

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

### 1.1 Product identifier:

**Trade name:** Diluent (BrightDiluent) detection System (Brightvision)

**Article number:** Diluents:  
BD09-xxx, UD09-xxx, RAD09-xxx, BAD09-XXX, YAD09-xxx

Detection systems:  
DPVBxxxHRP, c-DPVBxxxHRP, DPVBxxAP, c-DPVBxxxAP, DPVOxxxHRP,  
DPVOxxxAP, DPVOxxxHRPN, DPVMxxxHRP, DPVMxxxAP, DPVRxxxHRP,  
DPVRxxxAP, DPVO-mHRP-rAP, DPVO-rHRP-mAP, DPVBxxxHRP-CM,  
c-DPVBxxxHRP-CM, BxxxHRP-BGX, c-BxxxHRP-BGX, OxxxHRP-BGX

#### 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:

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.

Delta 52

6825 MS Arnhem

The Netherlands

Phone: +31 (0) 85 273 23 23

#### Informing department:

Product safety

[info@wellmed.nl](mailto: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

### 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:

2-methyl-2H-isothiazol-3-one

#### Hazard statements

H317 May cause an allergic skin reaction.

#### Precautionary statements

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

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P337+P313 If eye irritation persists: Get medical advice/attention.

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

#### Additional information: Restricted to professional users.

#### Labeling of packages where contents do not exceed 125 ml

#### Hazard pictograms



GHS07

**Signal word** Warning

#### Hazard-determining components of labelling:

2-methyl-2H-isothiazol-3-one

**Hazard statements**

H317 May cause an allergic skin reaction.

**Precautionary statements**

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

P303+P361+P353 IF ON SKIN (or hair): Immediately take off all contaminated clothing. Rinse skin with water.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Removes contact lenses, if present and easy to do. Continue rinsing.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P337+P313 If eye irritation persists: Get medical advice/attention.

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**
**3.2 Chemical characterization: Mixtures**
**Description:** In-vitro-Diagnostika

Dangerous Components:		
CAS: 2682-20-4 EINECS: 220-239-6 Index number: 613-326-00-9	2-Methyl-4-isothiazolin-3-one  Acute Tox. 3, H301; Acute Tox.3 , H311; Acute Tox.2, H330  Skinn Corr. 1B, H314; Eye Dam. 1, H318  Aquatic Acute 1, H400; Aquatic Chronic, H410  Skin Sens. 1A, H317	≥ 0,05 - ≤ 0,15 %

**Additional information** For the wording of the listed H-phrases please refer to Section 16

**SECTION 4: First aid measures**
**4.1 Description of first aid measures**
**General information First aider:** Take care of self-protection.

**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 water for several minutes.

Remove contact lenses if present and easy to do. Continue rinsing. Consult ophthalmologist.

**After swallowing**

Let rinse out mouth and then drink plenty of water.

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

**Information for doctor**

Show Safety Data Sheet

Treatment according to symptoms

**Danger** No further relevant information available.

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

No further relevant information available.

## SECTION 5: Firefighting measures

**5.1 Extinguishing media**

**Suitable extinguishing agents** Product itself does not burn. Use firefighting measures that suit the natural environment.

**For safety reasons unsuitable extinguishing agents** Water with full jet.

**5.2 Special hazards arising from the substance of mixture**

In the event of fire may develop:

Carbon monoxide (CO)

Carbon dioxide (CO<sub>2</sub>)

Hydrogen chloride (HCL)

Sulfur oxides

Ammonia

Nitrogen oxides (NO<sub>x</sub>)

Propionaldehyde

**5.3 Advice for firefighters**

**Protective equipment:**

In case of fire of large quantities:

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 contaminated fire fighting water separately. It must not enter drains.

Dispose of fire debris and contaminated fire fighting water in accordance with official 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. Avoid exposure to UV light as this can affect quality.

**Information about protection against explosives and fires:** No special measures required.

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

**Storage requirements to be met by storerooms and containers:**

Store only in the original container.

Store container tightly closed.

Store in a cool, dry, ventilated area.

Store at a temperature of 2 to 8 °C.

Avoid exposure to direct sunlight.

**Information about storage in one common storage facility:** Not required

**Further information about storage conditions:**

Store in a locked cabinet or area with access restricted to technical experts or their assistants.

**Storage class** Please see the respective 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****Components with critical values that require monitoring at the workplace:****DNELs** No further relevant information available.**PNECs** 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 priority 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 beverages.

**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**

<b>9.1 Information on basic physical and chemical properties</b>	
<b>General Information</b>	
<b>Appearance:</b>	
<b>Form:</b>	liquid
<b>Color:</b>	Colorless, clear Green (UD09-xxx), Yellow (YAD09-xxx), Red (RAD09-xxx), Blue (BAD09-xxx)
<b>Smell:</b>	odourless
<b>Odor threshold:</b>	Not determined
<b>pH value:</b>	>7.25 pH < 7.75
<b>Change in condition</b>	
<b>Melting point/freezing point:</b>	Not determined
<b>Initial boiling point and boiling range:</b>	Not determined
<b>Flash point:</b>	Not applicable
<b>Inflammability (solid, gaseous)</b>	Not applicable
<b>Ignition temperature:</b>	Not applicable
<b>Decomposition temperature:</b>	Not determined
<b>Self-inflammability:</b>	Not self-inflammable
<b>Explosive properties:</b>	Not explosive
<b>Critical values for explosion:</b>	
Lower explosion limit:	Not determined
Upper explosion limit:	Not determined
<b>Steam pressure:</b>	Not determined
<b>Density:</b>	Not determined
<b>Relative density:</b>	Not determined
<b>Vapor density:</b>	Not determined
<b>Evaporation rate:</b>	Not determined
<b>Solubility in /Miscibility with water:</b>	Fully miscible
<b>Partition coefficient: n-octanol/water:</b>	No information available
<b>Viscosity:</b>	
Dynamic:	Not determined
Kinematic:	Not determined
<b>Solvent content:</b>	
<b>Organic solvents:</b>	≥0.05%
<b>Water:</b>	<99.95%
<b>Solids content:</b>	0%
<b>9.2 Other information</b>	No further relevant information 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:** Warming
- 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 toxicity** Based on available data, the classification criteria are not met.
- Specific symptoms in biological essay:** No further relevant information available.
- Primary irritant effect:**
- Skin corrosion/irritation:** Based on available data, the classification criteria are not met.
- Serious eye damage/irritation:** Based on available data, the classification criteria are not met.
- After swallowing:** Mucosal irritations in mouth, pharynx and esophagus possible.
- After inhalation:** Irritations possible.
- Respiratory or skin sensitization:** May cause an allergic skin reaction.
- Other information (about experimental toxicology):** No further relevant information available.
- Subacute to chronic toxicity:** No further relevant information available
- Additional toxicological information:** No further relevant information available
- Toxicokinetic, metabolism and distribution:** No relevant information available
- Acute effects (acute toxicity, irritation and corrosivity):** No acute toxicity information available for this product.
- 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.
- Carcinogenicity:** Based on available data, the classification criteria are not met.
- Reproductive toxicity:** Based on available data, the classification criteria are not met.
- STOT-single exposure:** Based on available data, the classification criteria are not met.
- STOT-repeated exposure:** Based on available data, the classification criteria are not met.
- Aspiration hazard:** Based on available data, the classification criteria are not met.

## SECTION 12: Ecological information

### 12.1 Toxicity

**Aquatic toxicity:** No further relevant information available.

### 12.2 Persistence and degradability

No further relevant information available.

**Other information:** No further relevant information available

**Behaviour in environmental systems:**

**Components:** No further relevant information available.

### 12.3 Bioaccumulative potential

No further relevant information available.

### 12.4 Mobility in soil

No further relevant information available.

**Additional ecological information:**

**General notes:**

Water danger class 3 (Self-assessment): extremely hazardous for water.

Do not allow product to reach ground, water bodies or sewage system, even in small quantities.

Danger to drinking water if even extremely small quantities leak into soil.

### 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 Endocrine disrupting properties

Unknown

### 12.7 Other adverse effects

No further relevant information available.

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

Product residues have to be disposed of according to the Waste Framework Directive as well as national and regional regulations in each the latest versions.

**Uncleaned packaging's:**

**Recommendation:**

Disposal according to the respective national official regulations.

Packaging can be reused or recycled after cleaning.

**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, AND, IMDG, IATA Class	-
14.4 Packing group ADR, IMDG, 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 and in the form applicable in Germany (GGVSE). Possible national deviations in other countries are not considered.
UN "Model Regulation":	

**SECTION 15 Regulatory information**
**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
**Labelling 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

**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 or workers of childbearing age in the latest version.

Class	Share in %
I	0.2

**Water hazard class:** Water danger class 3 (Self-assessment): extremely hazardous for water.

**15.2 Chemical safety assessment:** Chemical safety assessment has not been carried out.

**SECTION 16 Other information**

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**

- 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.
- 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.

**Department issuing data specification sheet:** Product Safety

**Contact:** [info@wellmed.nl](mailto:info@wellmed.nl)

**Replaces version from:** 17.11.2020

**Reason for alteration:** General editorial revision

Commission Regulation (EU) 2020/878 L203/28-58

**Abbreviations and acronyms:**

ADR: Accord européen sur l'étransport de 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

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINECS: 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)

PBT: Persistent, Bioaccumulative and Toxic

Acute Tox. 3: Acute Toxicity - oral- Category 3

Acute Tox. 2: Acute Toxicity – inhalation – Category 2

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

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

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