

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**1.2 Relevant identified uses of the substance or mixture and uses advices 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.

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

Germany

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

Aquatic Chronic 2 H411

Skin Sens. 1 H317 May cause an allergic skin reaction

Classifications information

Classification and labelling with respect to skin sensitization and/or respiratory sensitization are based on toxicological studies performed on the product (mixture).

This product is assessed and classified using the methods and criteria below referred to in Article 9 of Regulation (EC) no 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)

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

Hazard pictograms



GHS07



GHS09

Signal word Warning

Hazard statements

H317 May cause an allergic skin reaction.

H411 Toxic to aquatic life with long lasting effects.

Precautionary statements

P273 Avoid release to the environment.

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

P391 collect spillage.

P501 Dispose of contents/container in accordance with regional/national regulations.

2.3 Other Hazards

Results of PBT and vPvB assesment

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 not a substance

3.2 Chemical characterization: Mixtures

Hazardous ingredients

Dangerous Components:			
CAS / EC / Index / REACH no	Classification (EC) 1272/2008 (CLP)	Concentration	%
CAS: 55965-84-9 - Index number: 613-167-00-5 -	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	0.025 - < 0.06	% - b.w.

Full text for all H-phrases and EUH-phrases: please see section 16

Note	Specific concentration limits	M-factor (acute)	M-factor (chronic)
B	Skin Sens. 1A; H317: C ≥ 0.0015% Eye Irrit. 2; H319: C ≥ 0.06% Skin Irrit. 2: H315: C ≥ 0.06% Skin Corr. 1C; H314: C ≥ 0.6% Eye Dam. 1; H318: C ≥ 0.6%	M = 100	M = 100

Full text for the notes: please 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

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 remove contaminated clothes.

Instantly wash with copious amounts of water.

In case of symptoms call a physician.

After eye contact

Rinse eyes cautiously with plenty of water.

Remove contact lenses if present and easy to do.

Continue rinsing.

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 call a physician.

4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available for this mixture

4.3 Indication of any immediate medical attention and special treatment needed**Information for doctor**

Show Safety Data Sheet.

Treatment according to symptoms.

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.

5.2 Special hazards arising from the substance or mixture

In case of combustion evolution of dangerous gases are possible

5.3 Advice for firefighters

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.

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, skin and clothing.

Advice for emergency responders:

Protective equipment: see section 8.

No further data available

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.

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.

Information about protection against explosives and fires:

No special measures required.

7.2 Conditions for safe storage, including any incompatibilities:

Technical measures and storage conditions

No special measures necessary

Recommended storage temperature:

Store at a temperature of 2 to 8 °C.

Requirements for storage rooms and vessels:

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

Incompatible products

Not necessary

7.3 Specific end use(s):

No data available.

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

No parameters available for monitoring.

8.2 Exposure controls**Appropriate engineering controls**

Na data available.

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.

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 > 30 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:	almost odourless
Odor threshold:	Not determined
pH value:	7.0 – 7.4
Reference temperature:	20 °C
Change in condition	
Melting point/freezing point:	appr. 0 °C
Initial boiling point and boiling range:	appr. 100 °C
Flash point:	Not applicable
Inflammability (solid, gaseous)	Not applicable
Ignition temperature:	Not applicable
Decomposition temperature:	Not determined
Self-inflammability:	Not self-inflammable
Explosive properties:	Not explosive
Critical values for explosion:	
Lower explosion limit:	Not determined
Upper explosion limit:	Not determined
Steam pressure:	Not determined
Density:	Not determined
Relative density:	Not determined
Vapor density:	Not determined
Vapor pressure:	23 hPa
Reference temperature	20°C
Evaporation rate:	Not determined
Solubility in /Miscibility with water:	Fully miscible
Partition coefficient: n-octanol/water:	No information available
Viscosity:	
Dynamic:	Not determined
Kinematic:	Not determined
Solvent content:	
Organic solvents:	≥0.05%
Water:	<99.95%
Solids content:	0%

9.2 Other information

Other information
No data available

SECTION 10: Stability and reactivity
10.1 Reactivity

No further relevant information available.

10.2 Chemical stability

The product is chemically stable under the indicated storage conditions.

Thermal decomposition / conditions to be avoided:

No decomposition if used and stored according to the specifications.

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.

Additional information:

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.

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

Serious eye damage/irritation:	
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	Sensitization possible
Route of exposure	Respiratory tract
Comments	No sensitizing effects are known

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 sensation through skin contact.

Other information:

After swallowing: Mucosal irritations in mouth, pharynx and oesophagus possible.

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 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 No further relevant information available.

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 Transport ADR/RID/AND

Class	9
Classification code	M6
Packing group	III
Hazard identification no.	90
UN number	UN3082
Proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
Technical name	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)
Tunnel restriction code	-
Label	9
Environmentally hazardous	Symbol "fish and tree"
Substance mark	


14.2 Transport IMDG

Class	9
Packing group	III
UN number	UN3082
Proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
Technical name	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)
Label	9
Marine pollutant mark	Symbol "fish and tree"


14.3 Transport ICAO-TI / IATA

Class	9
Packing group	III
UN number	UN3082
Proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.

Technical name 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)

Label 9

Enviromenmetally hazardous Symbol "fish and tree"

Substance mark



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

To be transported always in closed, upright and safe containers. Make sure that persons handling these containers are aware of the rules of conduct in case of incident or spillage.

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 authorization)

According to the data available and/or specifications supplied by upstream suppliers, this product does not contain any substances considered as substances requiring authorization 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 annex XVII

No 3

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

This product is subject to Part I of Annex I, risk category:

E2

Other regulations

Employment restrictions, according to 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

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.

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 mentioned in each case.

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

Relevant phrases in full text

EUH071	Corrosive to the respiratory tract.
H301	Toxic if swallowed.
H314	Causes severe skin burns and eye damage.
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:

Product Safety

Contact: info@wellmed.nl

First version: 09-07-2021
