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Information about Compilation of Safety Data Sheets

Product: TMB 2-Component Microwell Peroxidase Substrate Kit
Company: SeraCare Life Sciences
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 numbers 50-76-01, 50-76-02), a Safety Data Sheet had been compiled (enclosure).
For the other kit component Peroxidase Substrate Solution B (article numbers 50-65-00, 50-65-02), no Safety Data Sheet is required after classification 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: November 2017

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

Printing date 02.11.2017 Version number 2 Revision: 02.11.2017

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 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:

Giftinformationszentrum-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 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/CLP).

Hazard pictograms



GHS07 GHS08

Signal word Danger

Hazard-determining components of labelling:
N,N-dimethylformamide

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Hazard statements
H319 Causes serious eye irritation.
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 (<125 ml):
Labelling of packages where the contents do not exceed 125 ml
Hazard pictograms



GHS07 GHS08

Signal word Danger

Hazard-determining components of labelling:
N,N-dimethylformamide
Hazard statements
H360D May damage the unborn child.
Precautionary statements
P201 Obtain special instructions before use.
P308+P313 IF exposed or concerned: Get medical advice/attention.
P405 Store locked up.

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

3.1. Chemical characterisatiion: substances Not applicable. Product is a mixture.

3.2 Chemical characterisation: Mixtures
Description: Immunochemical reagent / auxiliary reagent

Dangerous components:

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

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.

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In case of symptoms call a physician.
After skin contact
Instantly remove contaminated clothes.
Wash with cupious 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 cupious amounts of water.
Let drink water (2 glasses maximum).
In case of symptoms call a physician.

4.2 Most important symptoms and effects, both acute and delayed
Gastric or intestinal trouble
Irritant effects.
Information for doctor Show Safety Data Sheet.

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_2, 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 (NOx)
Carbon dioxide (CO_2)
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.

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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 stong 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.

SECTION 8: Exposure controls/personal protection

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

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/m³, 20 ppm Long-term value: 30 mg/m³, 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.
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.
Protection of hands: 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.

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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 > 120 min.
Eye protection: Safety glasses (standard EN 166).
Body protection: Protective work clothing.
Limitation and supervision of exposure into the 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
Colour:	Colourless to slightly bluish.
Smell:	slightly amine-like
Odour threshold:	No information available.
Important information on protection of health and environment, and on safety.	No further relevant information available.
pH-value:	No information available.
Change in condition	Not applicable.
Melting point/freezing point:	No information available.
Flash point:	No informarion available.
Inflammability (solid, gaseous)	Not applicable.
Ignition temperature:	No information available.
Decomposition temperature:	No information available.
Self-inflammability:	Not self-inflammable.
Explosive properties:	Not explosive.
Critical values for explosion:	
Lower:	Not applicable.
Upper:	Not applicable.
Oxidising properties	No information available.
Steam pressure:	No information available.
Density	No information available.
Relative density	No information available.
Vapour density	No information available.
Evaporation rate	No information available.
Solubility in / Miscibility with	
Water:	Fully miscible.
Partition coefficient: n-octanol/water:	<1 log POW
Viscosity:	
dynamic:	No information available.
kinematic:	No information available.
Solvent content:	
Organic solvents:	< 30 %
Water:	> 60 %
Solids content:	< 5 %
9.2 Other information	No further relevant information available.

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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.
Thernak 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 burning of larger amounts: 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.

LD/LC50 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.
Primary irritant effect:
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.
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.
CMR effects (carcinogenity, 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
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.

SECTION 12: Ecological information

12.1 Toxicity
Aquatic toxicity: No further relevant information available.

12.2 Persistence and degradability No further relevant information available.

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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 Hogh mobility (source: ECHA).
Ecotoxical effects:
Remark:
Toxicity to fish:
LC_{50}: Lepomis macrochirus: 6300 mg/l / 96h.
LC_{50}: Onchorhynchus mykiss: 9800 mg/l / 96h.
LC_{50}: Plimephales promelas: 10600 mg/l / 96h.
Toxicity to daphnia:
LC_{50}: Daphnia magna: 15700 mg/l / 48h.
Toxicity to algae:
LC_{50}: Desmodesmus subspicatus IC50 > 500 mg/l / 96h.
Additional ecological information:
General notes: Void.

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 Other adverse effects No relevant information available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods
Product residues have to 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 **ADR, ADN, IMDG, IATA**	-
14.2 UN proper shipping name **ADR, ADN, IMDG, IATA**	-
14.3 Transport hazard class(es) **ADR, ADN, IMDG, IATA** **Class**	-
14.4 Packing group **ADR, IMDG, IATA**	-
14.5 Environmental hazards: **Marine pollutant:**	No
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:	Not classified as dangerous in the meaning of transport regulations as issued in the latest version.

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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
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.
REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3, 9d, 30

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.

Class	Share in %
NK	26.0

Water hazard class: Void.

Other regulations, limitations and prohibitive regulations Void.
Substances of very high concern (SVHC) according to REACH, Article 57
68-12-2 N,N'-dimethylformamide

68-12-2	N,N-dimethylformamide

15.2 Chemical safety assessment: A chemical safety assessment has not been carried out.

SECTION 16: Other information

All information and recommodations 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 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: 08.12.2015
Reason for alteration:
Change of contact address.
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 européen sur le transport 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
EINECS: European Inventory of Existing Commercial Chemical Substances

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ELINCS: 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
SVHC: Substances of Very High Concern
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