

## Information about Compilation of Safety Data Sheets

**Product:** TMB 2-Component Micorwell Peroxidase Substrate Kit  
**Manufacturer:** LGC Clinical Diagnostics  
37 Birch Street, 01757 Milford MA, USA  
**Article numbers:** 5120-0047, 5120-0050, 5120-0053

All components of the aforementioned kit had been classified according to Regulation (EC) No. 1907/2006 (REACH) and to Regulation (EC) No. 1272/2008 (GHS/CLP).

For the kit component TMB Peroxidase Substrate (article number 50-76-01, 50-76-02), a Safety Data Sheet has been compiled (enclosure).

For the remaining kit component Peroxidase Substrate Solution B (article number 50-65-00, 50-65-02) no Safety Data Sheet is required after classifications according to the Regulation (EC) No. 1907/2006 (REACH) and the Regulation (EC) No. 1272/2008 (GHS/CLP).

When handling the kit components, the general and specific safety precautions for laboratories and the corresponding directives have to be followed.

Date of issue: June 2022

**medac**

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Attachment

**Safety data sheet  
according to 1907/2006/EC, Article 31**

Printing date 27.06.2022

Version number 3 (replaces version 2)

Revision: 27.06.2022

**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1 Product identifier****Trade name:** TMB Peroxidase Substrate**Article number:** 50-76-01, 50-76-02**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 UK 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:

RUO (Research Use Only).

Uses advised against:

For in vitro diagnosis.

**Sector of Use** SU24 Scientific research and development**Product category** PC21 Laboratory chemicals**Process category** PROC15 Use as laboratory reagent**Application of the substance / the mixture** Immunochemical reagent for detection / auxiliary reagent**1.3 Details of the supplier of the safety data sheet****Manufacturer/Distributor:**

Manufacturer:

SeraCare Life Sciences (KPL)

910 Clopper Road

Gaithersburgh, Maryland 20878, USA

Distributor:

medac GmbH

Theaterstrasse 6

22880 Wedel, Germany

phone: +49 4103 8006-0

**Informing department:**

Product Safety

productsafety@medac.de

**1.4 Emergency telephone number:**

GifTinformatiionszentrum-Nord, phone: +49 551 19 240 (service in German and English, 24 hours permanently accessible).

**SECTION 2: Hazards identification****2.1 Classification of the substance or mixture****Classification according to Regulation (EC) No 1272/2008**

The product is classified according to GB CLP regulation.

Eye Irrit. 2 H319 Causes serious eye irritation.

Repr. 1B H360D May damage the unborn child.

**2.2 Label elements****Labelling according to Regulation (EC) No 1272/2008**

The product is labelled according to Regulation (EC) No. 1272/2008 (GHS/GB CLP).

**Hazard pictograms**

GHS07 GHS08

**Signal word** Danger**Hazard statements**

H319 Causes serious eye irritation.

(Contd. on page 2)

GB

## Safety data sheet according to 1907/2006/EC, Article 31

Printing date 27.06.2022

Version number 3 (replaces version 2)

Revision: 27.06.2022

**Trade name: TMB Peroxidase Substrate**

(Contd. of page 1)

H360D May damage the unborn child.

**Precautionary statements**

P201 Obtain special instructions before use.

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

P308+P313 IF exposed or concerned: Get medical advice/attention.

P405 Store locked up.

**Additional information:**

Restricted to professional users.

Reduced labelling (&lt;125 ml):

**2.3 Other hazards**
**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

**3.2 Mixtures**
**3.1. Chemical characterisation: substances** Not applicable. Product is a mixture.

**Description:** Immunochemical reagent / auxiliary reagent

**Dangerous components:**

CAS: 68-12-2	N,N-dimethylformamide	25-30%
EINECS: 200-679-5	 Flam. Liq. 3, H226	
Index number: 616-001-00-X	 Repr. 1B, H360D	
RTECS: LQ 2100000	 Acute Tox. 4, H312; Acute Tox. 4, H332; Eye Irrit. 2, H319	
Reg.nr.: 01-2119475605-32-XXXX		

**SVHC**

68-12-2 | N,N-dimethylformamide

**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.

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.

Instantly consult ophthalmologist.

**After swallowing**

Wash out mouth with copious amounts of water.

Let drink water (2 glasses maximum).

In case of symptoms call a physician.

**Information for doctor** Show Safety Data Sheet.

**4.2 Most important symptoms and effects, both acute and delayed**

Gastric or intestinal trouble

Irritant effects.

(Contd. on page 3)

**Safety data sheet  
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Version number 3 (replaces version 2)

Revision: 27.06.2022

Trade name: TMB Peroxidase Substrate

(Contd. of page 2)

**4.3 Indication of any immediate medical attention and special treatment needed** Treatment according to symptoms.

## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

**Suitable extinguishing agents** CO<sub>2</sub>, foam or extinguishing powder.

**For safety reasons unsuitable extinguishing agents** For this mixture no limitations of extinguishing agents are given.

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

Formation of toxic gases is possible during heating or in case of fire.

In the event of fire may develop:

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

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

Carbon monoxide (CO)

### 5.3 Advice for firefighters

#### Protective equipment:

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

Prevent skin contact by keeping a safe distance or by wearing suitable protective clothing.

#### Additional information

Precipitate gases/fumes/mists with water spray jet.

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:

Avoid reagent contact with eyes and skin.

Provide sufficient ventilation.

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:

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

Afterwards clean with water and cleansing agent.

Dispose of contaminated material as waste according to Section 13.

### 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

Open and handle container with care.

**Information about protection against explosions and fires:** No danger of explosion.

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

Keep locked up or in an area accessible only to qualified or authorised persons.

#### Storage

**Requirements to be met by storerooms and containers:** Store at +2 °C to +8 °C.

**Information about storage in one common storage facility:** Store separately from strong oxidants and halogens.

**Further information about storage conditions:** No further relevant information available.

**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.

GB

(Contd. on page 4)

## Safety data sheet according to 1907/2006/EC, Article 31

Printing date 27.06.2022

Version number 3 (replaces version 2)

Revision: 27.06.2022

**Trade name: TMB Peroxidase Substrate**

(Contd. of page 3)

### SECTION 8: Exposure controls/personal protection

#### 8.1 Control parameters

**Components with critical values that require monitoring at the workplace:**
**68-12-2 N,N-dimethylformamide**

WEL	Short-term value: 61 mg/m <sup>3</sup> , 20 ppm
	Long-term value: 30 mg/m <sup>3</sup> , 10 ppm
	Sk

**DNELs** No further relevant information available.

**PNECs** No further relevant information available.

**CAS No. Designation of material % Type Value Unit**
**Additional Occupational Exposure Limit Values for possible hazards during processing:** Not applicable.

**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.

**Appropriate engineering controls** No further data; see Section 7.

**Individual protection measures, such as personal protective equipment**
**General protective and hygienic measures**

The usual precautionary measures should be adhered to 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 the work.

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

**Hand protection** Protective gloves (AQL 1.5).

**Material of gloves**

Nitrile rubber, NBR

Natural rubber, NR

Thickness 0.11 mm.

The product quality has to comply with DIN EN 455.

**Penetration time of glove material** Breakthrough time: > 120 min.

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

Product has not been designed for permanent contact.

**For the permanent contact 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.

Penetration time &gt; 120 min.

**Eye/face protection** Safety glasses (standard EN 166).

**Body protection:** Protective work clothing.

**Environmental exposure controls** 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**
**Colour:**

Colourless to slightly bluish.

(Contd. on page 5)

**Safety data sheet**  
**according to 1907/2006/EC, Article 31**

Printing date 27.06.2022

Version number 3 (replaces version 2)

Revision: 27.06.2022

**Trade name: TMB Peroxidase Substrate**

(Contd. of page 4)

<b>Smell:</b>	slightly amine-like
<b>Odour threshold:</b>	No information available.
<b>Melting point/freezing point:</b>	No information available.
<b>Flammability</b>	Not applicable.
<b>Lower and upper explosion limit</b>	
<b>Lower:</b>	Not applicable.
<b>Upper:</b>	Not applicable.
<b>Flash point:</b>	No information available.
<b>Ignition temperature:</b>	No information available.
<b>Decomposition temperature:</b>	No information available.
<b>pH</b>	No information available.
<b>Viscosity:</b>	
<b>Kinematic viscosity</b>	No information available.
<b>dynamic:</b>	No information available.
<b>Solubility</b>	
<b>Water:</b>	Fully miscible.
<b>Partition coefficient n-octanol/water (log value)</b>	<1 log POW
<b>Steam pressure:</b>	No information available.
<b>Density and/or relative density</b>	
<b>Density</b>	No information available.
<b>Relative density</b>	No information available.
<b>Vapour density</b>	No information available.

**9.2 Other information**

<b>Appearance:</b>	
<b>Form:</b>	liquid
<b>Important information on protection of health and environment, and on safety.</b>	No further relevant information available.
<b>Self-inflammability:</b>	Not self-inflammable.
<b>Explosive properties:</b>	Not explosive.
<b>Solvent content:</b>	
<b>Organic solvents:</b>	< 30 %
<b>Water:</b>	> 60 %
<b>Solids content:</b>	< 5 %
<b>Change in condition</b>	Not applicable.
<b>Softening point/range</b>	
<b>Oxidising properties</b>	No information available.
<b>Evaporation rate</b>	No information available.

**Information with regard to physical hazard classes**

<b>Explosives</b>	Void
<b>Flammable gases</b>	Void
<b>Aerosols</b>	Void
<b>Oxidising gases</b>	Void
<b>Gases under pressure</b>	Void
<b>Flammable liquids</b>	Void
<b>Flammable solids</b>	Void
<b>Self-reactive substances and mixtures</b>	Void
<b>Pyrophoric liquids</b>	Void
<b>Pyrophoric solids</b>	Void
<b>Self-heating substances and mixtures</b>	Void
<b>Substances and mixtures, which emit flammable gases in contact with water</b>	Void
<b>Oxidising liquids</b>	Void
<b>Oxidising solids</b>	Void
<b>Organic peroxides</b>	Void
<b>Corrosive to metals</b>	Void

(Contd. on page 6)

**Safety data sheet  
according to 1907/2006/EC, Article 31**

Printing date 27.06.2022

Version number 3 (replaces version 2)

Revision: 27.06.2022

Trade name: TMB Peroxidase Substrate

(Contd. of page 5)

Desensitised explosives

Void

**SECTION 10: Stability and reactivity****10.1 Reactivity** For this mixture no 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 according to specifications.

Conditions to be avoided:

Warming, light.

**10.3 Possibility of hazardous reactions** For these concentrations no relevant information available.**10.4 Conditions to avoid:** No further relevant information available.**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 hazard classes as defined in Regulation (EC) No 1272/2008****Acute toxicity** Based on available data, the classification criteria are not met.**LD/LC<sub>50</sub> values that are relevant for classification:****68-12-2 N,N-dimethylformamide**

Oral	LD50	2800 mg/kg (rat)
Dermal	LD50	1500 mg/kg (rabbit)
Inhalative	LC50/4 h	9-15 mg/l (rat)

**Specific symptoms in biological assay:** No further relevant information available.**Skin corrosion/irritation** Irritations possible.**Serious eye damage/irritation**

Causes serious eye irritation.

**after swallowing:** Mucosal irritations in mouth, pharynx and oesophagus possible.**after inhalation:** Irritations possible.**Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.**Germ cell mutagenicity** Based on available data, the classification criteria are not met.**Carcinogenicity** Based on available data, the classification criteria are not met.**Reproductive toxicity**

May damage the unborn child.

**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.**Other information (about experimental toxicology):** No further relevant information available.**Subacute to chronic toxicity:** Danger of cutaneous absorption.**Additional toxicological information:** No further relevant information available.**Toxicokinetics, metabolism and distribution** No relevant information available.**Acute effects (acute toxicity, irritation and corrosivity)** No acute toxicity information available for this product.**Sensitisation** No sensitising effect known.**Repeated dose toxicity** Hepatopathy.**11.2 Information on other hazards****Endocrine disrupting properties**

None of the ingredients is listed.

GB

(Contd. on page 7)

**Safety data sheet**  
**according to 1907/2006/EC, Article 31**

Printing date 27.06.2022

Version number 3 (replaces version 2)

Revision: 27.06.2022

Trade name: TMB Peroxidase Substrate

(Contd. of page 6)

## 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:** Accumulation in organisms is not to be expected.

### 12.3 Bioaccumulative potential

log Pow <1

Bioaccumulation is not to be expected.

**12.4 Mobility in soil** High mobility (source: ECHA).

### 12.5 Results of PBT and vPvB assessment

**PBT:** PBT assessment not available as chemical safety assessment not required/not conducted.

**vPvB:** vPvB assessment not available as chemical safety assessment not required/not conducted.

**12.6 Endocrine disrupting properties** For information on endocrine disrupting properties see section 11.

### 12.7 Other adverse effects

**Remark:**

Toxicity to fish:

LC<sub>50</sub>: Lepomis macrochirus: 6300 mg/l / 96h.

LC<sub>50</sub>: Onchorhynchus mykiss: 9800 mg/l / 96h.

LC<sub>50</sub>: Plimephales promelas: 10600 mg/l / 96h.

Toxicity to daphnia:

LC<sub>50</sub>: Daphnia magna: 15700 mg/l / 48h.

Toxicity to algae:

LC<sub>50</sub>: Desmodesmus subspicatus IC50 > 500 mg/l / 96h.

**Additional ecological information:**

**General notes:** Water hazard class 1 (Self-assessment): slightly hazardous for water.

## 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 packagings:**

**Recommendation:** Uncleaned packagings have to be disposed of in the same manner as the product residues.

## SECTION 14: Transport information

### 14.1 UN number or ID number

ADR, ADN, IMDG, IATA not regulated

### 14.2 UN proper shipping name

ADR, ADN, IMDG, IATA not regulated

### 14.3 Transport hazard class(es)

ADR, ADN, IMDG, IATA

Class not regulated

### 14.4 Packing group

ADR, IMDG, IATA not regulated

### 14.5 Environmental hazards:

Marine pollutant: No

(Contd. on page 8)

**Safety data sheet  
according to 1907/2006/EC, Article 31**

Printing date 27.06.2022

Version number 3 (replaces version 2)

Revision: 27.06.2022

**Trade name: TMB Peroxidase Substrate**

(Contd. of page 7)

<b>14.6 Special precautions for user</b>	Not applicable.
<b>14.7 Maritime transport in bulk according to IMO instruments</b>	Not applicable.
<b>Transport/Additional information:</b>	Not classified as dangerous in the meaning of transport regulations as issued in the latest version.
<b>UN "Model Regulation":</b>	not regulated

## 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

**Hazard pictograms** See Section 2.**Signal word** See Section 2.**Hazard-determining components of labelling:** See Section 2.**Hazard statements** See Section 2.**Precautionary statements** See Section 2.**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.

**Decree to be applied in case of technical fault:**

Class	Share in %
NK	26.0

**Water hazard class:** Water hazard class 1 (Self-assessment): slightly hazardous for water.**Other regulations, limitations and prohibitive regulations** Void.**15.2 Chemical safety assessment:** A 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 of this 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. medac GmbH shall not be held liable for any damage resulting from handling or from contact with the above product.

**Relevant phrases**

H226 Flammable liquid and vapour.

H312 Harmful in contact with skin.

H319 Causes serious eye irritation.

H332 Harmful if inhaled.

H360D May damage the unborn child.

**Department issuing data specification sheet:** Product Safety**Contact:** productsafety@medac.de**Replaces version from:** 02.11.2017**Reason for alteration:** General editorial revision.**Abbreviations and acronyms:**

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

ICAO: International Civil Aviation Organisation

ADR: Accord relatif 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

(Contd. on page 9)

GB

**Safety data sheet  
according to 1907/2006/EC, Article 31**

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Version number 3 (replaces version 2)

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**Trade name: TMB Peroxidase Substrate**

(Contd. of page 8)

GHS: Globally Harmonised System of Classification and Labelling of Chemicals  
EINECS: European Inventory of Existing Commercial Chemical Substances  
ELINCS: European List of Notified Chemical Substances  
CAS: Chemical Abstracts Service (division of the American Chemical Society)  
DNEL: Derived No-Effect Level (UK REACH)  
PNEC: Predicted No-Effect Concentration (UK REACH)  
LC50: Lethal concentration, 50 percent  
LD50: Lethal dose, 50 percent  
PBT: Persistent, Bioaccumulative and Toxic  
vPvB: very Persistent and very Bioaccumulative  
Flam. Liq. 3: Flammable liquids – Category 3  
Acute Tox. 4: Acute toxicity – Category 4  
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2  
Repr. 1B: Reproductive toxicity – Category 1B

**\* Data compared to the previous version altered.**

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