

Safety Data Sheet

In accordance with Regulation (EC) No. 1907/2006 (REACH)

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Item description ampliCube PCR Test

Item number: 50503/50502/50142/50143/50144/50001/50011/50002/50012/

55002//50401/50402/50403/50404/50405/5040650101/50111/50121/50131/50173/50174/50163/50164/50102/50112/50122/50132/50152/

50301/50302/50303/57801

1. Specification of substance / mixture and company

Trade name / description:

Trade name	Item
ampliCube Color Compensation (CC) for cobas z 480	50503
ampliCube Color Compensation (CC) for LC 480 II	50502
ampliCube Coronavirus Panel	50142
ampliCube Coronavirus SARS-CoV-2	50143 50144
ampliCube Gastrointestinal Bacterial Panel 1	50001
ampliCube Gastrointestinal Bacterial Panel 2	50011
ampliCube Gastrointestinal Viral Panel 1	50002
ampliCube Gastrointestinal Viral Panel 2	50012
ampliCube HEV 2.0 Quant	55002
ampliCube MDR Panel 1	50401
ampliCube MDR Panel 2	50402
ampliCube MDR Panel 3	50403
ampliCube MDR Panel 4	50404
ampliCube MDR Panel 5	50405
ampliCube MDR Panel 6	50406

Trade name	Item
ampliCube Respiratory Bacterial Panel 1	50101
ampliCube Respiratory Bacterial Panel 2	50111
ampliCube Respiratory Bacterial Panel 3	50121
ampliCube Respiratory Bacterial Panel 4	50131
ampliCube Respiratory Flu & SARS-CoV-2 LC	50173 50174
ampliCube Respiratory Flu & SARS-CoV-2	50163 50164
ampliCube Respiratory Viral Panel 1	50102
ampliCube Respiratory Viral Panel 2	50112
ampliCube Respiratory Viral Panel 3	50122
ampliCube Respiratory Viral Panel 4	50132
ampliCube Respiratory Viral Panel 5	50152
ampliCube STD Panel 1	50301
ampliCube STD Panel 2	50302
ampliCube STD Panel 3	50303
ampliCube Zika Virus	57801

Identified use: Laboratory chemicals:

Primer & Probe mix P&P MIX

Internal control CONTROL INT

Positive control | CONTROL | +

Negative control CONTROL -

Enzyme-mix ENZYME

Standard 1 (only ampliCube HEV 2.0 Quant) STANDARD 1

Standard 3 (only ampliCube HEV 2.0 Quant) STANDARD 3

Standard 4 (only ampliCube HEV 2.0 Quant) STANDARD 4

Details of the supplier providing the safety data sheet:

Mikrogen GmbH Floriansbogen 2-4

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Responsible for this MSDS: Ms Sonja Hendlmeier

EMERGENCY NUMBER: Munich Poison Control Centre: +49(0)89 - 19240

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2. Possible hazards

 Classification in accordance with Regulation (EC) No. 1272/2008 [CLP]: No classification according to 1272/2008

Identifying elements:

Hazard pictogram	Signal word
NONE	NONE

Hazard warnings:

The product does not require a hazard warning label under Regulation (EC) No. 1272/2008 (CLP). No special hazards.

However, please note the information contained in this safety data sheet.

3. Composition/details of the components

Description: Watery solution.

CAS No. designation: None.

Identification number(s): None.

4. First aid measures

- General information: Immediately remove items of clothing contaminated with product.
- After inhalation: Go into fresh air; if short of breath, call a doctor.
- After skin contact: Rinse with plenty of water. Contact a doctor if skin irritation persists.
- After eye contact: Rinse opened eyes with plenty of water. Consult an ophthalmologist.
- After swallowing: Rinse mouth out and drink water. Consult a doctor.

5. Fire-fighting procedures

Suitable extinguishing agent:

The product itself does not burn, adapt fire extinguishing measures to nearby fire.

Special hazards due to substance or mixture:

None known.

6. Accidental release measures

- Personal precautions: Do not inhale fumes. Wear respirator mask, safety goggles and rubber gloves.
- Environmental precautions: Do not empty into drains / surface water / groundwater.
- Methods and material for containment and cleaning up

Cleaning measures: Mechanically pick up. Make sure the room is well-ventilated and then clean.

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7. Handling and storage

- Handling
 - Safe handling: No special measures necessary if handled and stored correctly.
- Protection against fire and explosion: No special measures necessary.
- Storage
 - Requirements for storage rooms and containers: Seal opened containers carefully and store upright to prevent any leakage.
- Combined storage: None known.
- Further information about storage conditions: No special measures necessary.
- Recommended storage temperature: Value -20°C

8. Exposure limitation and controls / personal protection

Preventative medical examinations for the workplace should be made available.

- Exposure limit values: No data available.
- Personal protective clothing: No special measures necessary.
- Respiratory protection: No special measures necessary.
- Gloves: Protective gloves (DIN EN 455). The protective gloves should, in all cases, be checked for their workplace-specific suitability (e.g. mechanical resistance, product compatibility, anti-static properties). Follow the instructions and information from the protective glove manufacturer concerning the use, storage, maintenance and replacement of gloves. If damaged or showing initial wear marks, the protective gloves should be replaced immediately. Arrange work processes in such a way that the gloves need not be worn continuously.

Suitable material	Nitrile	Suitable material	Latex
Material thickness	0.4 mm	Material thickness	0.4 mm
Penetration time	> 120 min	Penetration time	>120 min

- Eye protection: Safety goggles (DIN EN 166)
- Body protection: Standard laboratory work clothing
- General protective and hygiene measures:
 - Do not smoke, eat or drink when working.
 - Keep away from food and drink.
 - Wash hands before breaks and after work.
 - Avoid contact with eyes and skin.
 - Immediately remove soiled or soaked clothing.

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9. Physical and chemical properties

Appearance

Form: Liquid Colour: Various

Smell:

Odourless

State change:

Melting point / melting range: Not determined. Boiling point / boiling range: Not determined.

Flash point:

Not suitable.

Risk of explosion:

The product is not an explosion risk.

Density:

Not determined.

Solubility in / miscibility with water:

No data available.

10. Stability and reactivity

- Conditions to avoid: None if used correctly.
- Substances to avoid: None known.
- Hazardous decomposition products: No hazardous decomposition products known.

11. Toxicological information

Not available.

12. Environmental information

The mixture is not classified in the hazard class "Hazardous to the Aquatic Environment".

13. Disposal considerations

- Product: The allocation of a waste code number must be made in accordance with the European Waste Catalogue (AVV - Waste List Ordinance) in consultation with the regional disposer.
- Packaging: Disposal in accordance with official regulations.

14. Transport information

Not subject to transport regulations according to ADR, RID, IATA and IMDG.

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ampliCube PCR Test



15. Regulatory information

Regulations regarding safety, health and environmental protection / specific legal provisions for the material or mixture

- National regulations:
 - Information about limitation of use:
 Note the limitations of use for young persons in accordance with Section 22 JArbSchG.
 - Hazardous Incidents Ordinance
 - o Classification according to VbF: Not applicable
 - Water hazard class: Not hazardous to water
 - o Chemical safety assessment: No chemical safety assessment has been carried out.

16. Other information

Further information

- The information is based upon our present knowledge. It is intended to describe our products in terms of safety requirements, but does not represent any undertaking as regards product quality, nor does it constitute any contractual legal obligation.
- Section issuing the data sheet: Department of Occupational Safety
- Contact: Ms Hendlmeier
- 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 Organization
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 Harmonized System of Classification and Labelling of Chemicals
EINECS	European Inventory of Existing Commercial Chemical Substances
CAS	Chemical Abstracts Service (division of the American Chemical Society)

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