

EC safety data sheet

Trade name: WB, BAC-DIL, VIR-DIL

Current version : 2.0.0, issued: 24.11.2017

Replaced version: 1.1.1, issued: 20.02.2017

Region: GB

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

1.1 Product identifier

Trade name

WB, BAC-DIL, VIR-DIL**Wash buffer, Sample diluent**

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

Relevant identified uses of the substance or mixtureImmunochemical analytical/auxiliary reagent
For in-vitro diagnosis**Uses advised against**

No data available.

1.3 Details of the supplier of the safety data sheet

Addressmedac Gesellschaft für klinische Spezialpräparate mbH
Theaterstrasse 6
22880 Wedel
Germany

Telephone no. +49-4103-8006-0

Fax no. +49-4103-8006-100

Information provided by / telephoneProduct Safety
Safety Health Environment
productsafety@medac.de**Advice on Safety Data Sheet**

sdb_info@umco.de

1.4 Emergency telephone number

For medical advice (in German and English):
+49-551-192-40 (Giftinformationszentrum Nord)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification in accordance with Regulation (EC) No 1272/2008 (CLP)

Skin Sens. 1; H317

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 (CLP Regulation)**Hazard pictograms**

GHS07

Signal word

Warning

Hazardous component(s) to be indicated on label:

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1)

Hazard statement(s)

H317 May cause an allergic skin reaction.

Precautionary statement(s)P280 Wear protective gloves/protective clothing/eye protection.
P302+P352 IF ON SKIN: Wash with plenty of soap and water.

2.3 Other hazards

PBT assessment

The components of this product are not considered to be a PBT.

vPvB assessment

The components of this product are not considered to be a vPvB.

EC safety data sheet

Trade name: WB, BAC-DIL, VIR-DIL

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Replaced version: 1.1.1, issued: 20.02.2017

Region: GB

SECTION 3: Composition/information on ingredients

3.1 Substances

Not applicable. The product is not a substance.

3.2 Mixtures

Hazardous ingredients

No	Substance name	Additional information	
	CAS / EC / Index / REACH no	Classification (EC) 1272/2008 (CLP)	Concentration
			%
1	reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1)		
	55965-84-9 - 613-167-00-5 -	Acute Tox. 3*; H301 Acute Tox. 3*; H311 Acute Tox. 3*; H331 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 Skin Corr. 1B; H314 Skin Sens. 1; H317	> 0.20 - < 0.55 %b.w.

Full Text for all H-phrases and EUH-phrases: pls. see section 16
 (*, **, ***, ****) Detailed explanation pls. refer to CLP regulation No. 1272/2008, annex VI, 1.2

No	Note	Specific concentration limits	M-factor (acute)	M-factor (chronic)
1	-	Skin Sens. 1; H317: C >= 0.0015% Eye Irrit. 2; H319: C >= 0.06% Skin Irrit. 2; H315: C >= 0.06% Skin Corr. 1B; H314: C >= 0.6%	-	-

SECTION 4: First aid measures

4.1 Description of first aid measures

General information

Adhere to personal protective measures when giving first aid.

After inhalation

Ensure supply of fresh air. In the event of symptoms take medical treatment.

After skin contact

Remove contaminated clothing. When in contact with the skin, clean with soap and water. In case of symptoms call a physician.

After eye contact

Remove contact lenses. Rinse eye thoroughly under running water keeping eyelids wide open and protecting the unaffected eye (at least 10 to 15 minutes). In case of onset of symptoms consult doctor.

After ingestion

Rinse out mouth and give plenty of water to drink. In case of symptoms call a physician.

4.2 Most important symptoms and effects, both acute and delayed

No data available.

4.3 Indication of any immediate medical attention and special treatment needed

Show Safety Data Sheet. Treat symptomatically.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Product itself is non-combustible; adapt fire extinguishing measures to surrounding areas.

Unsuitable extinguishing media

For this product no limitations of extinguishing agents are given.

5.2 Special hazards arising from the substance or mixture

In case of combustion evolution of dangerous gases possible.

5.3 Advice for firefighters

Stay in the danger area only with self-contained breathing apparatus. Prevent skin and eye contact by keeping a safe distance or by wearing suitable protective clothing. Run-off water from fire fighting must not be discharged into drains or enter surface water. Fire residues and contaminated firefighting water must be disposed of in accordance with the local regulations.

EC safety data sheet

Trade name: WB, BAC-DIL, VIR-DIL

Current version : 2.0.0, issued: 24.11.2017

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Region: GB

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Avoid contact with skin, eyes and clothing. Ensure adequate ventilation.

For emergency responders

Personal protective equipment (PPE) - see Section 8.

6.2 Environmental precautions

Do not allow to enter drains.

6.3 Methods and material for containment and cleaning up

Pick up with absorbent material (e.g., sand, kieselguhr, acid binder, universal binder, sawdust). Afterwards clean with water and cleansing agent. Dispose of absorbed material in accordance with the regulations. Ensure adequate ventilation.

6.4 Reference to other sections

Information regarding safe handling, see chapter 7. Information regarding personal protective measures, see chapter 8. Information regarding waste disposal, see chapter 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling

Open and handle container with care. Avoid contact with skin and eyes.

General protective and hygiene measures

Observe the usual precautions when handling chemicals. Remove contaminated clothing. Do not eat or drink during work time. Keep away from foodstuffs and beverages. Wash hands before breaks and after work.

Advice on protection against fire and explosion

No special measures necessary.

7.2 Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions

No special measures necessary.

Recommended storage temperature

Value 2 - 8 °C

Requirements for storage rooms and vessels

Containers which are opened must be carefully closed and kept upright to prevent leakage.

Advice on storage assembly

Not necessary.

7.3 Specific end use(s)

Recommendations

Apart from the uses mentioned in Section 1.2 no other specific uses are stipulated.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

No parameters available for monitoring.

8.2 Exposure controls

Appropriate engineering controls

No data available.

Personal protective equipment**Respiratory protection**

Not necessary.

Eye / face protection

Safety glasses (EN 166)

Hand protection

Protective gloves (EN 455)

Appropriate Material

nitrile rubber

Material thickness

0.11

mm

Appropriate Material

Latex

Material thickness

0.11

mm

Other

Standard laboratory clothing.

EC safety data sheet

Trade name: WB, BAC-DIL, VIR-DIL

Current version : 2.0.0, issued: 24.11.2017

Replaced version: 1.1.1, issued: 20.02.2017

Region: GB

Environmental exposure controls
Do not empty into drains.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Form/Colour			
liquid			
colourless; blue; orange			
Odour			
almost odourless			
Odour threshold			
No data available			
pH value			
Value	7.0	-	7.4
Reference temperature		20	°C
Boiling point / boiling range			
Value	appr.	100	°C
Melting point / melting range			
Value	appr.	0	°C
Decomposition point / decomposition range			
No data available			
Flash point			
Not applicable			
Ignition temperature			
Not applicable			
Auto-ignition temperature			
Not applicable			
Remarks	Product is not selfigniting.		
Oxidising properties			
No data available			
Explosive properties			
Product does not present an explosion hazard.			
Flammability (solid, gas)			
Not applicable			
Lower flammability or explosive limits			
Not applicable			
Upper flammability or explosive limits			
Not applicable			
Vapour pressure			
Value	23		hPa
Reference temperature	20		°C
Vapour density			
No data available			
Evaporation rate			
No data available			
Relative density			
No data available			
Density			
Value	1.01		g/cm³
Reference temperature	20		°C
Solubility in water			
Remarks	Completely miscible		

EC safety data sheet

Trade name: WB, BAC-DIL, VIR-DIL

Current version : 2.0.0, issued: 24.11.2017

Replaced version: 1.1.1, issued: 20.02.2017

Region: GB

Solubility(ies)		
No data available		
Partition coefficient: n-octanol/water		
No data available		
Viscosity		
No data available		
Solvent content		
Value	88.1	%
Solids content		
Value	11.3	%

9.2 Other information

Other information
No data available.

SECTION 10: Stability and reactivity

10.1 Reactivity

Dangerous reactions are not expected if the product is handled according to its intended use.

10.2 Chemical stability

Stable if stored and handled properly.

10.3 Possibility of hazardous reactions

No dangerous reactions known.

10.4 Conditions to avoid

None, if handled according to intended use.

10.5 Incompatible materials

None known.

10.6 Hazardous decomposition products

No hazardous decomposition products known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute oral toxicity	
No data available	
Acute dermal toxicity	
No data available	
Acute inhalational toxicity	
No data available	
Skin corrosion/irritation	
No	Product Name
1	WB, BAC-DIL, VIR-DIL Wash buffer, Sample diluent
Remarks	Slight irritations.
Serious eye damage/irritation	
No	Product Name
1	WB, BAC-DIL, VIR-DIL Wash buffer, Sample diluent
Remarks	Slight irritations.
Respiratory or skin sensitisation	
No	Product Name
1	WB, BAC-DIL, VIR-DIL Wash buffer, Sample diluent
Route of exposure	Skin
Remarks	sensitisation possible
Route of exposure	respiratory tract
Remarks	No sensitizing effects are known.

EC safety data sheet

Trade name: WB, BAC-DIL, VIR-DIL

Current version : 2.0.0, issued: 24.11.2017

Replaced version: 1.1.1, issued: 20.02.2017

Region: GB

Germ cell mutagenicity
No data available
Reproduction toxicity
No data available
Carcinogenicity
No data available
STOT - single exposure
No data available
STOT - repeated exposure
No data available
Aspiration hazard
No data available
Delayed and immediate effects as well as chronic effects from short and long-term exposure
Possibility of sensitisation through skin contact.
Other information
After swallowing: Slight mucosal irritations in mouth, pharynx and oesophagus. After inhalation: Slight irritations possible.

SECTION 12: Ecological information

12.1 Toxicity

Toxicity to fish (acute)
No data available
Toxicity to fish (chronic)
No data available
Toxicity to Daphnia (acute)
No data available
Toxicity to Daphnia (chronic)
No data available
Toxicity to algae (acute)
No data available
Toxicity to algae (chronic)
No data available
Bacteria toxicity
No data available

12.2 Persistence and degradability

No data available.

12.3 Bioaccumulative potential

Bioconcentration factor (BCF)	
No	Product Name
1	WB, BAC-DIL, VIR-DIL Wash buffer, Sample diluent
Remarks	Low potential to bioaccumulate.

12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment

Results of PBT and vPvB assessment	
PBT assessment	The components of this product are not considered to be a PBT.
vPvB assessment	The components of this product are not considered to be a vPvB.

12.6 Other adverse effects

No data available.

12.7 Other information

Other information
Ecological data are not available.
Do not discharge product unmonitored into the environment.

EC safety data sheet

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Region: GB

SECTION 13: Disposal considerations**13.1 Waste treatment methods****Product**

Allocation of a waste code number, according to the European Waste Catalogue, should be carried out in agreement with the regional waste disposal company.

Remove in accordance with local official regulations.

Packaging

Residuals must be removed from packaging and when emptied completely disposed of in accordance with the regulations for waste removal. Incompletely emptied packaging must be disposed of in the form of disposal specified by the regional disposer.

SECTION 14: Transport information**14.1 Transport ADR/RID/ADN**

The product is not subject to ADR/RID/ADN regulations.

14.2 Transport IMDG

The product is not subject to IMDG regulations.

14.3 Transport ICAO-TI / IATA

The product is not subject to ICAO-TI / IATA regulations.

14.4 Other information

No data available.

14.5 Environmental hazards

Information on environmental hazards, if relevant, please see 14.1 - 14.3.

14.6 Special precautions for user

No data available.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Not relevant

SECTION 15: Regulatory information**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture****EU regulations****Regulation (EC) No 1907/2006 (REACH) Annex XIV (List of substances subject to authorisation)**

According to the data available and/or specifications supplied by upstream suppliers, this product does not contain any substances considered as substances requiring authorisation as listed on Annex XIV of the REACH regulation (EC) 1907/2006.

REACH candidate list of substances of very high concern (SVHC) for authorisation

According to available data and the information provided by preliminary suppliers, the product does not contain substances that are considered substances meeting the criteria for inclusion in annex XIV (List of Substances Subject to Authorisation) as laid down in Article 57 and article 59 of REACH (EC) 1907/2006.

Regulation (EC) No 1907/2006 (REACH) Annex XVII: RESTRICTIONS ON THE MANUFACTURE, PLACING ON THE MARKET AND USE OF CERTAIN DANGEROUS SUBSTANCES, PREPARATIONS AND ARTICLES

The product is considered being subject to REACH regulation (EC) 1907/2006 annexe XVII.	No 3
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Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances

This product is not subject to Part 1 or 2 of Annex I.

Other regulations

Employment restrictions, according to the regulations for protection of expectant and nursing mothers and the youth health and safety regulations, serving to protect against hazardous materials, should be observed.

15.2 Chemical safety assessment

A chemical safety assessment has not been carried out for this mixture.

SECTION 16: Other information**Further information**

The information is based on our current knowledge however it does not represent a guarantee of product properties nor does it create any legal obligation.

Sources of key data used to compile the data sheet:

Regulation (EC) No 1907/2006 (REACH), 1272/2008 (CLP) as amended in each case.

EC Directives 2000/39/EC, 2006/15/EC, 2009/161/EU

National Threshold Limit Values of the corresponding countries as amended in each case.

Transport regulations according to ADR, RID, IMDG, IATA as amended in each case.

The data sources used to determine physical, toxic and ecotoxic data, are indicated directly in the corresponding chapter.

EC safety data sheet

Trade name: WB, BAC-DIL, VIR-DIL

Current version : 2.0.0, issued: 24.11.2017

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Full text of the H- and EUH- phrases drawn up in sections 2 and 3 (provided not already drawn up in these sections)

H301	Toxic if swallowed.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H331	Toxic if inhaled.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

Department issuing safety data sheet

UMCO GmbH

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Prod-ID 639993

EC safety data sheet

Trade name: ANTIGEN-DIL, CAL, CON, CONTROL -, CONTROL +

Current version : 1.0.0, issued: 06.02.2018

Replaced version: 1.0.0, issued: 24.11.2017

Region: GB

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

1.1 Product identifier

Trade name

ANTIGEN-DIL, CAL, CON, CONTROL -, CONTROL +**Antigen dilution buffer, calibrator, conjugate, negative control, positive control**

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

Relevant identified uses of the substance or mixture

For in-vitro diagnosis

Immunochemical analytical/auxiliary reagent

Uses advised against

No data available.

1.3 Details of the supplier of the safety data sheet

Address

medac Gesellschaft für klinische Spezialpräparate mbH
Theaterstrasse 6
22880 Wedel
Germany

Telephone no. +49-4103-8006-0

Fax no. +49-4103-8006-100

Information provided by / telephone

Product Safety
Safety Health Environment
productsafety@medac.de

Advice on Safety Data Sheet

sdb_info@umco.de

1.4 Emergency telephone number

For medical advice (in German and English):

+49-551-192-40 (Giftinformationszentrum Nord)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification information

This product is assessed and classified using the methods and criteria below referred to in Article 9 of Regulation (EC) n° 1272/2008:

Physical hazards: determined through assessment data based on the methods or standards referred to in part 2 of Annex I to CLP

Health hazards and environmental hazards: determined through toxicological and ecotoxicological assessment data based on the methods or standards referred to in Part 3, 4 and 5 of Annex I to CLP.

This product does not meet the classification criteria given in the Regulation (EC) No 1272/2008 (CLP).

2.2 Label elements

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

Hazard pictograms

-

Signal word

-

Hazard statement(s)

-

Hazard statements (EU)

EUH208

Contains reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1). May produce an allergic reaction.

EUH210

Safety data sheet available on request.

Precautionary statement(s)

-

Labelling information

The labelling (EU hazard statements) meets the criteria of annex II of Directive (EC) Nr. 1272/2008 (CLP).

2.3 Other hazards

PBT assessment

The components of this product are not considered to be a PBT.

EC safety data sheet

Trade name: ANTIGEN-DIL, CAL, CON, CONTROL -, CONTROL +

Current version : 1.0.0, issued: 06.02.2018

Replaced version: 1.0.0, issued: 24.11.2017

Region: GB

vPvB assessment

The components of this product are not considered to be a vPvB.

SECTION 3: Composition/information on ingredients

3.1 Substances

Not applicable. The product is not a substance.

3.2 Mixtures

Chemical characterization

aqueous solution

Hazardous ingredients

No	Substance name	Additional information	
	CAS / EC / Index / REACH no	Classification (EC) 1272/2008 (CLP)	Concentration %
1	reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1)		
	55965-84-9 - 613-167-00-5 -	Acute Tox. 3*; H301 Acute Tox. 3*; H311 Acute Tox. 3*; H331 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 Skin Corr. 1B; H314 Skin Sens. 1; H317	< 0.0015 %-b.w.

Full Text for all H-phrases and EUH-phrases: pls. see section 16

(*, **, ***, ****) Detailed explanation pls. refer to CLP regulation No. 1272/2008, annex VI, 1.2

No	Note	Specific concentration limits	M-factor (acute)	M-factor (chronic)
1	-	Skin Sens. 1; H317: C >= 0.0015% Eye Irrit. 2; H319: C >= 0.06% Skin Irrit. 2; H315: C >= 0.06% Skin Corr. 1B; H314: C >= 0.6%	-	-

SECTION 4: First aid measures

4.1 Description of first aid measures

General information

Adhere to personal protective measures when giving first aid.

After inhalation

Ensure supply of fresh air. In the event of symptoms take medical treatment.

After skin contact

Remove contaminated clothing. When in contact with the skin, clean with soap and water. In case of symptoms call a physician.

After eye contact

Remove contact lenses. Rinse eye thoroughly under running water keeping eyelids wide open and protecting the unaffected eye (at least 10 to 15 minutes). In case of onset of symptoms consult doctor.

After ingestion

Rinse out mouth and give plenty of water to drink. In case of symptoms call a physician.

4.2 Most important symptoms and effects, both acute and delayed

No data available.

4.3 Indication of any immediate medical attention and special treatment needed

Show Safety Data Sheet. Treat symptomatically.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Product itself is non-combustible; adapt fire extinguishing measures to surrounding areas.

Unsuitable extinguishing media

For this product no limitations of extinguishing agents are given.

5.2 Special hazards arising from the substance or mixture

In case of combustion evolution of dangerous gases possible.

EC safety data sheet

Trade name: ANTIGEN-DIL, CAL, CON, CONTROL -, CONTROL +

Current version : 1.0.0, issued: 06.02.2018

Replaced version: 1.0.0, issued: 24.11.2017

Region: GB

5.3 Advice for firefighters

Stay in the danger area only with self-contained breathing apparatus. Prevent skin and eye contact by keeping a safe distance or by wearing suitable protective clothing. Run-off water from fire fighting must not be discharged into drains or enter surface water. Fire residues and contaminated firefighting water must be disposed of in accordance with the local regulations.

SECTION 6: Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures****For non-emergency personnel**

Avoid contact with skin, eyes and clothing. Ensure adequate ventilation.

For emergency responders

Personal protective equipment (PPE) - see Section 8.

6.2 Environmental precautions

Do not allow to enter drains.

6.3 Methods and material for containment and cleaning up

Pick up with absorbent material (e.g., sand, kieselguhr, acid binder, universal binder, sawdust) and send for disposal. Afterwards clean with water and cleansing agent. When picked up, treat material as prescribed under heading "Disposal considerations".

6.4 Reference to other sections

Information regarding safe handling, see chapter 7. Information regarding personal protective measures, see chapter 8. Information regarding waste disposal, see chapter 13.

SECTION 7: Handling and storage**7.1 Precautions for safe handling****Advice on safe handling**

No special measures necessary if stored and handled as prescribed.

General protective and hygiene measures

Observe the usual precautions when handling chemicals. Remove contaminated clothing. Do not eat or drink during work time. Keep away from foodstuffs and beverages. Wash hands before breaks and after work.

Advice on protection against fire and explosion

No special measures necessary.

7.2 Conditions for safe storage, including any incompatibilities**Recommended storage temperature**

Value	2	-	8	°C
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Requirements for storage rooms and vessels

Containers which are opened must be carefully closed and kept upright to prevent leakage.

Advice on storage assembly

None known

7.3 Specific end use(s)**Recommendations**

Apart from the uses mentioned in Section 1.2 no other specific uses are stipulated.

SECTION 8: Exposure controls/personal protection**8.1 Control parameters**

No parameters available for monitoring.

8.2 Exposure controls**Appropriate engineering controls**

No data available.

Personal protective equipment**Respiratory protection**

No special measures required.

Eye / face protection

Safety glasses (EN 166)

Hand protection

Protective gloves (EN 455)

Appropriate Material	nitrile rubber		
Material thickness		0.11	mm
Appropriate Material	Latex		
Material thickness		0.11	mm

EC safety data sheet

Trade name: ANTIGEN-DIL, CAL, CON, CONTROL -, CONTROL +

Current version : 1.0.0, issued: 06.02.2018

Replaced version: 1.0.0, issued: 24.11.2017

Region: GB

Other

Standard laboratory clothing.

Environmental exposure controls

Do not empty into drains.

SECTION 9: Physical and chemical properties**9.1 Information on basic physical and chemical properties**

Form/Colour			
liquid			
product specific			
Odour			
odourless			
Odour threshold			
No data available			
pH value			
Value	7.2		
Reference temperature	20	°C	
Boiling point / boiling range			
Value	appr.	100	°C
Melting point / melting range			
Value	appr.	0	°C
Decomposition point / decomposition range			
No data available.			
Flash point			
Not applicable			
Ignition temperature			
Not applicable			
Auto-ignition temperature			
Remarks	Product is not selfigniting.		
Oxidising properties			
not oxidizing			
Explosive properties			
The product does not have explosive properties.			
Flammability (solid, gas)			
Not applicable			
Lower flammability or explosive limits			
Not applicable			
Upper flammability or explosive limits			
Not applicable			
Vapour pressure			
not determined			
Vapour density			
No data available			
Evaporation rate			
No data available			
Relative density			
No data available			
Density			
not determined			
Solubility in water			
Remarks	Completely miscible		

EC safety data sheet

Trade name: ANTIGEN-DIL, CAL, CON, CONTROL -, CONTROL +

Current version : 1.0.0, issued: 06.02.2018

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Solubility(ies)		
No data available		
Partition coefficient: n-octanol/water		
No data available		
Viscosity		
No data available		
Solvent content		
Value	0.1	%
Solids content		
Value	2	%

9.2 Other information

Other information		
No data available.		

SECTION 10: Stability and reactivity

10.1 Reactivity

Dangerous reactions are not expected if the product is handled according to its intended use.

10.2 Chemical stability

Stable if stored and handled properly.

10.3 Possibility of hazardous reactions

No dangerous reactions known.

10.4 Conditions to avoid

None, if handled according to intended use.

10.5 Incompatible materials

None known.

10.6 Hazardous decomposition products

No hazardous decomposition products known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute oral toxicity		
No data available		
Acute dermal toxicity		
No data available		
Acute inhalational toxicity		
No data available		
Skin corrosion/irritation		
No	Product Name	
1	ANTIGEN-DIL, CAL, CON, CONTROL -, CONTROL + Antigen dilution buffer, calibrator, conjugate, negative control, positive control	
Remarks		Slight irritations.
Serious eye damage/irritation		
No	Product Name	
1	ANTIGEN-DIL, CAL, CON, CONTROL -, CONTROL + Antigen dilution buffer, calibrator, conjugate, negative control, positive control	
Remarks		Slight irritations.
Respiratory or skin sensitisation		
No	Product Name	
1	ANTIGEN-DIL, CAL, CON, CONTROL -, CONTROL + Antigen dilution buffer, calibrator, conjugate, negative control, positive control	
Route of exposure		Skin
Remarks		sensitisation possible.
Route of exposure		respiratory tract
Remarks		No sensitizing effects are known.

EC safety data sheet

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Current version : 1.0.0, issued: 06.02.2018

Replaced version: 1.0.0, issued: 24.11.2017

Region: GB

Germ cell mutagenicity
No data available
Reproduction toxicity
No data available
Carcinogenicity
No data available
STOT - single exposure
No data available
STOT - repeated exposure
No data available
Aspiration hazard
No data available
Delayed and immediate effects as well as chronic effects from short and long-term exposure
Possibility of sensitisation through skin contact.
Other information
After swallowing: Slight mucosal irritations in mouth, pharynx and oesophagus. After inhalation: Slight irritations possible.

SECTION 12: Ecological information

12.1 Toxicity

Toxicity to fish (acute)
No data available
Toxicity to fish (chronic)
No data available
Toxicity to Daphnia (acute)
No data available
Toxicity to Daphnia (chronic)
No data available
Toxicity to algae (acute)
No data available
Toxicity to algae (chronic)
No data available
Bacteria toxicity
No data available

12.2 Persistence and degradability

No data available.

12.3 Bioaccumulative potential

Bioconcentration factor (BCF)	
No	Product Name
1	ANTIGEN-DIL, CAL, CON, CONTROL -, CONTROL + Antigen dilution buffer, calibrator, conjugate, negative control, positive control
Remarks	Low potential to bioaccumulate.

12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment

Results of PBT and vPvB assessment	
PBT assessment	The components of this product are not considered to be a PBT.
vPvB assessment	The components of this product are not considered to be a vPvB.

12.6 Other adverse effects

No data available.

12.7 Other information

Other information
Ecological data are not available.
Do not discharge product unmonitored into the environment.

EC safety data sheet

Trade name: ANTIGEN-DIL, CAL, CON, CONTROL -, CONTROL +

Current version : 1.0.0, issued: 06.02.2018

Replaced version: 1.0.0, issued: 24.11.2017

Region: GB

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

Allocation of a waste code number, according to the European Waste Catalogue, should be carried out in agreement with the regional waste disposal company.

Packaging

Residuals must be removed from packaging and when emptied completely disposed of in accordance with the regulations for waste removal. Incompletely emptied packaging must be disposed of in the form of disposal specified by the regional disposer.

SECTION 14: Transport information

14.1 Transport ADR/RID/ADN

The product is not subject to ADR/RID/ADN regulations.

14.2 Transport IMDG

The product is not subject to IMDG regulations.

14.3 Transport ICAO-TI / IATA

The product is not subject to ICAO-TI / IATA regulations.

14.4 Other information

No data available.

14.5 Environmental hazards

Information on environmental hazards, if relevant, please see 14.1 - 14.3.

14.6 Special precautions for user

No data available.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Not relevant

SECTION 15: Regulatory information

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

EU regulations

Regulation (EC) No 1907/2006 (REACH) Annex XIV (List of substances subject to authorisation)

According to the data available and/or specifications supplied by upstream suppliers, this product does not contain any substances considered as substances requiring authorisation as listed on Annex XIV of the REACH regulation (EC) 1907/2006.

REACH candidate list of substances of very high concern (SVHC) for authorisation

According to available data and the information provided by preliminary suppliers, the product does not contain substances that are considered substances meeting the criteria for inclusion in annex XIV (List of Substances Subject to Authorisation) as laid down in Article 57 and article 59 of REACH (EC) 1907/2006.

Regulation (EC) No 1907/2006 (REACH) Annex XVII: RESTRICTIONS ON THE MANUFACTURE, PLACING ON THE MARKET AND USE OF CERTAIN DANGEROUS SUBSTANCES, PREPARATIONS AND ARTICLES

According to the data available and/or specifications supplied by upstream suppliers, this product does not contain any substances requiring authorisation as listed on Annex XIV of the REACH regulation (EC) 1907/2006.

Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances

This product is not subject to Part 1 or 2 of Annex I.

Other regulations

Employment restrictions, according to the regulations for protection of expectant and nursing mothers and the youth health and safety regulations, serving to protect against hazardous materials, should be observed.

15.2 Chemical safety assessment

A chemical safety assessment has not been carried out for this mixture.

SECTION 16: Other information

Sources of key data used to compile the data sheet:

The data sources used to determine physical, toxic and ecotoxic data, are indicated directly in the corresponding chapter.

Regulation (EC) No 1907/2006 (REACH), 1272/2008 (CLP) as amended in each case.

Transport regulations according to ADR, RID, IMDG, IATA as amended in each case.

National Threshold Limit Values of the corresponding countries as amended in each case.

EC Directives 2000/39/EC, 2006/15/EC, 2009/161/EU

EC safety data sheet

Trade name: ANTIGEN-DIL, CAL, CON, CONTROL -, CONTROL +

Current version : 1.0.0, issued: 06.02.2018

Replaced version: 1.0.0, issued: 24.11.2017

Region: GB

Full text of the H- and EUH- phrases drawn up in sections 2 and 3 (provided not already drawn up in these sections)

H301	Toxic if swallowed.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H331	Toxic if inhaled.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

Department issuing safety data sheet

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This information is based on our present knowledge and experience.

The safety data sheet describes products with a view to safety requirements.

It does not however, constitute a guarantee for any specific product properties and shall not establish a legally valid contractual relationship.

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Prod-ID 726756

EC safety data sheet

Trade name: STOP

Current version : 3.0.0, issued: 24.11.2017

Replaced version: 2.0.1, issued: 20.02.2017

Region: GB

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

1.1 Product identifier

Trade name

STOP**Stop solution**

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

Relevant identified uses of the substance or mixtureImmunochemical analytical/auxiliary reagent
For in-vitro diagnosis**Uses advised against**

No data available.

1.3 Details of the supplier of the safety data sheet

Addressmedac Gesellschaft für klinische Spezialpräparate mbH
Theaterstrasse 6
22880 Wedel
Germany

Telephone no. +49-4103-8006-0

Fax no. +49-4103-8006-100

Information provided by / telephoneProduct Safety
Safety Health Environment
productsafety@medac.de**Advice on Safety Data Sheet**

sdb_info@umco.de

1.4 Emergency telephone number

For medical advice (in German and English):
+49-551-192-40 (Giftinformationszentrum Nord)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification in accordance with Regulation (EC) No 1272/2008 (CLP)

Met. Corr. 1; H290

Classification informationThis product is assessed and classified using the methods and criteria below referred to in Article 9 of Regulation (EC) n° 1272/2008:
Physical hazards: determined through assessment data based on the methods or standards referred to in part 2 of Annex I to CLP
Health hazards and environmental hazards: determined through toxicological and ecotoxicological assessment data based on the methods or standards referred to in Part 3, 4 and 5 of Annex I to CLP.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 (CLP Regulation)**Hazard pictograms**

GHS05

Signal word

Warning

Hazard statement(s)

H290

May be corrosive to metals.

Labelling information

Due to its limited quantity the product is not subject to the labelling and packaging requirements of Art. 17 (please refer to Annex I, Number 1.5.2, EC Reg. No 1272/2008 (CLP)).

2.3 Other hazards

PBT assessment

The components of this product are not considered to be a PBT.

EC safety data sheet

Trade name: STOP

Current version : 3.0.0, issued: 24.11.2017

Replaced version: 2.0.1, issued: 20.02.2017

Region: GB

vPvB assessment

The components of this product are not considered to be a vPvB.

SECTION 3: Composition/information on ingredients**3.1 Substances**

Not applicable. The product is not a substance.

3.2 Mixtures**Hazardous ingredients**

No	Substance name	Additional information	
	CAS / EC / Index / REACH no	Classification (EC) 1272/2008 (CLP)	Concentration %
1	sulphuric acid		
	7664-93-9 231-639-5 016-020-00-8 -	Met. Corr. 1; H290	> 1.00 - < 5.00 %b.w.

Full Text for all H-phrases and EUH-phrases: pls. see section 16

No	Note	Specific concentration limits	M-factor (acute)	M-factor (chronic)
1	B	-	-	-

Full text for the notes: pls. see section 16 "Notes relating to the identification, classification and labelling of substances ((EC) No 1272/2008, Annex VI)".

SECTION 4: First aid measures**4.1 Description of first aid measures****General information**

Adhere to personal protective measures when giving first aid.

After inhalation

Ensure supply of fresh air. In the event of symptoms take medical treatment.

After skin contact

Remove contaminated clothing. In case of contact with skin wash off with water. In case of symptoms call a physician.

After eye contact

Remove contact lenses. Rinse eye thoroughly under running water keeping eyelids wide open and protecting the unaffected eye (at least 10 to 15 minutes). In case of onset of symptoms consult doctor.

After ingestion

Rinse out mouth and give plenty of water to drink. In case of symptoms call a physician.

4.2 Most important symptoms and effects, both acute and delayed

No data available.

4.3 Indication of any immediate medical attention and special treatment needed

Show Safety Data Sheet. Treat symptomatically.

SECTION 5: Firefighting measures**5.1 Extinguishing media****Suitable extinguishing media**

Product itself is non-combustible; adapt fire extinguishing measures to surrounding areas.

Unsuitable extinguishing media

For this product no limitations of extinguishing agents are given.

5.2 Special hazards arising from the substance or mixture

In case of combustion evolution of dangerous gases possible.

5.3 Advice for firefighters

Stay in the danger area only with self-contained breathing apparatus. Prevent skin and eye contact by keeping a safe distance or by wearing suitable protective clothing. Run-off water from fire fighting must not be discharged into drains or enter surface water. Fire residues and contaminated firefighting water must be disposed of in accordance with the local regulations.

SECTION 6: Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures****For non-emergency personnel**

Avoid contact with skin, eyes and clothing. Ensure adequate ventilation.

EC safety data sheet

Trade name: STOP

Current version : 3.0.0, issued: 24.11.2017

Replaced version: 2.0.1, issued: 20.02.2017

Region: GB

For emergency responders

Personal protective equipment (PPE) - see Section 8.

6.2 Environmental precautions

Do not allow to enter drains.

6.3 Methods and material for containment and cleaning up

Pick up with absorbent material (e.g., sand, kieselguhr, acid binder, universal binder, sawdust). Afterwards clean with water and cleansing agent. Dispose of absorbed material in accordance with the regulations. Ensure adequate ventilation.

6.4 Reference to other sections

Information regarding safe handling, see chapter 7. Information regarding personal protective measures, see chapter 8. Information regarding waste disposal, see chapter 13.

SECTION 7: Handling and storage**7.1 Precautions for safe handling****Advice on safe handling**

No special measures necessary if stored and handled as prescribed.

General protective and hygiene measures

Observe the usual precautions when handling chemicals. Remove contaminated clothing. Do not eat or drink during work time. Keep away from foodstuffs and beverages. Wash hands before breaks and after work.

Advice on protection against fire and explosion

No special measures necessary.

7.2 Conditions for safe storage, including any incompatibilities**Technical measures and storage conditions**

No special measures necessary.

Recommended storage temperature

Value 2 - 8 °C

Requirements for storage rooms and vessels

Containers which are opened must be carefully closed and kept upright to prevent leakage.

Advice on storage assembly

Not necessary.

7.3 Specific end use(s)**Recommendations**

Apart from the uses mentioned in Section 1.2 no other specific uses are stipulated.

SECTION 8: Exposure controls/personal protection**8.1 Control parameters****Occupational exposure limit values**

No	Substance name	CAS no.	EC no.
1	sulphuric acid	7664-93-9	231-639-5
	2009/161/EU		
	sulphuric acid (mist)		
	Mist		
	TWA	0.05	mg/m ³

8.2 Exposure controls**Appropriate engineering controls**

No data available.

Personal protective equipment**Respiratory protection**

Not necessary.

Eye / face protection

Safety glasses (EN 166)

Hand protection

Protective gloves (EN 455)

Appropriate Material

nitrile rubber

Material thickness

0.11

mm

Appropriate Material

Latex

Material thickness

0.11

mm

Other

Standard laboratory clothing.

EC safety data sheet

Trade name: STOP

Current version : 3.0.0, issued: 24.11.2017

Replaced version: 2.0.1, issued: 20.02.2017

Region: GB

Environmental exposure controls
Do not empty into drains.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Form/Colour			
liquid			
colourless			
Odour			
odourless			
Odour threshold			
not determined			
pH value			
Value	1		
Reference temperature	20	°C	
Boiling point / boiling range			
Value	appr.	100	°C
Melting point / melting range			
Value	appr.	0	°C
Decomposition point / decomposition range			
No data available.			
Flash point			
No data available			
Auto-ignition temperature			
Remarks	Product is not selfigniting.		
Oxidising properties			
No data available			
Explosive properties			
Product does not present an explosion hazard.			
Flammability (solid, gas)			
No data available			
Lower flammability or explosive limits			
No data available			
Upper flammability or explosive limits			
No data available			
Vapour pressure			
Value	23	hPa	
Reference temperature	20	°C	
Vapour density			
No data available			
Evaporation rate			
No data available			
Relative density			
No data available			
Density			
Value	1.01	g/cm³	
Reference temperature	20	°C	
Solubility in water			
Remarks	Completely miscible		

EC safety data sheet

Trade name: STOP

Current version : 3.0.0, issued: 24.11.2017

Replaced version: 2.0.1, issued: 20.02.2017

Region: GB

Solubility(ies)		
No data available		
Partition coefficient: n-octanol/water		
No data available		
Viscosity		
No data available		
Solids content		
Value	0	%

9.2 Other information

Other information
No data available.

SECTION 10: Stability and reactivity

10.1 Reactivity

Dangerous reactions are not expected if the product is handled according to its intended use.

10.2 Chemical stability

Stable if stored and handled properly.

10.3 Possibility of hazardous reactions

No dangerous reactions known.

10.4 Conditions to avoid

None, if handled according to intended use.

10.5 Incompatible materials

None known.

10.6 Hazardous decomposition products

No hazardous decomposition products known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute oral toxicity	
No data available	
Acute dermal toxicity	
No data available	
Acute inhalational toxicity	
No data available	
Skin corrosion/irritation	
No	Product Name
1	STOP Stop solution
Remarks	Irritations possible.
Serious eye damage/irritation	
No	Product Name
1	STOP Stop solution
Remarks	Irritations possible.
Respiratory or skin sensitisation	
No	Product Name
1	STOP Stop solution
Route of exposure	respiratory tract
Remarks	No sensitizing effects are known.
Route of exposure	Skin
Remarks	No sensitizing effects are known.

EC safety data sheet

Trade name: STOP

Current version : 3.0.0, issued: 24.11.2017

Replaced version: 2.0.1, issued: 20.02.2017

Region: GB

Germ cell mutagenicity
No data available
Reproduction toxicity
No data available
Carcinogenicity
No data available
STOT - single exposure
No data available
STOT - repeated exposure
No data available
Aspiration hazard
No data available
Delayed and immediate effects as well as chronic effects from short and long-term exposure
Irritates the eyes and the skin.
Other information
After ingestion: Irritations in the mouth, pharynx and oesophagus. After inhalation: Irritations.

SECTION 12: Ecological information

12.1 Toxicity

Toxicity to fish (acute)
No data available
Toxicity to fish (chronic)
No data available
Toxicity to Daphnia (acute)
No data available
Toxicity to Daphnia (chronic)
No data available
Toxicity to algae (acute)
No data available
Toxicity to algae (chronic)
No data available
Bacteria toxicity
No data available

12.2 Persistence and degradability

Biodegradability	
No	Product Name
1	STOP STOP solution
Remarks	The product is readily biodegradable.

12.3 Bioaccumulative potential

Bioconcentration factor (BCF)	
No	Product Name
1	STOP Stop solution
Remarks	Low potential to bioaccumulate.

12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment

Results of PBT and vPvB assessment	
Results of PBT and vPvB assessment	
PBT assessment	The components of this product are not considered to be a PBT.
vPvB assessment	The components of this product are not considered to be a vPvB.

EC safety data sheet

Trade name: STOP

Current version : 3.0.0, issued: 24.11.2017

Replaced version: 2.0.1, issued: 20.02.2017

Region: GB

12.6 Other adverse effects

No data available.

12.7 Other information**Other information**

Ecological data are not available.

Do not discharge product unmonitored into the environment.

SECTION 13: Disposal considerations**13.1 Waste treatment methods****Product**

Allocation of a waste code number, according to the European Waste Catalogue, should be carried out in agreement with the regional waste disposal company.

Remove in accordance with local official regulations.

Packaging

Residuals must be removed from packaging and when emptied completely disposed of in accordance with the regulations for waste removal. Incompletely emptied packaging must be disposed of in the form of disposal specified by the regional disposer.

SECTION 14: Transport information**14.1 Transport ADR/RID/ADN**

Class	8
Classification code	C1
Packing group	III
Hazard identification no.	80
UN number	UN3264
Technical name	CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. solution
Danger releasing substance	sulphuric acid
Tunnel restriction code	E
Label	8
Remarks	Limited Quantity LQ: 5 L Excepted Quantity EQ: (E1) 30 ml

14.2 Transport IMDG

Class	8
Packing group	III
UN number	UN3264
Proper shipping name	CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. Solution
Danger releasing substance	sulphuric acid
EmS	F-A+S-B
Label	8
Remarks	Limited Quantity LQ: 5 L Excepted Quantity EQ: (E1) 30 ml

14.3 Transport ICAO-TI / IATA

Class	8
Packing group	III
UN number	UN3264
Proper shipping name	Corrosive liquid, acidic, inorganic, n.o.s. Solution
Danger releasing substance	sulphuric acid
Label	8
Remarks	Limited Quantity LQ: 1 L Excepted Quantity EQ: (E1) 30 ml

14.4 Other information

No data available.

14.5 Environmental hazards

Information on environmental hazards, if relevant, please see 14.1 - 14.3.

14.6 Special precautions for user

No data available.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Not relevant

EC safety data sheet

Trade name: STOP

Current version : 3.0.0, issued: 24.11.2017

Replaced version: 2.0.1, issued: 20.02.2017

Region: GB

SECTION 15: Regulatory information

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

EU regulations**Regulation (EC) No 1907/2006 (REACH) Annex XIV (List of substances subject to authorisation)**

According to the data available and/or specifications supplied by upstream suppliers, this product does not contain any substances considered as substances requiring authorisation as listed on Annex XIV of the REACH regulation (EC) 1907/2006.

REACH candidate list of substances of very high concern (SVHC) for authorisation

According to available data and the information provided by preliminary suppliers, the product does not contain substances that are considered substances meeting the criteria for inclusion in annex XIV (List of Substances Subject to Authorisation) as laid down in Article 57 and article 59 of REACH (EC) 1907/2006.

Regulation (EC) No 1907/2006 (REACH) Annex XVII: RESTRICTIONS ON THE MANUFACTURE, PLACING ON THE MARKET AND USE OF CERTAIN DANGEROUS SUBSTANCES, PREPARATIONS AND ARTICLES

According to the data available and/or specifications supplied by upstream suppliers, this product does not contain any substances requiring authorisation as listed on Annex XIV of the REACH regulation (EC) 1907/2006.

Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances

This product is not subject to Part 1 or 2 of Annex I.

Other regulations

Employment restrictions, according to the regulations for protection of expectant and nursing mothers and the youth health and safety regulations, serving to protect against hazardous materials, should be observed.

15.2 Chemical safety assessment

A chemical safety assessment has not been carried out for this mixture.

SECTION 16: Other information

Further information

The data given above is based on our current knowledge. It shall describe our product in view of the safety requirements, but does not establish a guarantee of product properties and does not substantiate any contractual legal relationship.

Sources of key data used to compile the data sheet:

Regulation (EC) No 1907/2006 (REACH), 1272/2008 (CLP) as amended in each case.

EC Directives 2000/39/EC, 2006/15/EC, 2009/161/EU

National Threshold Limit Values of the corresponding countries as amended in each case.

Transport regulations according to ADR, RID, IMDG, IATA as amended in each case.

The data sources used to determine physical, toxic and ecotoxic data, are indicated directly in the corresponding chapter.

Notes relating to the identification, classification and labelling of substances and mixtures ((EC) No 1272/2008, Annex VI)

B Some substances (acids, bases, etc.) are placed on the market in aqueous solutions at various concentrations and, therefore, these solutions require different classification and labelling since the hazards vary at different concentrations. In Part 3 entries with Note B have a general designation of the following type: 'nitric acid ... %'. In this case the supplier must state the percentage concentration of the solution on the label. Unless otherwise stated, it is assumed that the percentage concentration is calculated on a weight/weight basis.

Department issuing safety data sheet

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