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

1.1 Product identifier

Trade name : Combur4 Test N

Product code : 11896822191

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Substance/Mixture : Laboratory chemicals, Refer to product literature for further details.

1.3 Details of the supplier of the safety data sheet

Company : Roche Diagnostics Deutschland GmbH
Sandhoferstrasse 116
68305 Mannheim
Deutschland

Telephone : +496217590
Telefax : +496217592890
Responsible Department : +49(0)621-759-4223
E-mail address : info.dia-sds@roche.com

1.4 Emergency telephone number

Im Notfall:	:	Werkschutzzentrale Roche Diagnostics GmbH	+49(0)621-759-2203
Giftnotruf:	:	Mainz	+49(0)6131-19240

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required

Additional Labelling

EUH210 Safety data sheet available on request.

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
cristobalite	14464-46-1 238-455-4	Acute Tox. 4; H332 Carc. 2; H351 Acute toxicity estimate Acute inhalation toxicity (dust/mist): 1,5 mg/l	>= 0,1 - < 1,0
Oxidase, glucose	9001-37-0 232-601-0	Resp. Sens. 1; H334 Skin Sens. 1; H317	< 0,1
Peroxidase	9003-99-0 232-668-6	Resp. Sens. 1; H334 Skin Sens. 1; H317	< 0,1
Substances with a workplace exposure limit :			
Polyethylene terephthalate	25038-59-9	Not classified	>= 1,0 - < 10,0

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice : Move out of dangerous area.
Show this safety data sheet to the doctor in attendance.
Do not leave the victim unattended.

If inhaled : Move to fresh air.
If unconscious, place in recovery position and seek medical advice.
If symptoms persist, call a physician.

In case of skin contact	:	If on skin, rinse well with water.
In case of eye contact	:	Immediately flush eye(s) with plenty of water. Remove contact lenses. Protect unharmed eye. Keep eye wide open while rinsing. If eye irritation persists, consult a specialist.
If swallowed	:	Keep respiratory tract clear. Do not give milk or alcoholic beverages. Never give anything by mouth to an unconscious person. If symptoms persist, call a physician. Take victim immediately to hospital. Rinse mouth with water.

4.2 Most important symptoms and effects, both acute and delayed

None known.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment	:	The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Unsuitable extinguishing media	:	High volume water jet

5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting	:	No information available.
Hazardous combustion products	:	Carbon oxides

5.3 Advice for firefighters

Special protective equipment for firefighters	:	Wear self-contained breathing apparatus for firefighting if necessary.
Further information	:	Standard procedure for chemical fires. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions	:	Use personal protective equipment. Avoid dust formation. Avoid breathing dust.

6.2 Environmental precautions

Environmental precautions	:	Prevent product from entering drains. Prevent further leakage or spillage if safe to do so.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up	:	Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

Treat recovered material as described in the section "Disposal considerations".

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling	:	Avoid formation of respirable particles. Do not breathe vapours/dust. Avoid exposure - obtain special instructions before use. Avoid contact with skin and eyes. For personal protection see section 8. Smoking, eating and drinking should be prohibited in the application area. Dispose of rinse water in accordance with local and national regulations.
Advice on protection against fire and explosion	:	Avoid dust formation. Provide appropriate exhaust ventilation at places where dust is formed.
Hygiene measures	:	When using do not eat or drink. When using do not smoke. Wash hands before breaks and at the end of workday.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers	:	Keep container tightly closed in a dry and well-ventilated place. Observe label precautions. Electrical installations / working materials must comply with the technological safety standards.
Further information on storage conditions	:	See label, package insert or internal guidelines
Storage class (TRGS 510)	:	11
Further information on storage stability	:	No decomposition if stored and applied as directed.

7.3 Specific end use(s)

Specific use(s)	:	Laboratory chemicals

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Polyethylene terephthalate	25038-59-9	AGW (Inhalable fraction)	10 mg/m3	DE TRGS 900
	Peak-limit: excursion factor (category): 2;(II)			
	Further information: When there is compliance with the OEL and biological tolerance values, there is no risk of harming the unborn child			
		AGW (Alveolate fraction)	1,25 mg/m3	DE TRGS 900
	Peak-limit: excursion factor (category): 2;(II)			
	Further information: When there is compliance with the OEL and biological tolerance values, there is no risk of harming the unborn child			
		BM (Alveolar dust fraction)	0,5 mg/m3	DE TRGS 527
cristobalite	14464-46-1	TWA (Respirable dust)	0,1 mg/m3	2004/37/EC
	Further information: Carcinogens or mutagens			
Oxidase, glucose	9001-37-0	IOEL	0,00006 mg/m3	Roche Industrial Hygiene Committee (RIHC)
Peroxidase	9003-99-0	IOEL	0,00006 mg/m3	Roche Industrial Hygiene Committee (RIHC)

8.2 Exposure controls

Engineering measures

No data available

Personal protective equipment

Eye/face protection : Eye wash bottle with pure water
Tightly fitting safety goggles

Hand protection

In case of contact through splashing:

Material	:	Nitrile rubber
Break through time	:	> 30 min
Glove thickness	:	> 0,11 mm

In case of full contact:

Material	:	butyl-rubber
Break through time	:	> 480 min
Glove thickness	:	> 0,4 mm

Remarks : The selected protective gloves have to satisfy the specifications of Regulation (EU) 2016/425 and the standard EN 374 derived from it. This recommendation is only valid for the product mentioned in the safety data sheet and provided by

us and for the application specified by us. Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion, and the contact time. The suitability for a specific workplace should be discussed with the producers of the protective gloves.

Skin and body protection : Choose body protection according to the amount and concentration of the dangerous substance at the work place.

Respiratory protection : In the case of dust or aerosol formation use respirator with an approved filter.
Effective dust mask

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	:	solid
Colour	:	No data available
Odour	:	odourless
Odour Threshold	:	Not applicable
Melting point/range	:	No data available
Boiling point/boiling range	:	No data available
Flammability	:	Sustains combustion
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Flash point	:	does not flash
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
pH	:	Not applicable
Viscosity		
Viscosity, dynamic	:	Not applicable
Viscosity, kinematic	:	Not applicable
Solubility(ies)		
Water solubility	:	insoluble

Solubility in other solvents	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Vapour pressure	:	No data available
Relative density	:	No data available
Relative vapour density	:	Not applicable
Particle characteristics		
Particle Size Distribution	:	No data available

9.2 Other information

Explosives	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Flammability (liquids)	:	Sustains combustion
Self-ignition	:	No data available
Evaporation rate	:	No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

No dangerous reaction known under conditions of normal use.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : No decomposition if stored and applied as directed.

10.4 Conditions to avoid

Conditions to avoid : No data available

10.5 Incompatible materials

Materials to avoid : No data available

10.6 Hazardous decomposition products

No decomposition if stored and applied as directed.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity

Not classified due to lack of data.

Components:

cristobalite:

Acute inhalation toxicity : Acute toxicity estimate: 1,5 mg/l
Test atmosphere: dust/mist
Method: Expert judgement

Skin corrosion/irritation

Not classified due to lack of data.

Components:

cristobalite:

Remarks : This information is not available.

Peroxidase:

Remarks : May cause skin irritation and/or dermatitis.

Serious eye damage/eye irritation

Not classified due to lack of data.

Components:

cristobalite:

Remarks : This information is not available.

Peroxidase:

Remarks : Product dust may be irritating to eyes, skin and respiratory system.

Respiratory or skin sensitisation

Skin sensitisation

Not classified due to lack of data.

Respiratory sensitisation

Not classified due to lack of data.

Components:

Oxidase, glucose:

Assessment : May cause sensitisation by inhalation.

Assessment : May cause sensitisation by skin contact.

Peroxidase:

Assessment : May cause sensitisation by skin contact.

Assessment : May cause sensitisation by inhalation.

Germ cell mutagenicity

Not classified due to lack of data.

Carcinogenicity

Not classified due to lack of data.

Components:

cristobalite:

Carcinogenicity - Assessment : Limited evidence of a carcinogenic effect.

Oxidase, glucose:

Remarks : No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Polyethylene terephthalate:

Remarks : No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Reproductive toxicity

Not classified due to lack of data.

STOT - single exposure

Not classified due to lack of data.

Components:

cristobalite:

Assessment : The substance or mixture is not classified as specific target organ toxicant, single exposure.

Oxidase, glucose:

Assessment : The substance or mixture is not classified as specific target organ toxicant, single exposure.

STOT - repeated exposure

Not classified due to lack of data.

Components:

cristobalite:

Assessment : The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Oxidase, glucose:

Assessment : The substance or mixture is not classified as specific target

organ toxicant, repeated exposure.

Aspiration toxicity

Not classified due to lack of data.

Components:

cristobalite:

No data available

Oxidase, glucose:

No data available

11.2 Information on other hazards

Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 12: Ecological information

12.1 Toxicity

Components:

cristobalite:

Ecotoxicology Assessment

Acute aquatic toxicity : This product has no known ecotoxicological effects.

Chronic aquatic toxicity : This product has no known ecotoxicological effects.

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to the environment : No data available

Oxidase, glucose:

Ecotoxicology Assessment

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to the environment : No data available

Peroxidase:

Ecotoxicology Assessment

Acute aquatic toxicity	:	This product has no known ecotoxicological effects.
Chronic aquatic toxicity	:	This product has no known ecotoxicological effects.
Toxicity Data on Soil	:	Not expected to adsorb on soil.
Other organisms relevant to the environment	:	No data available

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

Components:

cristobalite:

Partition coefficient: n-octanol/water	:	Remarks: No data available

Oxidase, glucose:

Partition coefficient: n-octanol/water	:	Remarks: No data available

Peroxidase:

Partition coefficient: n-octanol/water	:	Remarks: No data available

Polyethylene terephthalate:

Partition coefficient: n-octanol/water	:	Remarks: No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Product:

Assessment	:	This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Product:

Assessment	:	The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at

levels of 0.1% or higher.

12.7 Other adverse effects

Components:

cristobalite:

Additional ecological information : No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Do not contaminate ponds, waterways or ditches with chemical or used container.
Send to a licensed waste management company.

Contaminated packaging : Empty remaining contents.
Dispose of as unused product.
Empty containers should be taken to an approved waste handling site for recycling or disposal.
Do not re-use empty containers.

SECTION 14: Transport information

14.1 UN number or ID number

ADR : Not regulated as a dangerous good

RID : Not regulated as a dangerous good

IMDG : Not regulated as a dangerous good

IATA : Not regulated as a dangerous good

14.2 UN proper shipping name

ADR : Not regulated as a dangerous good

RID : Not regulated as a dangerous good

IMDG : Not regulated as a dangerous good

IATA : Not regulated as a dangerous good

14.3 Transport hazard class(es)

ADR : Not regulated as a dangerous good

RID : Not regulated as a dangerous good

IMDG : Not regulated as a dangerous good

IATA : Not regulated as a dangerous good

14.4 Packing group

ADR : Not regulated as a dangerous good

RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
IATA (Cargo)	:	Not regulated as a dangerous good
IATA (Passenger)	:	Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Remarks	:	Not dangerous goods in the meaning of ADR/RID, ADN, IMDG-Code, ICAO/IATA-DGR

14.7 Maritime transport in bulk according to IMO instruments

Remarks	:	Not applicable

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)	:	Conditions of restriction for the following entries should be considered: Number on list 75 If you intend to use this product as tattoo ink, please contact your vendor. 3,3',5,5'-tetramethylbenzidine (Number on list 9d)
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).	:	Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer	:	Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast)	:	Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals	:	Not applicable
REACH - List of substances subject to authorisation (Annex XIV)	:	Not applicable
Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving	:	Not applicable

dangerous substances.

Water hazard class (Germany)	:	WGK 2 obviously hazardous to water Classification according to AwSV, Annex 1 (5.2)
TA Luft List (Germany)	:	5.2.1: Total dust: 5.2.2: Inorganic substances in powdered form: Not applicable 5.2.4: Inorganic substances in gaseous form: Not applicable 5.2.5: Organic Substances: Class 1: 1,99 % Polyethylene terephthalate, Citric acid monohydrate, (+)-tartaric acid, Oxidase, glucose, Peroxidase 5.2.7.1.1: Carcinogenic substance: Not applicable 5.2.7.1.1: Quartz fine dust PM4: others: 0,19 % cristobalite, Quartz (SiO2) 5.2.7.1.1: Formaldehyde: Not applicable 5.2.7.1.1: fibres: Not applicable 5.2.7.2: Poorly degradable, easily enrichable and highly toxic organic substances: Not applicable
Volatile organic compounds	:	Directive 2010/75/EU of 24 November 2010 on industrial emissions (integrated pollution prevention and control) Volatile organic compounds (VOC) content: 0,58 %

The components of this product are reported in the following inventories:

AIIC	:	Not in compliance with the inventory
DSL	:	This product contains the following components that are not on the Canadian DSL nor NDSL. non hazardous compounds Propiophan 1,2,3,4-tetrahydrobenzo[h]quinolin-3-ol 1-p-tolylsemicarbazide 4,4'-(4,5,6,7-tetrabromo-3H-2,1-benzoxathiol-3-ylidene)bis[2,6-dichlorophenol] S,S-dioxide Tri-lithium citrate-4-hydrate lithium iodate disodium 5,7-dinitro-8-oxidonaphthalene-2-sulphonate Peroxidase
NZIoC	:	Not in compliance with the inventory
ENCS	:	Not in compliance with the inventory
ISHL	:	Not in compliance with the inventory
KECI	:	Not in compliance with the inventory

PICCS	:	Not in compliance with the inventory
IECSC	:	Not in compliance with the inventory
TCSI	:	Not in compliance with the inventory
TSCA	:	Product contains substance(s) not listed on TSCA inventory.
TECI	:	Not in compliance with the inventory

15.2 Chemical safety assessment

Chemical Safety Assessments for all substances in this product are either Complete or Not applicable.

SECTION 16: Other information

Full text of H-Statements

H317	:	May cause an allergic skin reaction.
H332	:	Harmful if inhaled.
H334	:	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H351	:	Suspected of causing cancer.

Full text of other abbreviations

Acute Tox.	:	Acute toxicity
Carc.	:	Carcinogenicity
Resp. Sens.	:	Respiratory sensitisation
Skin Sens.	:	Skin sensitisation
2004/37/EC	:	Europe. Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work
DE TRGS 527	:	Germany. TRGS 527 - Activities with nanomaterials
DE TRGS 900	:	Germany. TRGS 900 - Occupational exposure limit values.
2004/37/EC / TWA	:	Long term exposure limit
DE TRGS 527 / BM	:	Assessment scale
DE TRGS 900 / AGW	:	Time Weighted Average

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test popula-

tion; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

DE / EN / 2304