based on available data, the classification criteria are not met.

**Serious eye damage/irritation:**

Based on available data, the classification criteria are not met.

**Respiratory or skin sensitisation:**

Contains ProClin ® 300. May produce an allergic reaction.

**Germ cell mutagenicity:**

Based on available data, the classification criteria are not met.

**Carcinogenicity:**

Based on available data, the classification criteria are not met.

**Reproductive toxicity:**

Based on available data, the classification criteria are not met.

**STOT-single exposure:**

Based on available data, the classification criteria are not met.

**STOT-repeated exposure:**

Based on available data, the classification criteria are not met.

**Aspiration hazard:**

Based on available data, the classification criteria are not met.

**Additional information:**

No data available

### 11.2. Information on other hazards

No data available

## SECTION 12: Ecological information

### 12.1. Toxicity

**Aquatic toxicity:**

Harmful to aquatic life with long lasting effects.

### 12.2. Persistence and degradability

**ProClin ® 300**

**Biodegradation:** Yes, slowly

### 12.3. Bioaccumulative potential

No data available

### 12.4. Mobility in soil

No data available

### 12.5. Results of PBT and vPvB assessment

**ProClin ® 300**

**Results of PBT and vPvB assessment:** This substance does not meet the PBT/vPvB criteria of REACH, Annex XIII.

# SAFETY DATA SHEET

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

Revision date: 2 Nov 2022

Print date: 29 Nov 2022

Version: 2

Page 6/8

## wash buffer, 50x conc.

### 12.6. Endocrine disrupting properties

No data available

### 12.7. Other adverse effects

No data available

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

#### 13.1.1. Product/Packaging disposal

Waste codes/waste designations according to EWC/AVV

Waste code product

18 02 03	wastes whose collection and disposal is not subject to special requirements in order to prevent infection
----------	---

Waste treatment options

Appropriate disposal / Product:

Consult the appropriate local waste disposal expert about waste disposal.

## SECTION 14: Transport information

Land transport (ADR/RID)	Inland waterway craft (ADN)	Sea transport (IMDG)	Air transport (ICAO-TI / IATA-DGR)
<b>14.1. UN number or ID number</b>			
No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.
<b>14.2. UN proper shipping name</b>			
No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.
<b>14.3. Transport hazard class(es)</b>			
not relevant	not relevant	not relevant	not relevant
<b>14.4. Packing group</b>			
not relevant	not relevant	not relevant	not relevant
<b>14.5. Environmental hazards</b>			
not relevant	not relevant	not relevant	not relevant
<b>14.6. Special precautions for user</b>			
not relevant	not relevant	not relevant	not relevant

### 14.7. Maritime transport in bulk according to IMO instruments

No data available

## SECTION 15: Regulatory information

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

#### 15.1.1. EU legislation

No data available

#### 15.1.2. National regulations

 [DE] National regulations

Water hazard class

WGK:

2 - deutlich wassergefährdend

### 15.2. Chemical Safety Assessment

No data available

# SAFETY DATA SHEET

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

**Revision date:** 2 Nov 2022

**Print date:** 29 Nov 2022

**Version:** 2

Page 7/8

## wash buffer, 50x conc.

### SECTION 16: Other information

#### 16.1. Indication of changes

Revision according to REACH Regulation (EC) No. 1907/2006, last amended by Regulation (EU) 2020/878

#### 16.2. Abbreviations and acronyms

°C centigrade

ABEK Gases and vapors from organic compounds with a boiling point >65°C (A), inorganic gases and vapors, except carbon monoxide (B), sulfur dioxide and other acidic gases and vapors (E) and ammonia and organic ammonia derivatives (K)

ADR European Agreement concerning the International Carriage of Dangerous Goods by Road ( Accord européen relatif au transport international des marchandises dangereuses par route)

AWSV Ordinance on systems for handling water-polluting substances

CO carbon monoxide

CO<sub>2</sub> carbon dioxide

EC/EU European Community/European Union

EN European standard

IATA International Air Transport Association

IBC bulk packaging (Intermediate Bulk Container)

IgA Immunoglobuline A

IgG Immunoglobulin G

IgM Immunoglobuline M

IMDG International Maritime Code for Dangerous Goods

IVD in vitro diagnostics

MARPOL International Convention for the Prevention of Marine Pollution

NIOSH National Institute for Occupational Safety and Health

PBT Persistent (P), Bioaccumulative (B), Toxic (T)

RID Regulations for the International Carriage of Dangerous Goods by Rail (Règlement concernant le transport international ferroviaire de marchandises Dangereuse)

UN United Nations

vPvB very Persistent (vP), very Bioaccumulative (vB)

#### 16.3. Key literature references and sources for data

No data available

# SAFETY DATA SHEET

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

**Revision date:** 2 Nov 2022

**Print date:** 29 Nov 2022

**Version:** 2

Page 8/8

## wash buffer, 50x conc.

### 16.4. Classification for mixtures and used evaluation method according to regulation (EC) No 1272/2008 [CLP]

Hazard classes and hazard categories	Hazard statements	Classification procedure
Hazardous to the aquatic environment ( <i>Aquatic Chronic 3</i> )	H412: Harmful to aquatic life with long lasting effects.	

### 16.5. Relevant R-, H- and EUH-phrases (Number and full text)

Hazard statements	
H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

### 16.6. Training advice

No data available

### 16.7. Additional information

The information is based on the current state of our knowledge.

# SAFETY DATA SHEET

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

**Revision date:** 27 Oct 2022

**Print date:** 28 Nov 2022

**Version:** 2

Page 1/10

## anti human IgG conjugate

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

**Trade name/designation:**

anti human IgG conjugate

**Article No.:**

3xxx

**UFI:**

NQ2Q-4HTP-WKGD-RXYV

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

**Use of the substance/mixture:**

This assay and its reagents are not for personal or veterinary use. The reagents should not be used for any purpose other than the intended purpose.

#### 1.3. Details of the supplier of the safety data sheet

**Manufacturer:**

ALPCO

26-G Keewaydin Drive

Salem, NH 03079 USA

phone: (800) 592-5726

email: ts@alpc.com

#### 1.4. Emergency telephone number

Dial 911 in the United States. If outside the US, dial local emergency number.

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

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

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

**Additional information:**

The mixture contains material of human or animal origin and is therefore classified as potentially infectious.

#### 2.2. Label elements

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

According to EC directives or the corresponding national regulations the product does not have to be labelled.

**Hazard statements:** none

**Supplemental hazard information**

EUH208

Contains ProClin ® 300. May produce an allergic reaction.

**Precautionary statements:** none

**Special rules for supplemental label elements for certain mixtures:**

1,5 % percent of the mixture consists of ingredient(s) of unknown acute toxicity (dermal).

2,8 % percent of the mixture consists of ingredient(s) of unknown acute toxicity (inhalative).

# SAFETY DATA SHEET

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

Revision date: 27 Oct 2022

Print date: 28 Nov 2022

Version: 2

Page 2/10

## anti human IgG conjugate

### 2.3. Other hazards

#### Adverse human health effects and symptoms:

This product does not contain a substance that has endocrine disrupting properties with respect to humans as no components meets the criteria.








#### Adverse environmental effects:

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

## SECTION 3: Composition/information on ingredients

### 3.2. Mixtures

#### Hazardous ingredients / Hazardous impurities / Stabilisers:

Product identifiers	Substance name Classification according to Regulation (EC) No 1272/2008 [CLP]	Concentration
	<b>ProClin ® 300</b> Acute Tox. 4 (H302), Aquatic Acute 1 (H400), Aquatic Chronic 1 (H410), Skin Corr. 1C (H314), Skin Sens. 1 (H317)    <b>Danger</b>	0 - ≤ 0.1 weight-%
<b>CAS No.:</b> 108-95-2 <b>EC No.:</b> 203-632-7 <b>Index No.:</b> 604-001-00-2	<b>phenol</b> Acute Tox. 3 (H301, H331, H311), Aquatic Chronic 2 (H411), Eye Dam. 1 (H318), Muta. 2 (H341), STOT RE 2 (H373), Skin Corr. 1B (H314)     <b>Danger</b> <b>Specific concentration limit (SCL)</b> Skin Corr. 1B; H314: C ≥ 3% Skin Irrit. 2; H315: 1% ≤ C < 3% Eye Dam. 1; H318: C ≥ 3% Eye Irrit. 2; H319: 1% ≤ C < 3%	0 - < 0.007 weight-%

Full text of H- and EUH-phrases: see section 16.

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

#### General information:

In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible). Remove victim out of the danger area. Remove contaminated, saturated clothing. If unconscious but breathing normally, place in recovery position and seek medical advice. Do not leave affected person unattended.

#### Following inhalation:

Provide fresh air.

#### Following ingestion:

Rinse mouth. Let 1 glass of water be drunken in little sips (dilution effect). Get medical advice/attention if you feel unwell.

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

No known symptoms to date.

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

Treat symptomatically.

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

#### Suitable extinguishing media:

Co-ordinate fire-fighting measures to the fire surroundings.

### 5.2. Special hazards arising from the substance or mixture

The product itself does not burn.

#### Hazardous combustion products:

In case of fire: Gases/vapours, toxic

# SAFETY DATA SHEET

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

**Revision date:** 27 Oct 2022

**Print date:** 28 Nov 2022

**Version:** 2

Page 3/10

## anti human IgG conjugate

### 5.3. Advice for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing.

### 5.4. Additional information

Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

#### 6.1.1. For non-emergency personnel

**Personal precautions:**

Remove persons to safety. Avoid breathing dust/fume/gas/mist/vapours/spray.

**Protective equipment:**

Wear protective gloves/protective clothing/eye protection/face protection.

#### 6.1.2. For emergency responders

**Personal protection equipment:**

Personal protection equipment: see section 8

### 6.2. Environmental precautions

Do not allow to enter into surface water or drains.

### 6.3. Methods and material for containment and cleaning up

**For containment:**

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents).

### 6.4. Reference to other sections

Safe handling: see section 7 Personal protection equipment: see section 8 Disposal: see section 13

### 6.5. Additional information

Use appropriate container to avoid environmental contamination.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

**Protective measures**

**Advices on safe handling:**

Wear personal protection equipment (refer to section 8).

**Fire prevent measures:**

No special measures are necessary.

**Advices on general occupational hygiene**

When using do not eat, drink, smoke, sniff. Avoid contact with skin, eyes and clothes.

### 7.2. Conditions for safe storage, including any incompatibilities

**Technical measures and storage conditions:**

Keep container tightly closed in a cool, well-ventilated place.

**Further information on storage conditions:**

Recommended storage temperature: 2-8°C

### 7.3. Specific end use(s)

**Recommendation:**

Item 1.2 and the instructions for use must be observed.

# SAFETY DATA SHEET

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

Revision date: 27 Oct 2022

Print date: 28 Nov 2022

Version: 2

Page 4/10

## anti human IgG conjugate

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

##### 8.1.1. Occupational exposure limit values

Limit value type (country of origin)	Substance name	① Long-term occupational exposure limit value ② Short-term occupational exposure limit value ③ Instantaneous value ④ Monitoring and observation processes ⑤ Remark
WEL (GB)	phenol CAS No.: 108-95-2 EC No.: 203-632-7	① 2 ppm (7.8 mg/m <sup>3</sup> ) ② 4 ppm (16 mg/m <sup>3</sup> ) ⑤ (may be absorbed through the skin)
TRGS 900 (DE)	phenol CAS No.: 108-95-2 EC No.: 203-632-7	① 2 ppm (8 mg/m <sup>3</sup> ) ② 4 ppm (16 mg/m <sup>3</sup> ) ⑤ (Aerosol und Dampf, kann über die Haut aufgenommen werden) EU, H, 11
ES	phenol CAS No.: 108-95-2 EC No.: 203-632-7	① 2 ppm (8 mg/m <sup>3</sup> ) ② 4 ppm (16 mg/m <sup>3</sup> ) ⑤ (puede ser absorbido a través dérmica) vía dérmica, VLB®, VLI
IOELV (EU)	phenol CAS No.: 108-95-2 EC No.: 203-632-7	① 2 ppm (8 mg/m <sup>3</sup> ) ② 4 ppm (16 mg/m <sup>3</sup> ) ⑤ (may be absorbed through the skin)
VRC (FR)	phenol CAS No.: 108-95-2 EC No.: 203-632-7	① 2 ppm (7.8 mg/m <sup>3</sup> ) ② 4 ppm (15.6 mg/m <sup>3</sup> ) ⑤ (peut être absorbé par la peau)
GR	phenol CAS No.: 108-95-2 EC No.: 203-632-7	① 2 ppm (8 mg/m <sup>3</sup> ) ② 4 ppm (16 mg/m <sup>3</sup> ) ⑤ (αναμένετε απορρόφηση από το δέρμα)
ACGIH (US)	phenol CAS No.: 108-95-2 EC No.: 203-632-7	① 5 ppm (19 mg/m <sup>3</sup> ) ⑤ (may be absorbed through the skin)

##### 8.1.2. Biological limit values

Limit value type (country of origin)	Substance name	Limit value	① Parameter ② Test material ③ Time of sampling: ④ Remark
TRGS 903 (DE)	phenol CAS No.: 108-95-2 EC No.: 203-632-7	120 mg/g Creatinin	① Phenol ② Urin ③ Expositionsende bzw. Schichtende
VLB (ES)	phenol CAS No.: 108-95-2 EC No.: 203-632-7	120 mg/g creatinina	① fenol ② orina ③ fin de exposición o fin de turno
ACGIH-BEI (US)	phenol CAS No.: 108-95-2 EC No.: 203-632-7	250 mg/g creatinine	① phenol ② urine ③ end of exposure or end of shift
BLV (EU)	phenol CAS No.: 108-95-2 EC No.: 203-632-7	120 mg/g creatinine	① phenol ② urine ③ no restriction

# SAFETY DATA SHEET

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

Revision date: 27 Oct 2022

Print date: 28 Nov 2022

Version: 2

Page 5/10

## anti human IgG conjugate

### 8.1.3. DNEL-/PNEC-values

No data available

### 8.2. Exposure controls

#### 8.2.1. Appropriate engineering controls

No data available

#### 8.2.2. Personal protection equipment

##### Eye/face protection:

Eye glasses with side protection EN 166

##### Skin protection:

Tested protective gloves must be worn EN ISO 374 Suitable material: Breakthrough time: min In the case of wanting to use the gloves again, clean them before taking off and air them well. Breakthrough times and swelling properties of the material must be taken into consideration.

#### 8.2.3. Environmental exposure controls

No data available

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

#### Appearance

Physical state: Liquid

Colour: blue

Odour: not determined

#### Safety relevant basis data

Parameter	Value	at °C	① Method ② Remark
pH	6.7 - 6.9	21 °C	
Melting point	<i>not determined</i>		
Freezing point	<i>not determined</i>		
Initial boiling point and boiling range	<i>not determined</i>		
Decomposition temperature	<i>not determined</i>		
Flash point	<i>not determined</i>		
Evaporation rate	<i>not determined</i>		
Auto-ignition temperature	<i>not determined</i>		
Upper/lower flammability or explosive limits	<i>not determined</i>		
Vapour pressure	<i>not determined</i>		
Vapour density	<i>not determined</i>		
Density	<i>not determined</i>		
Relative density	<i>not determined</i>		
Bulk density	<i>not determined</i>		
Water solubility	<i>not determined</i>		
Partition coefficient: n-octanol/water	<i>not determined</i>		
Dynamic viscosity	<i>not determined</i>		
Kinematic viscosity	<i>not determined</i>		

### 9.2. Other information

No data available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

The product itself does not burn. not relevant

### 10.2. Chemical stability

Empfohlenen Lagertemperatur: 2-8°C.

# SAFETY DATA SHEET

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

**Revision date:** 27 Oct 2022

**Print date:** 28 Nov 2022

**Version:** 2

Page 6/10

## anti human IgG conjugate

### 10.3. Possibility of hazardous reactions

No data available

### 10.4. Conditions to avoid

Light, heat, moisture (no dangerous reaction follows, the product becomes unusable).

### 10.5. Incompatible materials

No data available

### 10.6. Hazardous decomposition products

In case of fire: Gases/vapours, toxic

### Further information

Light, heat, moisture (no dangerous reaction follows, the product becomes unusable)

## SECTION 11: Toxicological information

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

<b>ProClin ® 300</b>
<b>LD<sub>50</sub> oral:</b> 862 mg/kg (Ratte)
<b>LD<sub>50</sub> dermal:</b> 2,800 mg/kg (Kaninchen)
<b>phenol CAS No.:</b> 108-95-2 <b>EC No.:</b> 203-632-7
<b>LD<sub>50</sub> oral:</b> 317 mg/kg (Ratte)
<b>LD<sub>50</sub> dermal:</b> 630 mg/kg (Kaninchen)

#### Acute oral toxicity:

Based on available data, the classification criteria are not met.

#### Acute dermal toxicity:

Based on available data, the classification criteria are not met.

#### Acute inhalation toxicity:

Based on available data, the classification criteria are not met.

#### Skin corrosion/irritation:

Based on available data, the classification criteria are not met.

#### Serious eye damage/irritation:

Based on available data, the classification criteria are not met.

#### Respiratory or skin sensitisation:

Contains ProClin ® 300. May produce an allergic reaction.

#### Germ cell mutagenicity:

Based on available data, the classification criteria are not met.

#### Carcinogenicity:

Based on available data, the classification criteria are not met.

#### Reproductive toxicity:

Based on available data, the classification criteria are not met.

#### STOT-single exposure:

Based on available data, the classification criteria are not met.

#### STOT-repeated exposure:

Based on available data, the classification criteria are not met.

#### Aspiration hazard:

Based on available data, the classification criteria are not met.

#### Additional information:

No data available

### 11.2. Information on other hazards

No data available

# SAFETY DATA SHEET

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

Revision date: 27 Oct 2022

Print date: 28 Nov 2022

Version: 2

Page 7/10

## anti human IgG conjugate

### SECTION 12: Ecological information

#### 12.1. Toxicity

<b>phenol</b> CAS No.: 108-95-2 EC No.: 203-632-7
---

LC <sub>50</sub> : 8.9 mg/L 4 d (fish)
--

EC <sub>50</sub> : 3.1 mg/L 2 d
---------------------------------

LC <sub>50</sub> : 21.93 mg/L (fish)
--------------------------------------

EC <sub>50</sub> : 10 mg/L
----------------------------

NOEC: 0.077 mg/L (fish)
-------------------------

#### 12.2. Persistence and degradability

<b>ProClin ® 300</b>
----------------------

Biodegradation: Yes, slowly
-----------------------------

<b>phenol</b> CAS No.: 108-95-2 EC No.: 203-632-7
---

Biodegradation: Yes, rapidly
------------------------------

#### 12.3. Bioaccumulative potential

<b>phenol</b> CAS No.: 108-95-2 EC No.: 203-632-7
---

Log K <sub>ow</sub> : 1.47
----------------------------

Bioconcentration factor (BCF): 17.5
-------------------------------------

#### 12.4. Mobility in soil

No data available

#### 12.5. Results of PBT and vPvB assessment

<b>ProClin ® 300</b>
----------------------

Results of PBT and vPvB assessment: This substance does not meet the PBT/vPvB criteria of REACH, Annex XIII.
--

<b>phenol</b> CAS No.: 108-95-2 EC No.: 203-632-7
---

Results of PBT and vPvB assessment: This substance does not meet the PBT/vPvB criteria of REACH, Annex XIII.
--

#### 12.6. Endocrine disrupting properties

No data available

#### 12.7. Other adverse effects

No data available

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

##### 13.1.1. Product/Packaging disposal

Waste codes/waste designations according to EWC/AVV

Waste code product

18 02 03	wastes whose collection and disposal is not subject to special requirements in order to prevent infection
----------	---

#### Waste treatment options

##### Appropriate disposal / Product:

Consult the appropriate local waste disposal expert about waste disposal.

#### 13.2. Additional information

Do not allow run-off from fire-fighting to enter drains or water courses.

# SAFETY DATA SHEET

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

Revision date: 27 Oct 2022

Print date: 28 Nov 2022

Version: 2

Page 8/10

## anti human IgG conjugate

### SECTION 14: Transport information

Land transport (ADR/RID)	Inland waterway craft (ADN)	Sea transport (IMDG)	Air transport (ICAO-TI / IATA-DGR)
<b>14.1. UN number or ID number</b>			
No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.
<b>14.2. UN proper shipping name</b>			
No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.
<b>14.3. Transport hazard class(es)</b>			
not relevant	not relevant	not relevant	not relevant
<b>14.4. Packing group</b>			
not relevant	not relevant	not relevant	not relevant
<b>14.5. Environmental hazards</b>			
not relevant	not relevant	not relevant	not relevant
<b>14.6. Special precautions for user</b>			
not relevant	not relevant	not relevant	not relevant

#### 14.7. Maritime transport in bulk according to IMO instruments

No data available

### SECTION 15: Regulatory information

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

##### 15.1.1. EU legislation

No data available

##### 15.1.2. National regulations

 [DE] National regulations

Water hazard class

#### 15.2. Chemical Safety Assessment

No data available

### SECTION 16: Other information

#### 16.1. Indication of changes

Revision according to REACH Regulation (EC) No. 1907/2006, last amended by Regulation (EU) 2020/878

#### 16.2. Abbreviations and acronyms

°C centigrade

ABEK Gases and vapors from organic compounds with a boiling point >65°C (A), inorganic gases and vapors, except carbon monoxide (B), sulfur dioxide and other acidic gases and vapors (E) and ammonia and organic ammonia derivatives (K)

ADR European Agreement concerning the International Carriage of Dangerous Goods by Road ( Accord européen relatif au transport international des marchandises dangereuses par route)

AwSV Ordinance on systems for handling water-polluting substances

CO carbon monoxide

# SAFETY DATA SHEET

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

**Revision date:** 27 Oct 2022

**Print date:** 28 Nov 2022

**Version:** 2

Page 9/10

## anti human IgG conjugate

CO2 carbon dioxide

EC/EU European Community/European Union

EN European standard

IATA International Air Transport Association

IBC bulk packaging (Intermediate Bulk Container)

IgA Immunoglobuline A

IgG Immunoglobulin G

IgM Immunoglobuline M

IMDG International Maritime Code for Dangerous Goods

IVD in vitro diagnostics

MARPOL International Convention for the Prevention of Marine Pollution

NIOSH National Institute for Occupational Safety and Health

PBT Persistent (P), Bioaccumulative (B), Toxic (T)

RID Regulations for the International Carriage of Dangerous Goods by Rail (Règlement concernant le transport international ferroviaire de marchandises Dangereuse)

UN United Nations

vPvB very Persistent (vP), very Bioaccumulative (vB)

### 16.3. Key literature references and sources for data

No data available

### 16.4. Classification for mixtures and used evaluation method according to regulation (EC) No 1272/2008 [CLP]

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

### 16.5. Relevant R-, H- and EUH-phrases (Number and full text)

Hazard statements	
H301	Toxic if swallowed.
H302	Harmful if swallowed.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H331	Toxic if inhaled.
H341	Suspected of causing genetic defects.
H373	May cause damage to organs through prolonged or repeated exposure.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H411	Toxic to aquatic life with long lasting effects.

# SAFETY DATA SHEET

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

**Revision date:** 27 Oct 2022

**Print date:** 28 Nov 2022

**Version:** 2

Page 10/10

## anti human IgG conjugate

### 16.6. Training advice

No data available

### 16.7. Additional information

The information is based on the current state of our knowledge.

# SAFETY DATA SHEET

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

**Revision date:** 28 Nov 2022

**Print date:** 28 Nov 2022

**Version:** 1

Page 1/7

## Substrate

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

**Trade name/designation:**

Substrate

**Other means of identification:**

SUB

**Article No.:**

3xxx

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

**Use of the substance/mixture:**

This assay and its reagents are not for personal or veterinary use. The reagents should not be used for any purpose other than the intended purpose.

#### 1.3. Details of the supplier of the safety data sheet

**Manufacturer:**

ALPCO  
26-G Keewaydin Drive  
Salem, NH 03079 USA  
phone: (800) 592-5726  
email: ts@alpco.com

#### 1.4. Emergency telephone number

Dial 911 in the United States. Use local emergency number outside the US.

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

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

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

#### 2.2. Label elements

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

According to EC directives or the corresponding national regulations the product does not have to be labelled.

**Hazard statements:** none

**Supplemental hazard information:** none

**Precautionary statements:** none

**Special rules for supplemental label elements for certain mixtures:**

1,6 % percent of the mixture consists of ingredient(s) of unknown acute toxicity (dermal).

2,9 % percent of the mixture consists of ingredient(s) of unknown acute toxicity (inhalative).

#### 2.3. Other hazards

**Other adverse effects:**

This mixture does not contain any substances presenting a health or environmental hazard within the means of Regulation (EC) No. 1272/2008, assigned a Community workplace exposure limit, classified as PBT/vPvB or included in the Candidate List.

# SAFETY DATA SHEET

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

**Revision date:** 28 Nov 2022

**Print date:** 28 Nov 2022

**Version:** 1

Page 2/7

## Substrate

### SECTION 3: Composition/information on ingredients

#### 3.2. Mixtures

No data available

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

##### General information:

In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible). Remove victim out of the danger area. Remove contaminated, saturated clothing. If unconscious but breathing normally, place in recovery position and seek medical advice. Do not leave affected person unattended.

##### Following inhalation:

Provide fresh air.

##### Following ingestion:

Rinse mouth. Let 1 glass of water be drunken in little sips (dilution effect). Get medical advice/attention if you feel unwell.

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

No known symptoms to date.

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

Treat symptomatically.

### SECTION 5: Firefighting measures

#### 5.1. Extinguishing media

##### Suitable extinguishing media:

Co-ordinate fire-fighting measures to the fire surroundings.

#### 5.2. Special hazards arising from the substance or mixture

The product itself does not burn.

##### Hazardous combustion products:

In case of fire: Gases/vapours, toxic

#### 5.3. Advice for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing.

#### 5.4. Additional information

Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

### SECTION 6: Accidental release measures

#### 6.1. Personal precautions, protective equipment and emergency procedures

##### 6.1.1. For non-emergency personnel

###### Personal precautions:

Remove persons to safety. Avoid breathing dust/fume/gas/mist/vapours/spray.

###### Protective equipment:

Wear protective gloves/protective clothing/eye protection/face protection.

##### 6.1.2. For emergency responders

###### Personal protection equipment:

Personal protection equipment: see section 8

#### 6.2. Environmental precautions

Do not allow to enter into surface water or drains.

#### 6.3. Methods and material for containment and cleaning up

##### For containment:

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents).

# SAFETY DATA SHEET

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

**Revision date:** 28 Nov 2022

**Print date:** 28 Nov 2022

**Version:** 1

Page 3/7

## Substrate

### 6.4. Reference to other sections

Safe handling: see section 7 Personal protection equipment: see section 8 Disposal: see section 13

### 6.5. Additional information

Use appropriate container to avoid environmental contamination.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

#### Protective measures

##### Advices on safe handling:

Wear personal protection equipment (refer to section 8).

##### Fire prevent measures:

No special measures are necessary.

##### Advices on general occupational hygiene

When using do not eat, drink, smoke, sniff. Avoid contact with skin, eyes and clothes.

### 7.2. Conditions for safe storage, including any incompatibilities

#### Technical measures and storage conditions:

Keep container tightly closed in a cool, well-ventilated place.

#### Further information on storage conditions:

Recommended storage temperature: 2-8°C

### 7.3. Specific end use(s)

#### Recommendation:

Item 1.2 and the instructions for use must be observed.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

No data available

### 8.2. Exposure controls

#### 8.2.1. Appropriate engineering controls

No data available

#### 8.2.2. Personal protection equipment

##### Eye/face protection:

Eye glasses with side protection EN 166

##### Skin protection:

Tested protective gloves must be worn EN ISO 374 Suitable material: Breakthrough time: min In the case of wanting to use the gloves again, clean them before taking off and air them well. Breakthrough times and swelling properties of the material must be taken into consideration.

#### 8.2.3. Environmental exposure controls

No data available

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

#### Appearance

**Physical state:** Liquid

**Colour:** clear

**Odour:** not determined

### 9.2. Other information

No data available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

The product itself does not burn. not relevant

# SAFETY DATA SHEET

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

**Revision date:** 28 Nov 2022

**Print date:** 28 Nov 2022

**Version:** 1

Page 4/7

## Substrate

### 10.2. Chemical stability

Light, heat, moisture (no dangerous reaction follows, the product becomes unusable).

### 10.3. Possibility of hazardous reactions

No data available

### 10.4. Conditions to avoid

Light, heat, moisture (no dangerous reaction follows, the product becomes unusable).

### 10.5. Incompatible materials

No data available

### 10.6. Hazardous decomposition products

In case of fire: Gases/vapours, toxic

### Further information

Light, heat, moisture (no dangerous reaction follows, the product becomes unusable)

## SECTION 11: Toxicological information

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

#### Acute oral toxicity:

Based on available data, the classification criteria are not met.

#### Acute dermal toxicity:

Based on available data, the classification criteria are not met.

#### Acute inhalation toxicity:

Based on available data, the classification criteria are not met.

#### Skin corrosion/irritation:

Based on available data, the classification criteria are not met.

#### Serious eye damage/irritation:

Based on available data, the classification criteria are not met.

#### Respiratory or skin sensitisation:

Based on available data, the classification criteria are not met.

#### Germ cell mutagenicity:

Based on available data, the classification criteria are not met.

#### Carcinogenicity:

Based on available data, the classification criteria are not met.

#### Reproductive toxicity:

Based on available data, the classification criteria are not met.

#### STOT-single exposure:

Based on available data, the classification criteria are not met.

#### STOT-repeated exposure:

Based on available data, the classification criteria are not met.

#### Aspiration hazard:

Based on available data, the classification criteria are not met.

#### Additional information:

No data available

### 11.2. Information on other hazards

No data available

## SECTION 12: Ecological information

### 12.1. Toxicity

No data available

### 12.2. Persistence and degradability

No data available

### 12.3. Bioaccumulative potential

No data available

# SAFETY DATA SHEET

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

Revision date: 28 Nov 2022

Print date: 28 Nov 2022

Version: 1

Page 5/7

## Substrate

### 12.4. Mobility in soil

No data available

### 12.5. Results of PBT and vPvB assessment

No data available

### 12.6. Endocrine disrupting properties

No data available

### 12.7. Other adverse effects

No data available

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

#### 13.1.1. Product/Packaging disposal

#### Waste codes/waste designations according to EWC/AVV

##### Waste code product

18 02 03	wastes whose collection and disposal is not subject to special requirements in order to prevent infection
----------	---

#### Waste treatment options

##### Appropriate disposal / Product:

Consult the appropriate local waste disposal expert about waste disposal.

### 13.2. Additional information

Do not allow to enter into surface water or drains.

## SECTION 14: Transport information

Land transport (ADR/RID)	Inland waterway craft (ADN)	Sea transport (IMDG)	Air transport (ICAO-TI / IATA-DGR)
<b>14.1. UN number or ID number</b>			
No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.
<b>14.2. UN proper shipping name</b>			
No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.
<b>14.3. Transport hazard class(es)</b>			
not relevant	not relevant	not relevant	not relevant
<b>14.4. Packing group</b>			
not relevant	not relevant	not relevant	not relevant
<b>14.5. Environmental hazards</b>			
not relevant	not relevant	not relevant	not relevant
<b>14.6. Special precautions for user</b>			
not relevant	not relevant	not relevant	not relevant

### 14.7. Maritime transport in bulk according to IMO instruments

No data available

## SECTION 15: Regulatory information

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

#### 15.1.1. EU legislation

No data available

# SAFETY DATA SHEET

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

**Revision date:** 28 Nov 2022

**Print date:** 28 Nov 2022

**Version:** 1

Page 6/7

## Substrate

### 15.1.2. National regulations

 **[DE] National regulations**

**Water hazard class**

**WGK:**

nwg - nicht wassergefährdend

### 15.2. Chemical Safety Assessment

No data available

## SECTION 16: Other information

### 16.1. Indication of changes

Revision according to REACH Regulation (EC) No. 1907/2006, last amended by Regulation (EU) 2020/878

### 16.2. Abbreviations and acronyms

°C centigrade

ABEK Gases and vapors from organic compounds with a boiling point >65°C (A), inorganic gases and vapors, except carbon monoxide (B), sulfur dioxide and other acidic gases and vapors (E) and ammonia and organic ammonia derivatives (K)

ADR European Agreement concerning the International Carriage of Dangerous Goods by Road ( Accord européen relatif au transport international des marchandises dangereuses par route)

AwSV Ordinance on systems for handling water-polluting substances

CO carbon monoxide

CO<sub>2</sub> carbon dioxide

EC/EU European Community/European Union

EN European standard

IATA International Air Transport Association

IBC bulk packaging (Intermediate Bulk Container)

IgA Immunoglobuline A

IgG Immunoglobulin G

IgM Immunoglobuline M

IMDG International Maritime Code for Dangerous Goods

IVD in vitro diagnostics

MARPOL International Convention for the Prevention of Marine Pollution

NIOSH National Institute for Occupational Safety and Health

PBT Persistent (P), Bioaccumulative (B), Toxic (T)

RID Regulations for the International Carriage of Dangerous Goods by Rail (Règlement concernant le transport international ferroviaire de marchandises Dangereuse)

UN United Nations

# SAFETY DATA SHEET

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

**Revision date:** 28 Nov 2022

**Print date:** 28 Nov 2022

**Version:** 1

Page 7/7

## Substrate

vPvB very Persistent (vP), very Bioaccumulative (vB)

### 16.3. Key literature references and sources for data

No data available

### 16.4. Classification for mixtures and used evaluation method according to regulation (EC) No 1272/2008 [CLP]

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

### 16.5. Relevant R-, H- and EUH-phrases (Number and full text)

No data available

### 16.6. Training advice

No data available

### 16.7. Additional information

The information is based on the current state of our knowledge.

# SAFETY DATA SHEET

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

Revision date: 25 Oct 2022

Print date: 29 Nov 2022

Version: 5

Page 1/9

## Stop

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

### 1.1. Product identifier

Trade name/designation:

Stop

Article No.:

3xxx

UFI:

AP97-W9QH-HXND-8YGK

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

Use of the substance/mixture:

This assay and its reagents are not for personal or veterinary use. The reagents should not be used for any purpose other than the intended purpose.

### 1.3. Details of the supplier of the safety data sheet

Manufacturer:

ALPCO  
26-G Keewaydin Drive  
Salem, NH 03079 USA  
phone: (800) 592-5726  
email: ts@alpco.com

### 1.4. Emergency telephone number

Dial 911 in United States. Outside United States dial local emergency number.

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

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

Hazard classes and hazard categories	Hazard statements	Classification procedure
Corrosive to metals ( <i>Met. Corr. 1</i> )	H290: May be corrosive to metals.	On basis of test data.

### 2.2. Label elements

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

Hazard pictograms:



**GHS05**

Corrosion

Signal word: Warning

Hazard statements for physical hazards	
H290	May be corrosive to metals.

# SAFETY DATA SHEET

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

Revision date: 25 Oct 2022

Print date: 29 Nov 2022

Version: 5

Page 2/9

## Stop

Supplemental hazard information: none

### Precautionary statements Prevention

P234 Keep only in original packaging.

### Precautionary statements Response

P390 Absorb spillage to prevent material damage.

Special rules for supplemental label elements for certain mixtures:

Reduced labeling ( $\leq 125$  ml)

Signal word: none

Symbol: none


### 2.3. Other hazards

No data available

## SECTION 3: Composition/information on ingredients

### 3.2. Mixtures

Hazardous ingredients / Hazardous impurities / Stabilisers:

Product identifiers	Substance name Classification according to Regulation (EC) No 1272/2008 [CLP]	Concentration
CAS No.: 7647-01-0 EC No.: 231-595-7 Index No.: 017-002-01-X	<b>hydrogen chloride</b> Met. Corr. 1 (H290), STOT SE 3 (H335), Skin Corr. 1B (H314)  <b>Danger</b> <b>Specific concentration limit (SCL)</b> Met. Corr. 1; H290: $C \geq 0.1\%$ Skin Corr. 1B; H314: $C \geq 25\%$ Skin Irrit. 2; H315: $10\% \leq C < 25\%$ Eye Dam. 1; H318: $C \geq 25\%$ Eye Irrit. 2; H319: $10\% \leq C < 25\%$ STOT SE 3; H335: $C \geq 10\%$	1 - $\leq$ 3 weight-%

Full text of H- and EUH-phrases: see section 16.

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

#### General information:

In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible). Remove victim out of the danger area. Remove contaminated, saturated clothing. If unconscious but breathing normally, place in recovery position and seek medical advice. Do not leave affected person unattended.

#### Following inhalation:

Provide fresh air. In case of respiratory tract irritation, consult a physician.

#### In case of skin contact:

After contact with skin, wash immediately with plenty of water and soap.

#### Following ingestion:

Rinse mouth. Let 1 glass of water be drunken in little sips (dilution effect). Get medical advice/attention if you feel unwell.

### 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.

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

#### Suitable extinguishing media:

Co-ordinate fire-fighting measures to the fire surroundings.

# SAFETY DATA SHEET

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

**Revision date:** 25 Oct 2022

**Print date:** 29 Nov 2022

**Version:** 5

Page 3/9

## Stop

### 5.2. Special hazards arising from the substance or mixture

The product itself does not burn.

#### Hazardous combustion products:

In case of fire: Gases/vapours, toxic

### 5.3. Advice for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing.

### 5.4. Additional information

Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

#### 6.1.1. For non-emergency personnel

##### Personal precautions:

Remove persons to safety.

##### Protective equipment:

Wear protective gloves/protective clothing/eye protection/face protection.

#### 6.1.2. For emergency responders

##### Personal protection equipment:

Personal protection equipment: see section 8

### 6.2. Environmental precautions

Do not allow to enter into surface water or drains.

### 6.3. Methods and material for containment and cleaning up

#### For containment:

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents).

### 6.4. Reference to other sections

Safe handling: see section 7 Personal protection equipment: see section 8 Disposal: see section 13

### 6.5. Additional information

Use appropriate container to avoid environmental contamination.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

#### Protective measures

##### Advices on safe handling:

Wear personal protection equipment (refer to section 8).

##### Fire prevent measures:

No special measures are necessary.

##### Advices on general occupational hygiene

When using do not eat, drink, smoke, sniff. Avoid contact with skin, eyes and clothes.

### 7.2. Conditions for safe storage, including any incompatibilities

#### Technical measures and storage conditions:

Keep container tightly closed in a cool, well-ventilated place.

#### Further information on storage conditions:

Lagerung bei +2°C bis +8°C.

### 7.3. Specific end use(s)

No data available

# SAFETY DATA SHEET

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

Revision date: 25 Oct 2022

Print date: 29 Nov 2022

Version: 5

Page 4/9

## Stop

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### 8.1.1. Occupational exposure limit values

Limit value type (country of origin)	Substance name	① Long-term occupational exposure limit value ② Short-term occupational exposure limit value ③ Instantaneous value ④ Monitoring and observation processes ⑤ Remark
TRGS 900 (DE)	hydrogen chloride CAS No.: 7647-01-0 EC No.: 231-595-7	① 2 ppm (3 mg/m <sup>3</sup> ) ② 4 ppm (6 mg/m <sup>3</sup> ) ⑤ (Chlorwasserstoff) DFG, EU, Y
ES	hydrogen chloride CAS No.: 7647-01-0 EC No.: 231-595-7	① 5 ppm (7.6 mg/m <sup>3</sup> ) ② 10 ppm (15 mg/m <sup>3</sup> ) ⑤ VLI
IOELV (EU)	hydrogen chloride CAS No.: 7647-01-0 EC No.: 231-595-7	① 5 ppm (8 mg/m <sup>3</sup> ) ② 10 ppm (15 mg/m <sup>3</sup> ) ⑤ (Hydrogen chloride)
VRC (FR)	hydrogen chloride CAS No.: 7647-01-0 EC No.: 231-595-7	② 5 ppm (7.6 mg/m <sup>3</sup> ) ⑤ (chlorure d'hydrogène)
WEL (GB)	hydrogen chloride CAS No.: 7647-01-0 EC No.: 231-595-7	① 1 ppm (2 mg/m <sup>3</sup> ) ② 5 ppm (8 mg/m <sup>3</sup> ) ⑤ (gas and aerosol mists)
GR	hydrogen chloride CAS No.: 7647-01-0 EC No.: 231-595-7	① 5 ppm (7 mg/m <sup>3</sup> ) ② 5 ppm (7 mg/m <sup>3</sup> ) ⑤ (υδροχλώριο)
ACGIH (US)	hydrogen chloride CAS No.: 7647-01-0 EC No.: 231-595-7	③ 2 ppm (2.98 mg/m <sup>3</sup> ) ⑤ (A4)

#### 8.1.2. Biological limit values

No data available

#### 8.1.3. DNEL-/PNEC-values

No data available

### 8.2. Exposure controls

#### 8.2.1. Appropriate engineering controls

No data available

#### 8.2.2. Personal protection equipment

##### Eye/face protection:

Eye glasses with side protection EN 166

##### Skin protection:

Tested protective gloves must be worn EN ISO 374 Suitable material: Breakthrough time: min In the case of wanting to use the gloves again, clean them before taking off and air them well. Breakthrough times and swelling properties of the material must be taken into consideration.

#### 8.2.3. Environmental exposure controls

No data available

# SAFETY DATA SHEET

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

Revision date: 25 Oct 2022

Print date: 29 Nov 2022

Version: 5

Page 5/9

## Stop

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

#### Appearance

Physical state: Liquid

Colour: clear

Odour: not determined

#### Safety relevant basis data

Parameter	Value	at °C	① Method ② Remark
pH	2.6 - 3.2	21 °C	
Melting point	<i>not determined</i>		
Freezing point	<i>not determined</i>		
Initial boiling point and boiling range	<i>not applicable</i>		
Decomposition temperature	<i>not determined</i>		
Flash point	<i>not determined</i>		
Evaporation rate	<i>not determined</i>		
Auto-ignition temperature	<i>not determined</i>		
Upper/lower flammability or explosive limits	<i>not determined</i>		
Vapour pressure	<i>not determined</i>		
Vapour density	<i>not determined</i>		
Density	<i>not determined</i>		
Relative density	<i>not determined</i>		
Bulk density	<i>not determined</i>		
Water solubility	<i>not determined</i>		
Partition coefficient: n-octanol/water	<i>not determined</i>		
Dynamic viscosity	<i>not determined</i>		
Kinematic viscosity	<i>not determined</i>		

### 9.2. Other information

No data available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

The product itself does not burn. May be corrosive to metals.

### 10.2. Chemical stability

Empfohlenen Lagertemperatur: 2-8°C.

### 10.3. Possibility of hazardous reactions

No data available

### 10.4. Conditions to avoid

No data available

### 10.5. Incompatible materials

No data available

### 10.6. Hazardous decomposition products

In case of fire: Gases/vapours, toxic

## SECTION 11: Toxicological information

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

hydrogen chloride CAS No.: 7647-01-0 EC No.: 231-595-7

LC<sub>50</sub> Acute inhalation toxicity (vapour): >5,010 mg/L (Rabbit)

# SAFETY DATA SHEET

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

**Revision date:** 25 Oct 2022

**Print date:** 29 Nov 2022

**Version:** 5

Page 6/9

## Stop

### Acute oral toxicity:

Based on available data, the classification criteria are not met.

### Acute dermal toxicity:

Based on available data, the classification criteria are not met.

### Acute inhalation toxicity:

Based on available data, the classification criteria are not met.

### Skin corrosion/irritation:

Based on available data, the classification criteria are not met.

### Serious eye damage/irritation:

Based on available data, the classification criteria are not met.

### Respiratory or skin sensitisation:

Based on available data, the classification criteria are not met.

### Germ cell mutagenicity:

Based on available data, the classification criteria are not met.

### Carcinogenicity:

Based on available data, the classification criteria are not met.

### Reproductive toxicity:

Based on available data, the classification criteria are not met.

### STOT-single exposure:

Based on available data, the classification criteria are not met.

### STOT-repeated exposure:

Based on available data, the classification criteria are not met.

### Aspiration hazard:

Based on available data, the classification criteria are not met.

### Additional information:

No data available

## 11.2. Information on other hazards

No data available

## SECTION 12: Ecological information

### 12.1. Toxicity

hydrogen chloride CAS No.: 7647-01-0 EC No.: 231-595-7

LC<sub>50</sub>: 250 mg/L 2 d

### 12.2. Persistence and degradability

No data available

### 12.3. Bioaccumulative potential

No data available

### 12.4. Mobility in soil

No data available

### 12.5. Results of PBT and vPvB assessment

hydrogen chloride CAS No.: 7647-01-0 EC No.: 231-595-7

Results of PBT and vPvB assessment: —

### 12.6. Endocrine disrupting properties

No data available

### 12.7. Other adverse effects

No data available

# SAFETY DATA SHEET

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

Revision date: 25 Oct 2022

Print date: 29 Nov 2022

Version: 5

Page 7/9

## Stop

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

##### 13.1.1. Product/Packaging disposal

#### Waste codes/waste designations according to EWC/AVV

##### Waste code product

18 02 03	wastes whose collection and disposal is not subject to special requirements in order to prevent infection
----------	---

#### Waste treatment options

##### Appropriate disposal / Product:

Consult the appropriate local waste disposal expert about waste disposal.

### SECTION 14: Transport information

Land transport (ADR/RID)	Inland waterway craft (ADN)	Sea transport (IMDG)	Air transport (ICAO-TI / IATA-DGR)
<b>14.1. UN number or ID number</b>			
No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.
<b>14.2. UN proper shipping name</b>			
No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.
<b>14.3. Transport hazard class(es)</b>			
not relevant	not relevant	not relevant	not relevant
<b>14.4. Packing group</b>			
not relevant	not relevant	not relevant	not relevant
<b>14.5. Environmental hazards</b>			
not relevant	not relevant	not relevant	not relevant
<b>14.6. Special precautions for user</b>			
not relevant	not relevant	not relevant	not relevant

#### 14.7. Maritime transport in bulk according to IMO instruments

No data available

### SECTION 15: Regulatory information

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

No data available

#### 15.2. Chemical Safety Assessment

No data available

### SECTION 16: Other information

#### 16.1. Indication of changes

Revision according to REACH Regulation (EC) No. 1907/2006, last amended by Regulation (EU) 2020/878

#### 16.2. Abbreviations and acronyms

°C centigrade

ABEK Gases and vapors from organic compounds with a boiling point >65°C (A), inorganic gases and vapors, except carbon monoxide (B), sulfur dioxide and other acidic gases and vapors (E) and ammonia and organic ammonia derivatives (K)

# SAFETY DATA SHEET

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

**Revision date:** 25 Oct 2022

**Print date:** 29 Nov 2022

**Version:** 5

Page 8/9

## Stop

ADR European Agreement concerning the International Carriage of Dangerous Goods by Road ( Accord européen relatif au transport international des marchandises dangereuses par route)

AwSV Ordinance on systems for handling water-polluting substances

CO carbon monoxide

CO<sub>2</sub> carbon dioxide

EC/EU European Community/European Union

EN European standard

IATA International Air Transport Association

IBC bulk packaging (Intermediate Bulk Container)

IgA Immunoglobuline A

IgG Immunoglobulin G

IgM Immunoglobuline M

IMDG International Maritime Code for Dangerous Goods

IVD in vitro diagnostics

MARPOL International Convention for the Prevention of Marine Pollution

NIOSH National Institute for Occupational Safety and Health

PBT Persistent (P), Bioaccumulative (B), Toxic (T)

RID Regulations for the International Carriage of Dangerous Goods by Rail (Règlement concernant le transport international ferroviaire de marchandises Dangereuse)

UN United Nations

vPvB very Persistent (vP), very Bioaccumulative (vB)

### 16.3. Key literature references and sources for data

No data available

### 16.4. Classification for mixtures and used evaluation method according to regulation (EC) No 1272/2008 [CLP]

Hazard classes and hazard categories	Hazard statements	Classification procedure
Corrosive to metals ( <i>Met. Corr. 1</i> )	H290: May be corrosive to metals.	On basis of test data.

### 16.5. Relevant R-, H- and EUH-phrases (Number and full text)

Hazard statements	
H290	May be corrosive to metals.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.

### 16.6. Training advice

No data available

# SAFETY DATA SHEET

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

**Revision date:** 25 Oct 2022

**Print date:** 29 Nov 2022

**Version:** 5

Page 9/9

## Stop

### 16.7. Additional information

The information is based on the current state of our knowledge.

# SAFETY DATA SHEET

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

**Revision date:** 27 Oct 2022

**Print date:** 29 Nov 2022

**Version:** 1

Page 1/10

## Reconstitution Buffer (RB)

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

**Trade name/designation:**

Reconstitution Buffer (RB)

**Other means of identification:**

RB

**Article No.:**

3602, 3603, 3604, 3605, 3606

**UFI:**

NQ2Q-4HTP-WKGD-RXYV

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

**Use of the substance/mixture:**

This enzyme immunoassay (in vitro diagnostic tool or component) is not intended for anything other than the detection and semi-quantitative determination of human IgA / IgG / IgM antibodies against specific antigens in autoimmune diagnostics. This assay and its reagents are not for personal or veterinary use. The reagents should not be used for any purpose other than the intended purpose.

#### 1.3. Details of the supplier of the safety data sheet

**Manufacturer:**

ALPCO  
26-G Keewaydin Drive  
Salem, NH 03079 USA  
phone: (800) 592-5726  
email: ts@alpc.com

#### 1.4. Emergency telephone number

Dial 911 in the United Statesw. If outside the US, dial local emergency number.

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

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

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

#### 2.2. Label elements

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

According to EC directives or the corresponding national regulations the product does not have to be labelled.

**Hazard statements:** none

**Supplemental hazard information**

EUH208 | Contains ProClin ® 300. May produce an allergic reaction.

**Precautionary statements:** none

#### 2.3. Other hazards

**Adverse human health effects and symptoms:**

This product does not contain a substance that has endocrine disrupting properties with respect to humans as no components meets the criteria.

# SAFETY DATA SHEET

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

**Revision date:** 27 Oct 2022

**Print date:** 29 Nov 2022

**Version:** 1

Page 2/10

## Reconstitution Buffer (RB)

### Adverse environmental effects:

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.



### Other adverse effects:

The mixture contains material of human or animal origin and is therefore classified as potentially infectious.

## SECTION 3: Composition/information on ingredients

### 3.2. Mixtures

#### Hazardous ingredients / Hazardous impurities / Stabilisers:

Product identifiers	Substance name Classification according to Regulation (EC) No 1272/2008 [CLP]	Concentration
	<b>ProClin ® 300</b> Acute Tox. 4 (H302), Aquatic Acute 1 (H400), Aquatic Chronic 1 (H410), Skin Corr. 1C (H314), Skin Sens. 1 (H317)  <b>Danger</b>	0 - ≤ 0.1 weight-%
<b>CAS No.:</b> 108-95-2 <b>EC No.:</b> 203-632-7 <b>Index No.:</b> 604-001-00-2	<b>phenol</b> Acute Tox. 3 (H301, H331, H311), Aquatic Chronic 2 (H411), Eye Dam. 1 (H318), Muta. 2 (H341), STOT RE 2 (H373), Skin Corr. 1B (H314)  <b>Danger</b> <b>Specific concentration limit (SCL)</b> Skin Corr. 1B; H314: C ≥ 3% Skin Irrit. 2; H315: 1% ≤ C < 3% Eye Dam. 1; H318: C ≥ 3% Eye Irrit. 2; H319: 1% ≤ C < 3%	0 - < 0.007 weight-%

Full text of H- and EUH-phrases: see section 16.

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

#### General information:

In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible). Remove victim out of the danger area. Remove contaminated, saturated clothing. If unconscious but breathing normally, place in recovery position and seek medical advice. Do not leave affected person unattended.

#### Following inhalation:

Provide fresh air.

#### Following ingestion:

Rinse mouth. Let 1 glass of water be drunken in little sips (dilution effect). Get medical advice/attention if you feel unwell.

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

No known symptoms to date.

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

Treat symptomatically.

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

#### Suitable extinguishing media:

Co-ordinate fire-fighting measures to the fire surroundings.

### 5.2. Special hazards arising from the substance or mixture

The product itself does not burn.

#### Hazardous combustion products:

In case of fire: Gases/vapours, toxic

### 5.3. Advice for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing.

# SAFETY DATA SHEET

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

**Revision date:** 27 Oct 2022

**Print date:** 29 Nov 2022

**Version:** 1

Page 3/10

## Reconstitution Buffer (RB)

### 5.4. Additional information

Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

#### 6.1.1. For non-emergency personnel

**Personal precautions:**

Remove persons to safety. Avoid breathing dust/fume/gas/mist/vapours/spray.

**Protective equipment:**

Wear protective gloves/protective clothing/eye protection/face protection.

#### 6.1.2. For emergency responders

**Personal protection equipment:**

Personal protection equipment: see section 8

### 6.2. Environmental precautions

Do not allow to enter into surface water or drains.

### 6.3. Methods and material for containment and cleaning up

**For containment:**

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents).

### 6.4. Reference to other sections

Safe handling: see section 7 Personal protection equipment: see section 8 Disposal: see section 13

### 6.5. Additional information

Use appropriate container to avoid environmental contamination.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

**Protective measures**

**Advices on safe handling:**

Wear personal protection equipment (refer to section 8).

**Fire prevent measures:**

No special measures are necessary.

**Advices on general occupational hygiene**

When using do not eat, drink, smoke, sniff. Avoid contact with skin, eyes and clothes.

### 7.2. Conditions for safe storage, including any incompatibilities

**Technical measures and storage conditions:**

Keep container tightly closed in a cool, well-ventilated place.

**Further information on storage conditions:**

Recommended storage temperature: 2-8°C

### 7.3. Specific end use(s)

**Recommendation:**

Item 1.2 and the instructions for use must be observed.

# SAFETY DATA SHEET

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

Revision date: 27 Oct 2022

Print date: 29 Nov 2022

Version: 1

Page 4/10

## Reconstitution Buffer (RB)

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

##### 8.1.1. Occupational exposure limit values

Limit value type (country of origin)	Substance name	① Long-term occupational exposure limit value ② Short-term occupational exposure limit value ③ Instantaneous value ④ Monitoring and observation processes ⑤ Remark
WEL (GB)	phenol CAS No.: 108-95-2 EC No.: 203-632-7	① 2 ppm (7.8 mg/m <sup>3</sup> ) ② 4 ppm (16 mg/m <sup>3</sup> ) ⑤ (may be absorbed through the skin)
TRGS 900 (DE)	phenol CAS No.: 108-95-2 EC No.: 203-632-7	① 2 ppm (8 mg/m <sup>3</sup> ) ② 4 ppm (16 mg/m <sup>3</sup> ) ⑤ (Aerosol und Dampf, kann über die Haut aufgenommen werden) EU, H, 11
ES	phenol CAS No.: 108-95-2 EC No.: 203-632-7	① 2 ppm (8 mg/m <sup>3</sup> ) ② 4 ppm (16 mg/m <sup>3</sup> ) ⑤ (puede ser absorbido a través dérmica) vía dérmica, VLB®, VLI
IOELV (EU)	phenol CAS No.: 108-95-2 EC No.: 203-632-7	① 2 ppm (8 mg/m <sup>3</sup> ) ② 4 ppm (16 mg/m <sup>3</sup> ) ⑤ (may be absorbed through the skin)
VRC (FR)	phenol CAS No.: 108-95-2 EC No.: 203-632-7	① 2 ppm (7.8 mg/m <sup>3</sup> ) ② 4 ppm (15.6 mg/m <sup>3</sup> ) ⑤ (peut être absorbé par la peau)
GR	phenol CAS No.: 108-95-2 EC No.: 203-632-7	① 2 ppm (8 mg/m <sup>3</sup> ) ② 4 ppm (16 mg/m <sup>3</sup> ) ⑤ (αναμένετε απορρόφηση από το δέρμα)
ACGIH (US)	phenol CAS No.: 108-95-2 EC No.: 203-632-7	① 5 ppm (19 mg/m <sup>3</sup> ) ⑤ (may be absorbed through the skin)

##### 8.1.2. Biological limit values

Limit value type (country of origin)	Substance name	Limit value	① Parameter ② Test material ③ Time of sampling: ④ Remark
TRGS 903 (DE)	phenol CAS No.: 108-95-2 EC No.: 203-632-7	120 mg/g Creatinin	① Phenol ② Urin ③ Expositionsende bzw. Schichtende
VLB (ES)	phenol CAS No.: 108-95-2 EC No.: 203-632-7	120 mg/g creatinina	① fenol ② orina ③ fin de exposición o fin de turno
ACGIH-BEI (US)	phenol CAS No.: 108-95-2 EC No.: 203-632-7	250 mg/g creatinine	① phenol ② urine ③ end of exposure or end of shift
BLV (EU)	phenol CAS No.: 108-95-2 EC No.: 203-632-7	120 mg/g creatinine	① phenol ② urine ③ no restriction

# SAFETY DATA SHEET

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

Revision date: 27 Oct 2022

Print date: 29 Nov 2022

Version: 1

Page 5/10

## Reconstitution Buffer (RB)

### 8.1.3. DNEL-/PNEC-values

No data available

### 8.2. Exposure controls

#### 8.2.1. Appropriate engineering controls

No data available

#### 8.2.2. Personal protection equipment

##### Eye/face protection:

Eye glasses with side protection EN 166

##### Skin protection:

Tested protective gloves must be worn EN ISO 374 Suitable material: Breakthrough time: min In the case of wanting to use the gloves again, clean them before taking off and air them well. Breakthrough times and swelling properties of the material must be taken into consideration.

#### 8.2.3. Environmental exposure controls

No data available

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

#### Appearance

Physical state: Liquid

Colour: red

Odour: not determined

#### Safety relevant basis data

Parameter	Value	at °C	① Method ② Remark
pH	6.7 - 6.9	21 °C	
Melting point	<i>not determined</i>		
Freezing point	<i>not determined</i>		
Initial boiling point and boiling range	<i>not determined</i>		
Decomposition temperature	<i>not determined</i>		
Flash point	<i>not determined</i>		
Evaporation rate	<i>not determined</i>		
Auto-ignition temperature	<i>not determined</i>		
Upper/lower flammability or explosive limits	<i>not determined</i>		
Vapour pressure	<i>not determined</i>		
Vapour density	<i>not determined</i>		
Density	<i>not determined</i>		
Relative density	<i>not determined</i>		
Bulk density	<i>not determined</i>		
Water solubility	<i>not determined</i>		
Partition coefficient: n-octanol/water	<i>not determined</i>		
Dynamic viscosity	<i>not determined</i>		
Kinematic viscosity	<i>not determined</i>		

### 9.2. Other information

No data available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

The product itself does not burn. not relevant

### 10.2. Chemical stability

Recommended storage temperature: 2-8°C No known hazardous reactions.

# SAFETY DATA SHEET

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

**Revision date:** 27 Oct 2022

**Print date:** 29 Nov 2022

**Version:** 1

Page 6/10

## Reconstitution Buffer (RB)

### 10.3. Possibility of hazardous reactions

Light, heat, moisture (no dangerous reaction follows, the product becomes unusable).

### 10.4. Conditions to avoid

Light, heat, moisture (no dangerous reaction follows, the product becomes unusable).

### 10.5. Incompatible materials

No data available

### 10.6. Hazardous decomposition products

In case of fire: Gases/vapours, toxic

### Further information

Light, heat, moisture (no dangerous reaction follows, the product becomes unusable)

## SECTION 11: Toxicological information

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

<b>ProClin ® 300</b>
<b>LD<sub>50</sub> oral:</b> 862 mg/kg (Ratte)
<b>LD<sub>50</sub> dermal:</b> 2,800 mg/kg (Kaninchen)
<b>phenol CAS No.:</b> 108-95-2 <b>EC No.:</b> 203-632-7
<b>LD<sub>50</sub> oral:</b> 317 mg/kg (Ratte)
<b>LD<sub>50</sub> dermal:</b> 630 mg/kg (Kaninchen)

#### Acute oral toxicity:

Based on available data, the classification criteria are not met.

#### Acute dermal toxicity:

Based on available data, the classification criteria are not met.

#### Acute inhalation toxicity:

Based on available data, the classification criteria are not met.

#### Skin corrosion/irritation:

Based on available data, the classification criteria are not met.

#### Serious eye damage/irritation:

Based on available data, the classification criteria are not met.

#### Respiratory or skin sensitisation:

Contains ProClin ® 300. May produce an allergic reaction.

#### Germ cell mutagenicity:

Based on available data, the classification criteria are not met.

#### Carcinogenicity:

Based on available data, the classification criteria are not met.

#### Reproductive toxicity:

Based on available data, the classification criteria are not met.

#### STOT-single exposure:

Based on available data, the classification criteria are not met.

#### STOT-repeated exposure:

Based on available data, the classification criteria are not met.

#### Aspiration hazard:

Based on available data, the classification criteria are not met.

#### Additional information:

No data available

### 11.2. Information on other hazards

No data available

# SAFETY DATA SHEET

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

Revision date: 27 Oct 2022

Print date: 29 Nov 2022

Version: 1

Page 7/10

## Reconstitution Buffer (RB)

### SECTION 12: Ecological information

#### 12.1. Toxicity

<b>phenol</b> CAS No.: 108-95-2 EC No.: 203-632-7
---

LC <sub>50</sub> : 8.9 mg/L 4 d (fish)
--

EC <sub>50</sub> : 3.1 mg/L 2 d
---------------------------------

LC <sub>50</sub> : 21.93 mg/L (fish)
--------------------------------------

EC <sub>50</sub> : 10 mg/L
----------------------------

NOEC: 0.077 mg/L (fish)
-------------------------

#### 12.2. Persistence and degradability

<b>ProClin ® 300</b>
----------------------

Biodegradation: Yes, slowly
-----------------------------

<b>phenol</b> CAS No.: 108-95-2 EC No.: 203-632-7
---

Biodegradation: Yes, rapidly
------------------------------

#### 12.3. Bioaccumulative potential

<b>phenol</b> CAS No.: 108-95-2 EC No.: 203-632-7
---

Log K <sub>ow</sub> : 1.47
----------------------------

Bioconcentration factor (BCF): 17.5
-------------------------------------

#### 12.4. Mobility in soil

No data available

#### 12.5. Results of PBT and vPvB assessment

<b>ProClin ® 300</b>
----------------------

Results of PBT and vPvB assessment: This substance does not meet the PBT/vPvB criteria of REACH, Annex XIII.
--

<b>phenol</b> CAS No.: 108-95-2 EC No.: 203-632-7
---

Results of PBT and vPvB assessment: This substance does not meet the PBT/vPvB criteria of REACH, Annex XIII.
--

#### 12.6. Endocrine disrupting properties

No data available

#### 12.7. Other adverse effects

No data available

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

##### 13.1.1. Product/Packaging disposal

Waste codes/waste designations according to EWC/AVV

Waste code product

18 02 03	wastes whose collection and disposal is not subject to special requirements in order to prevent infection
----------	---

#### Waste treatment options

##### Appropriate disposal / Product:

Consult the appropriate local waste disposal expert about waste disposal.

#### 13.2. Additional information

Do not allow to enter into surface water or drains.

# SAFETY DATA SHEET

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

Revision date: 27 Oct 2022

Print date: 29 Nov 2022

Version: 1

Page 8/10

## Reconstitution Buffer (RB)

### SECTION 14: Transport information

Land transport (ADR/RID)	Inland waterway craft (ADN)	Sea transport (IMDG)	Air transport (ICAO-TI / IATA-DGR)
<b>14.1. UN number or ID number</b>			
No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.
<b>14.2. UN proper shipping name</b>			
No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.
<b>14.3. Transport hazard class(es)</b>			
not relevant	not relevant	not relevant	not relevant
<b>14.4. Packing group</b>			
not relevant	not relevant	not relevant	not relevant
<b>14.5. Environmental hazards</b>			
not relevant	not relevant	not relevant	not relevant
<b>14.6. Special precautions for user</b>			
not relevant	not relevant	not relevant	not relevant

#### 14.7. Maritime transport in bulk according to IMO instruments

No data available

### SECTION 15: Regulatory information

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

##### 15.1.1. EU legislation

No data available

##### 15.1.2. National regulations

 [DE] National regulations

Water hazard class

#### 15.2. Chemical Safety Assessment

No data available

### SECTION 16: Other information

#### 16.1. Indication of changes

Revision according to REACH Regulation (EC) No. 1907/2006, last amended by Regulation (EU) 2020/878

#### 16.2. Abbreviations and acronyms

°C centigrade

ABEK Gases and vapors from organic compounds with a boiling point >65°C (A), inorganic gases and vapors, except carbon monoxide (B), sulfur dioxide and other acidic gases and vapors (E) and ammonia and organic ammonia derivatives (K)

ADR European Agreement concerning the International Carriage of Dangerous Goods by Road ( Accord européen relatif au transport international des marchandises dangereuses par route)

AwSV Ordinance on systems for handling water-polluting substances

CO carbon monoxide

# SAFETY DATA SHEET

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

**Revision date:** 27 Oct 2022

**Print date:** 29 Nov 2022

**Version:** 1

Page 9/10

## Reconstitution Buffer (RB)

CO2 carbon dioxide

EC/EU European Community/European Union

EN European standard

IATA International Air Transport Association

IBC bulk packaging (Intermediate Bulk Container)

IgA Immunoglobuline A

IgG Immunoglobulin G

IgM Immunoglobuline M

IMDG International Maritime Code for Dangerous Goods

IVD in vitro diagnostics

MARPOL International Convention for the Prevention of Marine Pollution

NIOSH National Institute for Occupational Safety and Health

PBT Persistent (P), Bioaccumulative (B), Toxic (T)

RID Regulations for the International Carriage of Dangerous Goods by Rail (Règlement concernant le transport international ferroviaire de marchandises Dangereuse)

UN United Nations

vPvB very Persistent (vP), very Bioaccumulative (vB)

### 16.3. Key literature references and sources for data

No data available

### 16.4. Classification for mixtures and used evaluation method according to regulation (EC) No 1272/2008 [CLP]

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

### 16.5. Relevant R-, H- and EUH-phrases (Number and full text)

Hazard statements	
H301	Toxic if swallowed.
H302	Harmful if swallowed.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H331	Toxic if inhaled.
H341	Suspected of causing genetic defects.
H373	May cause damage to organs through prolonged or repeated exposure.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H411	Toxic to aquatic life with long lasting effects.

# SAFETY DATA SHEET

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

**Revision date:** 27 Oct 2022

**Print date:** 29 Nov 2022

**Version:** 1

Page 10/10

## Reconstitution Buffer (RB)

### 16.6. Training advice

No data available

### 16.7. Additional information

The information is based on the current state of our knowledge.

# SAFETY DATA SHEET

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

**Revision date:** 2 Nov 2022

**Print date:** 29 Nov 2022

**Version:** 2

Page 1/8

## GAD65-Biotin A

### SECTION 1: Identification of the substance/mixture and of the company/ undertaking

#### 1.1. Product identifier

**Trade name/designation:**

GAD65-Biotin

**Other means of identification:**

GAD65-Biotin

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against Use of the substance/mixture:

This assay and its reagents are not for personal or veterinary use. The reagents should not be used for any purpose other than the intended purpose.

#### 1.3. Details of the supplier of the safety data sheet

**Manufacturer:**

ALPCO  
26-G Keewaydin Drive  
Salem, NH 03079 USA  
phone: 800-592-5726  
email: ts@alpc.com

#### 1.4. Emergency telephone number

Dial 911 in the United States. If outside the US, dial local emergency number.

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

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

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

#### 2.2. Label elements

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

According to EC directives or the corresponding national regulations the product does not have to be labelled.

**Hazard statements:** none

**Supplemental hazard information:** none

**Precautionary statements:** none

#### 2.3. Other hazards

**Adverse human health effects and symptoms:**

This product does not contain a substance that has endocrine disrupting properties with respect to humans as no components meets the criteria.

# SAFETY DATA SHEET

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

**Revision date:** 2 Nov 2022

**Print date:** 29 Nov 2022

**Version:** 2

Page 2/8

## GAD65-Biotin

### Adverse environmental effects:

This mixture does not contain any substances presenting a health or environmental hazard within the means of Regulation (EC) No. 1272/2008, assigned a Community workplace exposure limit, classified as PBT/vPvB or included in the Candidate List.

### Other adverse effects:

The mixture contains material of human or animal origin and is therefore classified as potentially infectious.

## SECTION 3: Composition/information on ingredients

### 3.2. Mixtures

No data available

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

#### General information:

In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible). Remove victim out of the danger area. Remove contaminated, saturated clothing. If unconscious but breathing normally, place in recovery position and seek medical advice. Do not leave affected person unattended.

#### Following inhalation:

Provide fresh air.

#### After eye contact:

Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

#### Following ingestion:

Rinse mouth. Let 1 glass of water be drunk in little sips (dilution effect). Get medical advice/attention if you feel unwell.

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

No known symptoms to date.

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

Treat symptomatically.

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

#### Suitable extinguishing media:

Co-ordinate fire-fighting measures to the fire surroundings.

### 5.2. Special hazards arising from the substance or mixture

The product itself does not burn.

#### Hazardous combustion products:

In case of fire: Gases/vapours, toxic

### 5.3. Advice for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing.

### 5.4. Additional information

Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

#### 6.1.1. For non-emergency personnel

##### Personal precautions:

Remove persons to safety. Avoid breathing dust/fume/gas/mist/vapours/spray.

# SAFETY DATA SHEET

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

**Revision date:** 2 Nov 2022

**Print date:** 29 Nov 2022

**Version:** 2

Page 3/8

## GAD65-Biotin

### Protective equipment:

Wear protective gloves/protective clothing/eye protection/face protection.

### 6.1.2. For emergency responders

#### Personal protection equipment:

Personal protection equipment: see section 8

### 6.2. Environmental precautions

Do not allow to enter into surface water or drains.

### 6.3. Methods and material for containment and cleaning up

#### For containment:

Collect spillage. Measures to prevent aerosol and dust generation Wet clean or vacuum up solids.

#### For cleaning up:

Water (with cleaning agent)

### 6.4. Reference to other sections

Safe handling: see section 7 Personal protection equipment: see section 8 Disposal: see section 13

### 6.5. Additional information

Use appropriate container to avoid environmental contamination.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

#### Protective measures

#### Advices on safe handling:

Wear personal protection equipment (refer to section 8).

#### Measures to prevent aerosol and dust generation:

Dust should be exhausted directly at the point of origin.

#### Advices on general occupational hygiene

When using do not eat, drink, smoke, sniff. Avoid contact with skin, eyes and clothes.

### 7.2. Conditions for safe storage, including any incompatibilities

#### Technical measures and storage conditions:

Keep container tightly closed in a cool, well-ventilated place.

#### Further information on storage conditions:

Recommended storage temperature: 2-8°C

### 7.3. Specific end use(s)

#### Recommendation:

Item 1.2 and the instructions for use must be observed.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

No data available

### 8.2. Exposure controls

#### 8.2.1. Appropriate engineering controls

No data available

#### 8.2.2. Personal protection equipment

##### Eye/face protection:

Eye glasses with side protection EN 166

##### Skin protection:

Tested protective gloves must be worn EN ISO 374 Suitable material: Breakthrough time: min In the case of wanting to use the gloves again, clean them before taking off and air them well.

##### Respiratory protection:

Particle filter device (EN 143)

# SAFETY DATA SHEET

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

Revision date: 2 Nov 2022

Print date: 29 Nov 2022

Version: 2

Page 4/8

## GAD65-Biotin

### 8.2.3. Environmental exposure controls

No data available

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

#### Appearance

Physical state: solid

Colour: whitish

Odour: not determined

#### Safety relevant basis data

Parameter	Value	at °C	① Method ② Remark
pH	6.4 - 6.8	21 °C	
Melting point	<i>not determined</i>		
Freezing point	<i>not determined</i>		
Initial boiling point and boiling range	<i>not determined</i>		
Decomposition temperature	<i>not determined</i>		
Flash point	<i>not determined</i>		
Evaporation rate	<i>not determined</i>		
Auto-ignition temperature	<i>not determined</i>		
Upper/lower flammability or explosive limits	<i>not determined</i>		
Vapour pressure	<i>not determined</i>		
Vapour density	<i>not determined</i>		
Density	<i>not determined</i>		
Relative density	<i>not determined</i>		
Bulk density	<i>not determined</i>		
Water solubility	<i>not determined</i>		
Partition coefficient: n-octanol/water	<i>not determined</i>		
Dynamic viscosity	<i>not determined</i>		
Kinematic viscosity	<i>not determined</i>		

### 9.2. Other information

No data available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

The product itself does not burn. not relevant

### 10.2. Chemical stability

Light, heat, moisture (no dangerous reaction follows, the product becomes unusable).

### 10.3. Possibility of hazardous reactions

Light, heat, moisture (no dangerous reaction follows, the product becomes unusable).

### 10.4. Conditions to avoid

Light, heat, moisture (no dangerous reaction follows, the product becomes unusable).

### 10.5. Incompatible materials

No data available

### 10.6. Hazardous decomposition products

In case of fire: Gases/vapours, toxic

### Further information

Recommended storage temperature: 2-8°C

# SAFETY DATA SHEET

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

**Revision date:** 2 Nov 2022

**Print date:** 29 Nov 2022

**Version:** 2

Page 5/8

## GAD65-Biotin

### SECTION 11: Toxicological information

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

**Acute oral toxicity:**

Based on available data, the classification criteria are not met.

**Acute dermal toxicity:**

Based on available data, the classification criteria are not met.

**Acute inhalation toxicity:**

Based on available data, the classification criteria are not met.

**Skin corrosion/irritation:**

Based on available data, the classification criteria are not met.

**Serious eye damage/irritation:**

Based on available data, the classification criteria are not met.

**Respiratory or skin sensitisation:**

Based on available data, the classification criteria are not met.

**Germ cell mutagenicity:**

Based on available data, the classification criteria are not met.

**Carcinogenicity:**

Based on available data, the classification criteria are not met.

**Reproductive toxicity:**

Based on available data, the classification criteria are not met.

**STOT-single exposure:**

Based on available data, the classification criteria are not met.

**STOT-repeated exposure:**

Based on available data, the classification criteria are not met.

**Aspiration hazard:**

Based on available data, the classification criteria are not met.

**Additional information:**

No data available

#### 11.2. Information on other hazards

No data available

### SECTION 12: Ecological information

#### 12.1. Toxicity

No data available

#### 12.2. Persistence and degradability

No data available

#### 12.3. Bioaccumulative potential

No data available

#### 12.4. Mobility in soil

No data available

#### 12.5. Results of PBT and vPvB assessment

No data available

#### 12.6. Endocrine disrupting properties

No data available

#### 12.7. Other adverse effects

No data available

# SAFETY DATA SHEET

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

Revision date: 2 Nov 2022

Print date: 29 Nov 2022

Version: 2

Page 6/8

## GAD65-Biotin

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

##### 13.1.1. Product/Packaging disposal

#### Waste codes/waste designations according to EWC/AVV

##### Waste code product

18 02 03	wastes whose collection and disposal is not subject to special requirements in order to prevent infection
----------	---

#### Waste treatment options

##### Appropriate disposal / Product:

Consult the appropriate local waste disposal expert about waste disposal.

#### 13.2. Additional information

Do not allow to enter into surface water or drains.

### SECTION 14: Transport information

Land transport (ADR/RID)	Inland waterway craft (ADN)	Sea transport (IMDG)	Air transport (ICAO-TI / IATA-DGR)
<b>14.1. UN number or ID number</b>			
No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.
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No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.
<b>14.3. Transport hazard class(es)</b>			
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<b>14.4. Packing group</b>			
not relevant	not relevant	not relevant	not relevant
<b>14.5. Environmental hazards</b>			
not relevant	not relevant	not relevant	not relevant
<b>14.6. Special precautions for user</b>			
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#### 14.7. Maritime transport in bulk according to IMO instruments

No data available

### SECTION 15: Regulatory information

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

##### 15.1.1. EU legislation

No data available

##### 15.1.2. National regulations

 [DE] National regulations

Water hazard class

#### 15.2. Chemical Safety Assessment

No data available

# SAFETY DATA SHEET

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

**Revision date:** 2 Nov 2022

**Print date:** 29 Nov 2022

**Version:** 2

Page 7/8

## GAD65-Biotin

### SECTION 16: Other information

#### 16.1. Indication of changes

Revision according to REACH Regulation (EC) No. 1907/2006, last amended by Regulation (EU) 2020/878

#### 16.2. Abbreviations and acronyms

°C centigrade

ABEK Gases and vapors from organic compounds with a boiling point >65°C (A), inorganic gases and vapors, except carbon monoxide (B), sulfur dioxide and other acidic gases and vapors (E) and ammonia and organic ammonia derivatives (K)

ADR European Agreement concerning the International Carriage of Dangerous Goods by Road ( Accord européen relatif au transport international des marchandises dangereuses par route)

AWSV Ordinance on systems for handling water-polluting substances

CO carbon monoxide

CO<sub>2</sub> carbon dioxide

EC/EU European Community/European Union

EN European standard

IATA International Air Transport Association

IBC bulk packaging (Intermediate Bulk Container)

IgA Immunoglobuline A

IgG Immunoglobulin G

IgM Immunoglobuline M

IMDG International Maritime Code for Dangerous Goods

IVD in vitro diagnostics

MARPOL International Convention for the Prevention of Marine Pollution

NIOSH National Institute for Occupational Safety and Health

PBT Persistent (P), Bioaccumulative (B), Toxic (T)

RID Regulations for the International Carriage of Dangerous Goods by Rail (Règlement concernant le transport international ferroviaire de marchandises Dangereuse)

UN United Nations

vPvB very Persistent (vP), very Bioaccumulative (vB)

#### 16.3. Key literature references and sources for data

No data available

#### 16.4. Classification for mixtures and used evaluation method according to regulation (EC) No 1272/2008 [CLP]

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# SAFETY DATA SHEET

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

**Revision date:** 2 Nov 2022

**Print date:** 29 Nov 2022

**Version:** 2

Page 8/8

## GAD65-Biotin

### 16.5. Relevant R-, H- and EUH-phrases (Number and full text)

No data available

### 16.6. Training advice

No data available

### 16.7. Additional information

The information is based on the current state of our knowledge.