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

### 1.1 Product identifier

Trade name : Control-Test M

Product code : 11379194263

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

Recommended restrictions on use : For further information, refer to the product technical data sheet.

### 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

| | | | |
|---|---|---|---|
| In case of emergencies: | : | Central Works Security<br>Roche Diagnostics GmbH | +49(0)621-759-2203 |
| Centre for detoxification: | : | 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

### 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**
For explanation of abbreviations see section 16.
Remarks : No hazardous ingredients

## SECTION 4: First aid measures

### 4.1 Description of first aid measures

General advice : 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.
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.
Rinse mouth with water.

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

Symptoms : No information available.

### 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.

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

Specific hazards during firefighting : No information available.

Hazardous combustion products : No hazardous combustion products are known

### 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 : Avoid dust formation.

### 6.2 Environmental precautions

Environmental precautions : Local authorities should be advised if significant spillages cannot be contained.

### 6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Pick up and arrange disposal without creating dust.
Sweep up and shovel.
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 : For personal protection see section 8.
Smoking, eating and drinking should be prohibited in the application area.

Advice on protection against fire and explosion : Provide appropriate exhaust ventilation at places where dust is formed.

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

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

| | | |
|---|---|---|
| Requirements for storage areas and containers | : | Electrical installations / working materials must comply with the technological safety standards. |
| Further information on storage conditions | : | See label, package insert or internal guidelines |
| Advice on common storage | : | No materials to be especially mentioned. |
| 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**

Contains no substances with occupational exposure limit values.

**8.2 Exposure controls**

**Engineering measures**

No data available

**Personal protective equipment**

| | | |
|---|---|---|
| Eye/face protection | : | Use eye protection according to EN 166. |
| | | Safety glasses |
| 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 : Protective suit

Respiratory protection : No personal respiratory protective equipment normally required.

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

| | | |
|---|---|---|
| Physical state | : | solid |
| Colour | : | No data available |
| Odour | : | Not applicable |
| 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 | : | Not applicable |
| 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<br>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 | : | Stable under recommended storage conditions.<br>No hazards to be specially mentioned. |

**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**

Hazardous decomposition products formed under fire conditions.

## 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.

**Skin corrosion/irritation**

Not classified due to lack of data.

**Serious eye damage/eye irritation**

Not classified due to lack of data.

**Respiratory or skin sensitisation**

**Skin sensitisation**

Not classified due to lack of data.

**Respiratory sensitisation**

Not classified due to lack of data.

**Germ cell mutagenicity**

Not classified due to lack of data.

**Carcinogenicity**

Not classified due to lack of data.

**Reproductive toxicity**

Not classified due to lack of data.

**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 toxicity**

Not classified due to lack of data.

### 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

No data available

### 12.2 Persistence and degradability

No data available

### 12.3 Bioaccumulative potential

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

No data available

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

Product : The product has to be disposed of as laboratory chemical in accordance with local regulations.

Contaminated packaging : 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) | : | Not applicable |
| 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- | : | Not applicable |

accident hazards involving dangerous substances.

| | | |
|---|---|---|
| Water hazard class (Germany) | : | WGK 1 slightly hazardous to water<br>Remarks: Classification according VwVwS, Annex 3. Classification according to AwSV §6(4) |
| TA Luft List (Germany) | : | 5.2.1: Total dust:<br>5.2.2: Inorganic substances in powdered form:<br>Not applicable<br>5.2.4: Inorganic substances in gaseous form:<br>Not applicable<br>5.2.5: Organic Substances:<br>Not applicable<br>5.2.7.1.1: Carcinogenic substance:<br>Not applicable<br>5.2.7.1.1: Quartz fine dust PM4:<br>Not applicable<br>5.2.7.1.1: Formaldehyde:<br>Not applicable<br>5.2.7.1.1: fibres:<br>Not applicable<br>5.2.7.1.2: Germ cell mutagens:<br>Not applicable<br>5.2.7.1.3: Substances toxic to reproduction:<br>Not applicable<br>5.2.7.2: Poorly degradable, easily enrichable and highly toxic organic substances:<br>Not applicable |
| Volatile organic compounds | : | Directive 2010/75/EU of 24 November 2010 on industrial emissions (integrated pollution prevention and control)<br>Not applicable |

**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.<br><br>non hazardous compounds |
| NZIoC | : | On the inventory, or 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 other abbreviations**

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 population; 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