

Check-Direct CPE (Catalog no. 18-0080 and 18-0084)
4-Color Compensation Set for Check-Direct CPE (Catalog no. 18-0070)

1. Identification of the substance/preparation and the company/undertaking

Product name	Check-Direct CPE; 4-Color Compensation Set for Check-Direct CPE
Supplier	Check-Points Health B.V. Binnenhaven 5 6709 PD Wageningen The Netherlands Tel: +31 317 453 908 E-mail: info@check-points.com
Emergency telephone number	+31 317 453 908
E-mail address of person responsible for this SDS	info@check-points.com
Recommended use	Check-Direct CPE is a rapid molecular assay for the detection of carbapenemases by real-time PCR directly from rectal swabs (18-0080) or directly from culture (18-0084). 4-Color Compensation Set for Check-Direct CPE is used to generate a color compensation object when the Check-Direct CPE assay is to be performed on the LightCycler® 480 system I or II.
Remarks	A kit contains vials with ready-for-use reagents.

2. Hazards identification

This product is not classified as dangerous according to Directive 1999/45/EC and its amendments.

Classification	Not classified.
Human health hazards	Based on the available data of this product no hazardous properties are known.
Environmental hazards	Based on the available data of this product no hazardous properties are known.
Physical/chemical hazards	Based on the available data of this product no hazardous properties are known.

3. Composition/information on ingredients

Occupational exposure limits, if available, are listed in section 8.

4. First-aid measures

Effects and symptoms

Inhalation	There is no known acute effect after over-exposure to this product.
Ingestion	There is no known acute effect after over-exposure to this product.
Skin contact	There is no known acute effect after over-exposure to this product.
Eye contact	Irritating effects cannot be excluded.

First-aid measures

General	Move exposed person to fresh air.
Inhalation	If inhaled, remove to fresh air. Obtain medical attention if symptoms occur.
Ingestion	If swallowed, rinse mouth with water (only if the person is conscious). Obtain medical attention if symptoms occur.
Skin contact	Wash with soap and water. Remove contaminated clothing and shoes. Obtain medical attention if symptoms occur.
Eye contact	Rinse with plenty of running water. Obtain medical attention if symptoms occur.

First aid facilities No special recommendations.

5. Fire-fighting measures

Extinguishing media

Small fire

Suitable Non-combustible. Use extinguishing media suitable for surrounding materials.

Large fire

Suitable Non-combustible. Use extinguishing media suitable for surrounding materials.

Unusual fire/explosion hazards No specific hazard.

Hazardous thermal decomposition products No specific data.

Special fire-fighting procedures No special measures required.

Protection of fire-fighters Wear suitable protective clothing. Self-contained breathing apparatus.

6. Accidental release measures

Personal precautions	Use suitable protective equipment (section 8).
Environmental precautions	Prevent entry into sewers, basements or confined areas. Dyke if necessary.
Clean-up Methods	
Small spill and leak	Take up with suitable material. Place in a suitable container. Clean up affected area with large amount of water.
Large spill and leak	Absorb spill with inert material (e.g. dry sand or earth) and place in a chemical waste container. Recycle, if possible. Clean up affected area with a large amount of water.

Note: see section 8 for personal protective equipment and section 13 for waste disposal.

7. Handling and storage

Handling	Use with adequate ventilation.
Storage	Store specific solutions (as indicated in the respective product's user manual) in the dark.
Storage temperature	<p><u>Check-Direct CPE (Catalog no. 18-0080 and 18-0084)</u> Store between the following temperatures: +2°C and +8°C.</p> <p><u>4-Color Compensation Set for Check-Direct CPE (Catalog no. 18-0070)</u> Store between the following temperatures: -30°C and -20°C.</p>

Note: See section 10 for stability and reactivity.

8. Exposure controls/personal protection

Occupational exposure limits	Not applicable.
Engineering measures	None required. However, use of adequate ventilation is good industrial practice.
Hygiene measures	When using, do not eat, drink or smoke. Wash hands after handling compounds and before eating, smoking and using the lavatory and at the end of the day.

Personal protective equipment – Production scale

Respiratory system	No special protection is required. In case of insufficient ventilation, wear suitable respiratory equipment.
Skin and body	Working clothes.
Eyes	Safety glasses with side shields.
Hands	Wear suitable gloves.

Advice on personal protection is applicable for high exposure levels. Select proper personal protection based on a risk assessment of the actual exposure situation.

9. Physical and chemical properties

Physical state	Liquid. [The test consists of vials filled with various solutions.]
Color	Colorless.
Odor	Odorless.
Flash point	Not applicable.
Lower explosion limit	Not applicable.
Upper explosion limit	Not applicable.
Density (g/cm ³)	Not available.
Remarks	More detailed information on the physical and chemical properties can be requested from the supplier.

10. Stability and reactivity

Stability	Stable under recommended storage and handling conditions (see section 7).
Conditions to avoid	No special recommendations.
Materials to avoid	No special recommendations.

11. Toxicological information

Potential acute health effects	
Inhalation	No known significant effects or critical hazards.
Ingestion	No known significant effects or critical hazards.
Skin contact	No known significant effects or critical hazards.

Eye contact	No known significant effects or critical hazards.
Acute toxicity	No known significant effects or critical hazards.
Potential chronic health effects	
Chronic effects	No known significant effects or critical hazards.
Carcinogenicity	No known significant effects or critical hazards.
Mutagenicity	No known significant effects or critical hazards.
Teratogenicity	No known significant effects or critical hazards.
Developmental effects	No known significant effects or critical hazards.
Fertility effects	No known significant effects or critical hazards.
Chronic toxicity	No specific data.
Carcinogenicity	No specific data.
Mutagenicity	No specific data.
Teratogenicity	No specific data.
Reproductive toxicity	No specific data.

12. Ecological information

Environmental effects	No known significant effects or critical hazards.
Aquatic ecotoxicity	No known significant effects or critical hazards.
Persistence/degradability	No known significant effects or critical hazards.
Other adverse effects	No known significant effects or critical hazards.
AOX	No known significant effects or critical hazards.

13. Disposal considerations

Methods of disposal (waste of residues; contaminated packaging)	Waste must be disposed of in accordance with national and local environmental regulations.
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14. Transport information

International transport regulations

Regulatory information	UN number	Proper shipping name	Class	PG*	Label	Additional information
ADR/RID Class	Not regulated.	-	-	-	-	-
ADNR Class	Not regulated.	-	-	-	-	-
IMDG Class	Not regulated.	-	-	-	-	-
IATA Class	Not regulated.	-	-	-	-	-

PG* = Packaging group

Attention, please read EMS notations like _E-S_ or _F-D_ as E-S or F-D

15. Regulatory information

EU regulations

Risk phrases	According to the EU Directives 67/548/EEC and 1999/45/EC this product does not require labeling with symbols and/or R-phrases.
Additional warning phrases	Not applicable.

16. Other information

Internal code SDSCPE2019092604

History

Date of printing	26 September 2019
Date of issue	26 September 2019
Version	4

Notice to reader

The statements in this Safety Data Sheet were made to the best of our knowledge and are as accurate as possible.

They are given for information only. They do not constitute a contractual guarantee of a product's properties. They must neither be altered nor transferred to other products.

The user is responsible for ensuring that appropriate precautions are taken and for satisfying themselves that the data are suitable and sufficient for the product's intended purpose. In case of any uncertainty we advise consulting the supplier or an expert.

Training advice

Before handling this substance/preparation, the personnel involved should be instructed by means of this safety data sheet.