

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier:****Trade name:** Antibody Diluent for Immunohistochemistry**Article number/reference:** B1-31CW**Registration number**

This product is a mixture (see chapter 3). Registration number(s) is/are not available for this substance/these substances as the substance(s) or its/their use are exempted from registration according to Article 2 REACH Regulation (EC) No. 1907/2006, the annual tonnage does not require registration or the registration is envisaged for a later registration deadline.

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

Immunochemical analytical/auxiliary reagent
For in-vitro diagnosis

Uses advised against:

No further relevant information available.

Sector of Use SU20 Health services**Product category** PC21 Laboratory chemicals**Process category** PROC15 Use of laboratory reagent**Application of the substance / the mixture**

Immunochemical reagent / Auxiliary reagent for in-vitro diagnosis

1.3 Details of the supplier of the safety data sheet:**Manufacturer:**

WellMed B.V.
't Holland 31
6921 GX Duiven
The Netherlands
Phone: +31 (0) 85 273 23 23

Distributor:

medac GmbH
Theaterstrasse 6
22880 Wedel, Deutschland
Phone: +49 (0)4103 8006-0

Informing department :

Product safety
info@wellmed.nl

1.4 Emergency telephone number:

(24 hour), +31(0) 30 2748888, only for the doctor.
Vergiftiging informatie centrum Utrecht, The Netherlands

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture:

Classification according to Regulation (EC) No 12712/2008

Skin Sens. 1 H317 May cause an allergic skin reaction.
Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008

The product is classified according to Regulation (EC) No 1272/2008 (GHS/CLP)

Hazard pictograms



GHS07

Signal word Warning

Hazard-determining components of labelling:

Gemisch aus/Mixture of: 5-Chlor-2-methyl-2H-isothiazol-3-on [EG-Nr. 247-500-7] and 2-Methyl-2H-isothiazol-3-on [EG-Nr. 220-239-6] (3:1)

Hazard statements

H317 May cause an allergic skin reaction.
H412 Harmful to aquatic life with long lasting effects.

Precautionary statements

Restricted to professional users.
P273 Avoid release to the environment.
P280 Wear protective gloves / protective clothing /eye protection.
P302+P352 IF ON SKIN: Wash with plenty of water.
P333+P313 If skin irritation or rash occurs: get medical advice/attention.

Additional information: Restricted to professional users

Labelling of packages where the contents do not exceed 125 ml

Hazard pictograms



GHS07

Signal word Warning

Hazard-determining components of labelling:

Gemisch aus/Mixture of: 5-Chlor-2-methyl-2H-isothiazol-3-on [EG-Nr. 247-500-7] and 2-Methyl-2H-isothiazol-3-on [EG-Nr. 220-239-6] (3:1)

Hazard statements

H317 May cause an allergic skin reaction.

H412 Harmful to aquatic life with long lasting effects.

Precautionary statements

Restricted to professional users.

P273 Avoid release to the environment.

P280 Wear protective gloves / protective clothing /eye protection.

2.3 Other Hazards No further information available.

Results of PBT and vPvB assessment

PBT : Substance(s) does/do not meet the criteria for PBT according to Regulation (EC) No 1907/2006, Annex XIII.





vPvB : Substance(s) does/do not meet the criteria for vPvB according to Regulation (EC) No 1907/2006, Annex XIII.

SECTION 3: Composition/information on ingredients
3.1 Substances

Not applicable. The product is a mixture.

Description: Immunochemical reagent / Auxiliary reagent

3.2 Chemical characterization: Mixtures

Dangerous Components:		
CAS / EC / Index / REACH no	Classification (EC) 1272/2008 (CLP)	Concentration
CAS: 55965-84-9 - Index number: 613-167-00-5 -	Gemisch aus/ Mixture 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)  Acute Tox. 3, H301; Acute Tox.2 , H310; Acute Tox.2, H330  Skinn Corr. 1B, H314; Eye Dam. 1, H318  Aquatic Acute 1, H400; Aquatic Chronic, H410  Skin Sens. 1A, H317	0,0085%

Additional information Full text for the notes: please see Section 16

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

Take care of self-protection / protective measures when giving first aid.

After inhalation

Supply fresh air.

In case of symptoms call a physician.

After skin contact

Instantly wash with copious amounts of water.

Remove contaminated clothes.

In case of symptoms call a physician.

After eye contact

Rinse eyes cautiously with plenty of water for several minutes. Remove contact lenses if present and easy to do.

In case of symptoms consult an ophthalmologist/doctor.

After swallowing

Let rinse out mouth and then give plenty of water to drink.

In case of symptoms or disorders call a physician.

Information for doctor/physician.

Show Safety Data Sheet.

Treatment according to symptoms.

4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available for this mixture.

Acute and delayed symptoms and effects due to improper handling of this preparation have not been investigated.

Danger No further relevant information available

4.3 Indication of any immediate medical attention and special treatment needed

Information for doctor

No further relevant information available.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing agents

Product itself does not burn or combust. Use firefighting measures that suit the environment.

For safety reasons unsuitable extinguishing agents

No limitations of extinguishing agents are given for this mixture.

5.2 Special hazards arising from the substance of mixture

In the event of the fire, evolution of dangerous fumes or vapours is possible

5.3 Advice for firefighters

Protective equipment:

Stay in danger area only with self-contained breathing apparatus.

Prevent skin and eye contact by keeping a safe distance or by wearing suitable protective clothing/safety glasses.

Additional information:

Collect Run-off water from firefighting separately, do not enter into drains or 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

Advice for non-emergency personnel:

Provide sufficient ventilation.

Avoid reagent contact with eyes and skin.

Advice for emergency responders:

Protective equipment: see section 8.

6.2 Environmental precautions: Do not empty into drains.

6.3 Methods and material for containment and cleaning up:

Ensure adequate ventilation.

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

Dispose of the material collected according to respective national regulations.

Afterwards clean with water and cleansing agent.

6.4 Reference to other sections

See section 7 for information on safe handling.

See section 8 for information on personal protection equipment.

See section 13 for information on disposal.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Observe label precautions.

Open and handle container with care.

Prevent inhalation, swallowing and contact with the skin and eyes.

Information about protection against explosives and fires:

No special measures required.

7.2 Conditions for safe storage, including any incompatibilities:

Requirements for storage rooms and vessels:

Store in a cool, dry, ventilated area.

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

Store at a temperature of +2 to +8 °C.

Information about storage in one common storage facility: For this mixture no further information is available.

Further information about storage conditions: The indications are valid for the whole package

Storage class: See national guidelines.

7.3 Specific end use(s): 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**

Additional information about design of technical systems: No further data; see Section 7.

Components with critical values that require monitoring at the workplace:

No further relevant information available.

Additional information: The official lists that were valid during the compilation were used as basis.

8.2 Exposure controls

Technical measures and appropriate working operations should be given over the use of personal protective equipment. See Section 7.

Personal protective equipment

General protective and hygienic measures

The usual precautionary measures should also be adhered in handling the chemicals.

Avoid contact with the eyes and skin.

Remove contaminated clothing immediately.

Do not eat or drink while working.

Keep away from food and beverages.

Wash hands during breaks and at the end of work.

Breathing equipment: No special precautions are necessary if handled correctly.

Protect of hands: Protective gloves (AQL 1.5)

The breakthrough times stated below are based on laboratory test methods which cannot fully simulate working conditions. It is the responsibility of the end user to choose the appropriate gloves for this application. When working with substances or mixtures that are harmful in contact with skin, check the gloves beforehand for holes and fissures. Selection of the glove material in consideration of the penetration times, rates of diffusion and the degradation.

Material of gloves

Nitrile rubber, NBR

Natural rubber, NR

Thickness 0.11 mm

Product quality must comply with standard EN 374

Penetration time of glove material Permeation time > 120 min.

For the permanent contact in work areas without heightened risk of injury (e.g. Laboratory) gloves made of the following materials are suitable:

Product has not been designed for permanent contact

For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable: Product has not been designed for permanent contact

As protection from splashes, gloves made of the following materials are suitable:

Nitrile rubber, NBR

Natural rubber, NR

Thickness 0.11 mm

Eye protection: Safety glasses (standard EN 166)

Body protection: Protective work clothing.

Limitation and supervision of exposure into environment Do not empty into drains.

Risk management measures Void.

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

General information	
Appearance:	
Form:	liquid
Color:	colorless; blue; orange
Smell:	odourless
Odor 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	
Comments	Product is not self-igniting
Oxidizing 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	

Solubility(ies)	
No data available	
Value	1.01 g/cm ³
Reference temperature	20 °C
Solubility in water	
Comments	Completely miscible
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

No other information 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

The product is chemically stable under the indicated storage conditions.

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:

For these concentrations no further relevant information available.

10.6 Hazardous decomposition products:

In case of fire of large quantities: See section 5.

No further relevant information available.

SECTION 11: Toxicological information
11.1 Information on toxicological effects

Acute oral toxicity		
No data available		
Acute dermal toxicity		
No data available		
Acute inhalation toxicity		
No data available		
LD/LC₅₀ values that are relevant for classification:		
55965-84-9 Gemisch aus/Mixture of: 5-Chlor-2-methyl-2H-isothiazol-3-on [EG-Nr.247-500-7] and 2-Methyl-2H-isothiazol-3-on [EG-Nr. 220-239-6] (3:1)		
Oral	LD ₅₀	3.5 mg/kg (rat)
Dermal	LD ₅₀	> 5,000 mg/kg (rat)
Inhalative	LC ₅₀ /4 h	0.33 mg/L (rat)

Skin corrosion/irritation:	
NO	Product name
1	Antibody Diluent for Immunohistochemistry Reference: B1-31C
Comments	Slight irritations.

Serious eye damage/irritation: Based on the available data, the classification criteria are not met.	
NO	Product name
1	Antibody Diluent for Immunohistochemistry Reference: B1-31C
Comments	Slight irritations.

Respiratory or skin sensitisation	
NO	Product name
1	Antibody Diluent for Immunohistochemistry Reference: B1-31C
Route of exposure	Skin
Comments	May cause an allergic reaction.
Route of exposure	Respiratory tract
Comments	Slight Irritations possible.
Route of exposure	After swallowing
Comments	Mucosal irritations in mouth, pharynx and oesophagus possible.

Acute effects (acute toxicity, irritation and corrosivity) No acute toxicity information available for this product.

Sensitisation No sensitizing effect known

Repeated dose toxicity No further relevant information available.

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

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

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

Carcinogenicity 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.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Possibility of sensation through skin contact.

SECTION 12 : Ecological information

12.1 Toxicity

Aquatic toxicity: Toxic to aquatic life with long-lasting effects.

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 further relevant information available.

12.3 Bioaccumulative potential

Bioconcentration factor (BCF)	
No	Product name
1	Antibody Diluent for Immunohistochemistry Reference: B1-31C
Comments	Low potential to bioaccumulate

12.4 Mobility in soil No further relevant information available.

12.5 Results of PBT and vPvB assessment

PBT: Substance(s) does/do not meet the criteria for PBT according to Regulation (EC) No 1907/2006, Annex XIII.

vPvB: Substance(s) does/do not meet the criteria for vPvB according to Regulation (EC) No 1907/2006, Annex XIII.

12.6 Other adverse effects Harmful to aquatic organisms.

12.7 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

Remove in accordance with local official regulations.

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 UN-Number ADR, IMDG, IATA	-
14.2 UN proper shipping name ADR, IMDG, IATA	-
14.3 Transport hazard class(es) ADR, ADN, IMDG, IATA Class Substance mark	-
14.4 Packing group ADRIMDG, IATA	-
14.5 Environmental hazards:	Not applicable
14.6 Special precautions for user	Not applicable
14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable
Transport/Additional information:	The transport regulations are cited according to international regulations. Possible national deviations per country are not considered.
UN "Model Regulation":	-

SECTION 15 Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
Labeling according to Regulation (EC) No 1272/2008 See Section 2.
Hazard pictograms See Section 2.
Signal word See section 2

Hazard-determining components of labeling: See Section 2.

Hazard statements See Section 2.

Precautionary statements See Section 2.

Chemical safety assessment A chemical safety assessment was not carried out.

Directive 2012/18/EU

Named dangerous substances – ANNEX I Contains none of the listed substances

REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3

DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II

None of the ingredients is listed

National regulations

Information about limitation of use:

Take note of the directive on the protection of young people at work in the latest version.

Take note of the directive on the safety and health at work for pregnant and breast feeding mothers and workers of childbearing age in the latest version.

Degree to be applied in case of technical fault:

Class	Share in %
NK	0.2

Water hazard class: Water hazard class 2 (Self-assessment): hazardous for water

15.2 Chemical safety assessment

A chemical safety assessment has not been carried out.

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.

All information and recommendations are believed to be correct as of the date Safety Data Sheet but shall not be taken to be all inclusive and shall be used only as a guide. All chemicals and preparations may present unknown hazards and should be used with caution. WellMed B.V. shall not be held liable for any damage resulting from handling or from contact with the above product.

Relevant phrases in full text

H301	Toxic if swallowed.
H310	Fatal in contact with skin.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H330	Fatal if inhaled.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

Notes relating to the identification, classification and labeling 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 classifications and labeling 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 weight/weight basis.

Department issuing data specification sheet:

WellMed - Product Safety

Contact: info@wellmed.nl**Latest version:** 19-10-2021**Abbreviations and acronyms:**

ADR: Accord relative au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINICS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

DNEL: Derived No-Effect Level (REACH)

PNEC: Predicted No-Effect Concentration (REACH)

LC50: Lethal concentration, 50 percent

LD50: Lethal Dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Acute Tox. 3: Acute toxicity – category 3

Acute Tox. 2: Acute toxicity – category 2

Skin Corr. 1C: Skin corrosion/irritation – Category 1C

Eye Dam. 1: Serious eye damage/eye irritation – category 1

Skin Sens 1: Skin sensation – Category 1

Skin Sens 1A: Skin sensation – Category 1A

Aquatic Acute 1: Hazardous to the aquatic environment – acute aquatic hazard – Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment – long term aquatic hazard – Category 1

Aquatic Chronic 3: Hazardous to the aquatic environment – long term aquatic hazard – Category 3