



Order information

REF	Ţ <u>i</u>	CONTENT		Analyzer(s) on which cobas c pack(s) can be used
05422485190	05422485500	EcoTergent* (60 mL)	System-ID 07 6946 1	cobas c 311

^{*}The value encoded in the instrument settings is 55.9 mL to account for the dead volume of the bottles.

English

System information **ECO-D:** ACN 946

Intended use

EcoTergent is an additive to the reaction bath to reduce surface tension on cobas c 311 systems.

EcoTergent is added to the reaction bath. It acts as a surfactant to minimize the formation of bubbles that could potentially interfere with the photometer readings

Reagents - working solutions

Detergent

Detergent is in position B and C.

Precautions and warnings

For in vitro diagnostic use for healthcare professionals. Exercise the normal precautions required for handling all laboratory reagents.

Infectious or microbial waste:

Warning: handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Environmental hazards:

Apply all relevant local disposal regulations to determine the safe disposal. Safety data sheet available for professional user on request.

This kit contains components classified as follows in accordance with the Regulation (EC) No. 1272/2008:





Danger

H314 Causes severe skin burns and eye damage.

H410 Very toxic to aquatic life with long lasting effects.

Prevention:

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protection/

face protection/ hearing protection.

Response:

P303 + P361 IF ON SKIN (or hair): Take off immediately all contaminated

+ P353 clothing. Rinse skin with water.

P304 + P340 IF INHALED: Remove person to fresh air and keep

+ P310 comfortable for breathing.

Immediately call a POISON CENTER/ doctor.

P305 + P351 IF IN EYES: Rinse cautiously with water for several + P338 minutes. Remove contact lenses, if present and easy to do.

+ P310 Continue rinsing. Immediately call a POISON CENTER/

doctor.

P391 Collect spillage.

Product safety labeling follows EU GHS guidance.

Contact phone: all countries: +49-621-7590, USA: 1-800-428-2336

Hazardous components:

- 1-Decanaminium, N-decyl-N, N-dimethyl-, hexanedioate (2:1)
- Alcohols, C12-14-secondary, ethoxylated
- N-(3-aminopropyl)-N-dodecylpropane-1, 3-diamine

Reagent handling

Ready for use

Storage and stability

Store protected from light.

Shelf life at 15-25 °C: See expiration date on cobas c pack label.

On-board in use and refrigerated on the analyzer: 4 weeks

Materials provided

See "Reagents – working solutions" section for reagents.

Materials required (but not provided)

See "Order information" section

Assay

Use EcoTergent as specified in the respective instructions for use.

A point (period/stop) is always used in this Method Sheet as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard (for USA: see navifyportal.roche.com for definition of symbols used):

CONTENT Contents of kit Volume for reconstitution GTIN Global Trade Item Number

For USA: Caution: Federal law restricts this Rx only

device to sale by or on the order of a

physician.

FOR US CUSTOMERS ONLY: LIMITED WARRANTY

Roche Diagnostics warrants that this product will meet the specifications stated in the labeling when used in accordance with such labeling and will be free from defects in material and workmanship until the expiration date printed on the label. THIS LIMITED WARRANTY IS IN LIEU OF ANY OTHER WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR PARTICULAR PURPOSE. IN NO EVENT SHALL ROCHE DIAGNOSTICS BE LIABLE FOR INCIDENTAL, INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES.

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For USA: Rx only



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