heipha ICRplus Neutralizer A Contact Plate

The all-purpose neutralizing plate for isolators and cleanrooms

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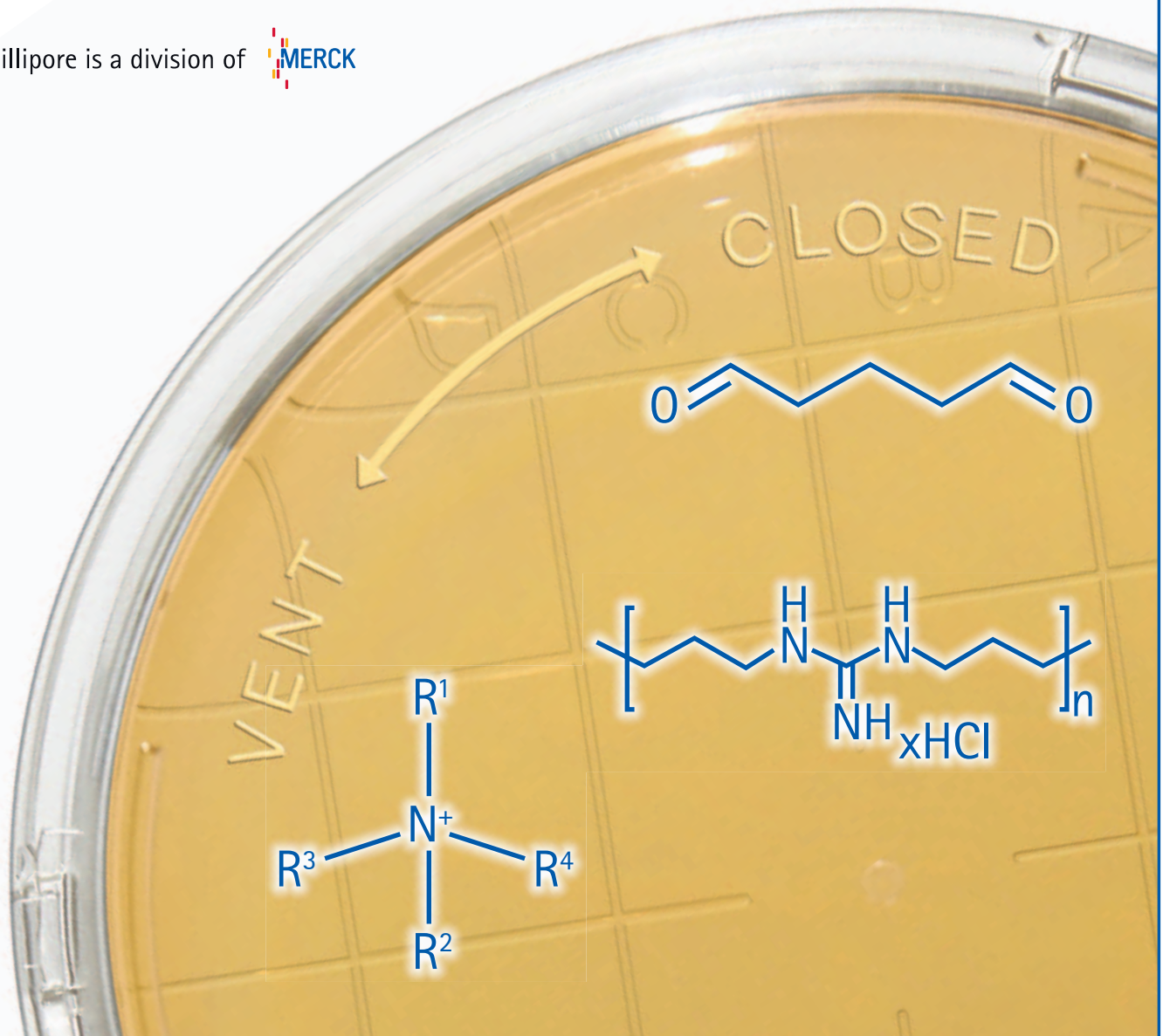

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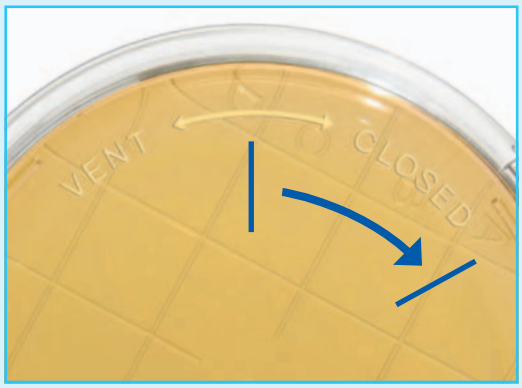
The heipha ICRplus Neutralizer A Contact Plate is a newly developed formulation for detection of microorganisms on disinfected surfaces. A number of disinfectants leave remaining residues of active agents on surfaces, specifically polyhexamethylene biguanides (PHMB) and quaternary ammonium compounds (QAC), which cannot be neutralized by the use of common neutralizers, such as lecithin, Tween 80, histidine and thiosulfate. Therefore a new neutralizing mixture was developed in order to overcome inhibition of microbial growth in the presence of these types of disinfectants. Using this new formulation will reduce the risk of false negatives, and ensure reliable results.

Technical specifications

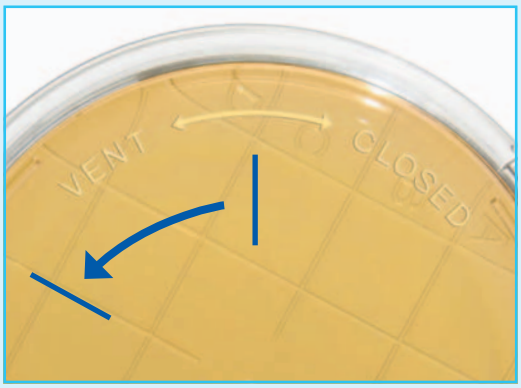
- Lockable 50 mm plates
- Triple bagged, gamma irradiated (9–20 kGy)
- Transparent, H_2O_2-impermeable sleeves
- Inner bag with hole for hanging in isolators
- Individual data matrix code on each plate (product code 825)
- Shelf life 6 months
- Clear appearance of agar medium
- Storage at 15–25°C

Two way closure system

- Lock plates in CLOSED-position in order to avoid loss of lid during transport to inspection area (laboratory, incubators).
- Lock plates in VENT-position mandatory for microaerophilic and anaerobic incubation.



Turn lid clockwise and click in **CLOSED-position**



Turn lid counter clockwise and click in **VENT-position**

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Intended use

The heipha ICRplus Neutralizer A Contact Plate is used for the total viable count of microorganisms on dry, disinfected surfaces in cleanrooms and isolators.

The formulation of the basic medium complies with the formulation of casein soya bean digest agar according to the recommendation of the current EP, JP and USP (European, Japanese and US Pharmacopoeia). To inactivate residues of disinfectants, the medium is supplemented with a mixture of active ingredients called Neutralizer A.

Storage conditions and shelf life

The product has to be stored upright at 15–25°C. It has to be protected from light as well as from strong temperature variations.

Abrupt temperature changes as well as storage other than in an upright position may increase the formation of condensing water. The shelf life of the product is indicated on the product label and is valid for original packed media. The media should not be used after the expiration date.

Typical composition per liter

Composition (g/l)	
Casein Peptone 15 g	NaCl 5 g
Soy Peptone 5 g	Neutralizer A
Agar 15 g	Supplements
pH 7.2 ± 0.2	

The agar medium is clear and yellowish.

Performance characteristics and procedure

The heipha ICRplus Neutralizer A Contact Plate is suitable for the determination of the total viable count on sanitized, dry surfaces in isolators and cleanrooms (ICR: **I**solator and **C**lean**R**ooms).

The combination of peptones from casein and soy beans provides the microorganisms with essential amino acids, low molecular peptides and soluble proteins. The carbohydrates derived from soy peptone promote the growth of yeast and molds. Also microaerophilic and anaerobic microorganisms are able to grow under adequate incubation conditions.

The mixture of neutralizers, called Neutralizer A, is able to inactivate residuals of a broad range of disinfectants on sanitized surfaces such as polyhexamethylene biguanides, quaternary ammonium compounds, aldehydes, hydrogen peroxide, peracetic acid as well as mixtures of those active substances. Some of those cannot be neutralized by the commonly used neutralizers LTHTh (**L**ecithin, **T**ween 80, **H**istidine and sodium **Th**iosulfate).

Performance characteristics: In the presence of the below listed disinfectants several microbial strains, such as gram positive cocci and rods, spore building gram positive bacteria, gram negative bacteria, yeasts and molds, were recovered with a rate of ≥ 50 % (data available on request):

Disinfectant[1]	Supplier	Active ingredients
Actril®	Minntech	Hydrogen peroxide, peracetic acid
Amphospray®	Anios	Ethanol, biguanides, QAC*
Klercide™ 70/30	Shield Medicare	70 % Isopropanol
Klercide-CR™ Biocide A	Shield Medicare	QAC, biguanides
Klercide-CR™ Biocide B	Shield Medicare	QAC, sodium chlorite, alcohol ethoxylate, Isopropanol
Melsept® SF	B. Braun	QAC, aldehydes, alcohol ethoxylate

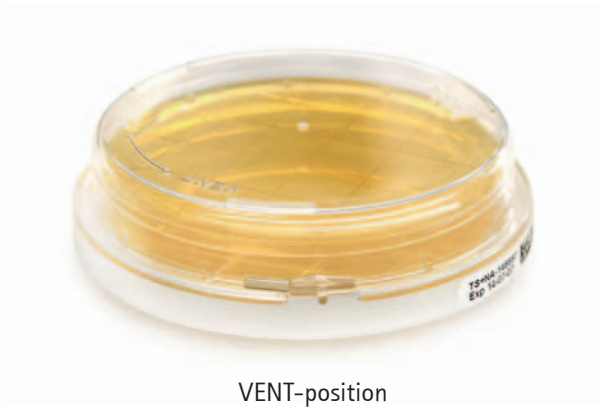
* QAC = Quaternary ammonium compounds
[1] All trademarks belong to their respective proprietor.

Principle of procedure

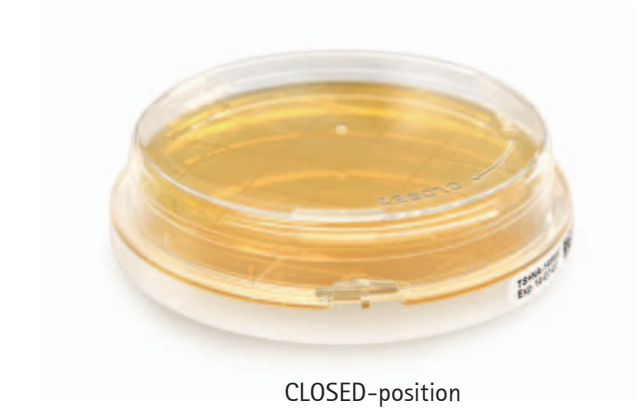
The plates are triple-bagged and gamma-irradiated in the final packaging at 9-20 kGy for use in cleanrooms and isolators. The plates may be transferred into grade A cleanrooms by removing one bag in each material lock. For use in isolators the inner bag has a hole in the sealing to hang up the bag during decontamination. Leave the plates inside the tight inner sleeve during the decontamination cycle of an isolator.

The agar surface is pressed on the dry surface to be tested with a steady pressure. After sampling, the plates are incubated and analyzed.

The plate model (plus or "+") is supplied with a lockable lid. For safe transport after sampling, plates can be locked in the CLOSED-position, as well as for aerobic incubation. For anaerobic or microaerophilic, incubation in the VENT-position is mandatory.



VENT-position



CLOSED-position

Culture conditions

Plates, which are used for environmental monitoring, may be incubated as listed below:

Reference	Yeast and Molds	Bacteria
Aseptic Guide (2004; FDA)	20-25°C; 5-7 days	30-35°C; 48-72 hours
USP 36 <1116>	20-35°C; ≥ 72 hours	20-35°C; ≥ 72 hours

The actual incubation conditions can be chosen out of these recommendations and should be validated by the user.

In critical areas any contaminated unit should be investigated. The microorganisms may be identified after re-growth to the species level. The investigation should survey the possible causes for contamination.

Quality control

Test strain	Inoculum / Incubation conditions	Growth characteristics
Staphylococcus aureus ATCC 6538	10–100 CFU / 20–24 h at 30–35°C	recovery ≥ 50 %
Escherichia coli ATCC 8739	10–100 CFU / 20–24 h at 30–35°C	recovery ≥ 50 %
Pseudomonas aeruginosa ATCC 9027	10–100 CFU / 20–24 h at 30–35°C	recovery ≥ 50 %
Bacillus subtilis ATCC 6633	10–100 CFU / 20–24 h at 30–35°C	recovery ≥ 50 %
Candida albicans ATCC 10231	10–100 CFU / 44–48 h at 20–25°C	recovery ≥ 50 %
Aspergillus brasiliensis ATCC 16404	10–100 CFU / 70–74 h at 20–25°C	recovery ≥ 50 %
Bacillus subtilis ATCC 6633 in the presence of 25 µl Klercide-CR Biocide A	10–100 CFU / 20–24 h at 30–35°C	recovery ≥ 50 %

Please refer to the quality control of batch related CoA's.

Disposal

Please mind the respective regulations for the disposal of used culture medium (e. g. autoclave for 20 min at 121°C, disinfect, incinerate etc.).

Ordering information of heipha ICRplus Neutralizer A Contact Plate

Product Name	Package size	Ord. No.
Neutralizer A Contact – ICRplus	20	1.46697.0020
Neutralizer A Contact – ICRplus	200	1.46697.0200

References

EN ISO 14698-1:2003: Cleanrooms and associated controlled environments – Biocontamination control – Part 1: General principles and methods (ISO 14698-1:2003).

Guidance for Industry (2004): Sterile Drug Products produced by aseptic processing – Current Good Manufacturing Practice.

United States Pharmacopoeia 36 NF 31 (2013): <1116> Microbiological control and monitoring of aseptic processing environments.

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