

Information about Compilation of Safety Data Sheets

Product: ABTS® 2-Component Microwell Peroxidase Substrate Kit
Manufacturer: LGC Clinical Diagnostics Inc.
910 Copper Road, Gaithersburgh
Maryland 20878, USA
Article number: 5120-0032

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 ABTS Peroxidase Substrate Solution A (article number 50-64-00), a Safety Data Sheet has been compiled (enclosure).

For the remaining kit component Peroxidase Substrate Solution B (article number 50-65-00), 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: April 2022

medac

Product Safety
Health, Safety & Environment (HSE)
Phone: +49 4103 8006-0
Fax: +49 4103 8006-100
E-mail: productsafety@medac.de

Theaterstrasse 6
22880 Wedel
Germany

Attachment

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

Printing date 26.04.2022

Version number 3 (replaces version 2)

Revision: 25.04.2022

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier****Trade name:** ABTS Microwell Peroxidase 2-Component Substrate Solution A for article 5120-0032, 5120-0033**Article number:** 50-64-00, 50-64-02**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:

LGC Clinical Diagnostics Inc.

910 Clopper Road

Gaithersburgh, Maryland 20878, USA

Distributor:

medac GmbH

Theaterstrasse 6

22880 Wedel, Deutschland

Tel.: +49 (0)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**

According to Regulation (EC) No. 1272/2008 the mixture is classified as non-hazardous.

Void

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

Product is not subject to labelling according to Regulation (EC) No. 1272/2008 (GHS/GB CLP).

Hazard pictograms Void**Signal word** Void**Hazard statements** Void**Additional information:**

Safety data sheet available on request.

2.3 Other hazards Void.**Results of PBT and vPvB assessment****PBT:** Not applicable.

(Contd. on page 2)

GB

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Version number 3 (replaces version 2)

Revision: 25.04.2022

Trade name: ABTS Microwell Peroxidase 2-Component Substrate Solution A for article 5120-0032, 5120-0033

vPvB: Not applicable.

(Contd. of page 1)

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: 77-92-9	citric acid	Eye Irrit. 2, H319	≥0.1-<1%
EINECS: 201-069-1			
RTECS: GE 7350000			

SVHC Not applicable.

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.

Seek medical treatment in case of complaints.

After skin contact

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.

In case of onset of symptoms consult ophthalmologist.

After swallowing

Let rinse out mouth and then drink plenty of water.

In case of disorders consult doctor.

Information for doctor

Show Safety Data Sheet.

Treatment according to symptoms.

4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.

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 fire fighting measures that suit the environment.

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 No further relevant information available.

5.3 Advice for firefighters

Protective equipment:

In case of fire of large quantities:

Stay in the 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.

(Contd. on page 3)

GB

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Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

(Contd. of page 2)

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Advice for non-emergency personnel:

Avoid contact with skin and eyes.

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 No special precautions necessary if handled correctly.

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

7.2 Conditions for safe storage, including any incompatibilities No further relevant information available.

Storage

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

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

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

Storage class 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: Not applicable.

DNELs Not applicable.

PNECs Not applicable.

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: Not required.

(Contd. on page 4)

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

Printing date 26.04.2022

Version number 3 (replaces version 2)

Revision: 25.04.2022

Trade name: ABTS Microwell Peroxidase 2-Component Substrate Solution A for article 5120-0032, 5120-0033

(Contd. of page 3)

Hand protection Disposable medical 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 Not applicable.

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.

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
Smell:	No information available.
Odour threshold:	No information available.
Melting point/freezing point:	No information available.
Boiling point or initial boiling point and boiling range	100 °C
Flammability	Not applicable.
Lower and upper explosion limit	
Lower:	Not applicable.
Upper:	Not applicable.
Flash point:	Not applicable.
Ignition temperature:	Not applicable.
Decomposition temperature:	No information available.
pH	No information available.
Viscosity:	
Kinematic viscosity	No information available.
dynamic:	No information available.
Solubility	
Water:	Fully miscible.
Partition coefficient n-octanol/water (log value)	No information available.
Steam pressure:	No information available.
Density and/or relative density	
Density	No information available.
Relative density	No information available.
Vapour density	No information available.

9.2 Other information

Appearance:	No further relevant information available.
Form:	liquid
Important information on protection of health and environment, and on safety.	No further relevant information available.
Self-inflammability:	Not self-inflammable.

(Contd. on page 5)

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

Printing date 26.04.2022

Version number 3 (replaces version 2)

Revision: 25.04.2022

Trade name: ABTS Microwell Peroxidase 2-Component Substrate Solution A for article 5120-0032, 5120-0033

(Contd. of page 4)

Explosive properties:	Not explosive.
Solvent content:	
Organic solvents:	0.0 %
Water:	90.0 %
Solids content:	0.1 %
Change in condition	
Softening point/range	
Oxidising properties	Not applicable.
Evaporation rate	No information available.

Information with regard to physical hazard classes

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

SECTION 10: Stability and reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical stability Product is under normal ambient conditions (room temperature) chemically stable.
Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.

10.3 Possibility of hazardous reactions No dangerous reactions known.

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:

For this/these concentration/s no dangerous products of decomposition are known.

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/LC₅₀ values that are relevant for classification: Quantitative data about toxicity of this product are not available.

Specific symptoms in biological assay: No further relevant information available.

Skin corrosion/irritation Slight irritations possible.

Serious eye damage/irritation Slight irritations possible.

after swallowing: Slight mucosal irritations in mouth, pharynx and oesophagus possible.

after inhalation: Slight 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.

(Contd. on page 6)

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

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Trade name: ABTS Microwell Peroxidase 2-Component Substrate Solution A for article 5120-0032, 5120-0033

(Contd. of page 5)

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.
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.
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 No further relevant information available.
CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction) No relevant information available.

11.2 Information on other hazards

Endocrine disrupting properties

None of the ingredients is listed.

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 Bioaccumulation is not to be expected.

12.4 Mobility in soil Mobility in soil due to the liquid status.

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 For information on endocrine disrupting properties see section 11.

12.7 Other adverse effects No relevant information available.

Additional ecological information:

General notes:

At present there are no ecotoxicological assessments.

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 not regulated

(Contd. on page 7)

**Safety data sheet
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Trade name: ABTS Microwell Peroxidase 2-Component Substrate Solution A for article 5120-0032, 5120-0033

(Contd. of page 6)

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
14.6 Special precautions for user	Not applicable.
14.7 Maritime transport in bulk according to IMO instruments	Not applicable.
Transport/Additional information:	Not classified as dangerous in the meaning of transport regulations as issued in the latest version. 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":	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 See Section 2.

Directive 2012/18/EU

Named dangerous substances - ANNEX I Contains none of the listed substances.

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.

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

Other regulations, limitations and prohibitive regulations Void.

Substances of very high concern (SVHC) according to REACH, Article 57 Not applicable.

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

H319 Causes serious eye irritation.

Department issuing data specification sheet: Product Safety

Contact: productsafety@medac.de

Replaces version from: 21.07.2017

Reason for alteration:

Change of manufacturer's address and of article number(s).

General editorial revision.

(Contd. on page 8)

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

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Trade name: ABTS Microwell Peroxidase 2-Component Substrate Solution A for article 5120-0032, 5120-0033

(Contd. of page 7)

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

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

SVHC: Substances of Very High Concern

vPvB: very Persistent and very Bioaccumulative

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

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

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