

Technical Data Sheet

Sabouraud Dextrose (4%) Agar (SDA) w. Chloramphenicol

Ordering number: 1.46394.0006

Sabouraud Dextrose Agar (SDA) with Chloramphenicol is designed for the determination of the total count of yeasts and molds.

The formulation of the basic medium (Sabouraud Dextrose Agar) is prepared according to the recommendations of the current European, Japanese and United States Pharmacopoeia (EP, 2.6.13.; JP, 4.05 and USP, 62).

Sabouraud Dextrose Agar (SDA) w. Chloramphenicol is available with identical media formulation in different filling volumes:

- Sabouraud Dextrose Agar (SDA) w. Chloramphenicol (article number 146298, DMC: 565): 25 ml-tube, filling volume 18 ml
- Sabouraud Dextrose Agar (SDA) w. Chloramphenicol (article number 146394, DMC: 152): 250 ml-bottle with **screw cap**, filling volume 200 ml
- Sabouraud Dextrose Agar (SDA) w. Chloramphenicol (article number 146466, DMC: 179): 500 ml-bottle with **screw cap**, filling volume 400 ml

Mode of Action

SDA is a complex medium for cultivation and isolation of yeasts and molds. The media is used for microbiological examination of non-sterile products. The high concentration of Dextrose in addition with the low pH promotes the growth of yeast and molds while inhibiting bacterial growth. The media also promotes the formation of spores (conidia and sporangia) as well as the formation of pigments of yeasts and molds. The addition of chloramphenicol will further inhibit the growth of the accompanying bacterial flora of heavily contaminated material, due to its wide spectrum.

Typical Composition

Casein Peptone (pancreatic digest)	5 g/l
Meat Peptone (peptic digest)	5 g/l
Dextrose	40 g/l
Chloramphenicol	50 mg/l
Agar	15 g/l

The appearance of the medium is clear and yellowish. The pH value is in the range of 5.4-5.8. The medium can be adjusted and/or supplemented according to the performance criteria required.

Application and Interpretation

Sabouraud Dextrose Agar w. Chloramphenicol, provided in tube or bottle, can be used to prepare plates for surface spread or for pour plate method.

Prior to use, melt the agar using a 95°C water bath or an autoclave. **Slightly open the screw cap in order to avoid pressure building before heating the media. Please note that use of a microwave is not advised.**

Melting time differs significantly based on the volume of the medium - around 10 minutes for tube, 45 minutes for 200ml agar and 60 minutes for 400ml agar. Once the agar is liquefied, allow the media to cool down in a 45-50°C water bath. The cooling times correlate with the respective heating times of the different volumes of agar. When pouring, media should not exceed a temperature of 45°C.

For surface inoculation, pour the liquid medium into an empty petri dish (volume will depend on the diameter of the petri dish, i.e. ~15-20ml for 90mm plates). Allow to solidify for at least 30 minutes. Once the agar is solidified, the plates should be wrapped, stored at cold temperature as at 2°C to 8°C and used within few days.

For the pour plate method, add the prepared sample into the empty dish and cover with medium. Gently mix the plate and allow the agar to solidify prior to incubation.

For total yeast and mold count (Microbial Limit Test), plates should be incubated for 5 to 7 days at 20-25 °C (EP/USP) prior to colony counting.

Note: Agar media should not be melted a second time after solidifying.

Storage and Shelf Life

The product can be used for sampling until the expiry date if stored upright, protected from light and properly sealed at +2 °C to +25 °C.

The testing procedures as described on the CoA can be started up to the expiry date printed on the label.

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.).

Quality Control (for bottle)

Control Strains	ATCC #	Inoculum CFU	Incubation	Expected Result Recovery in %
<i>Candida albicans</i>	10231	10-100	20-24 h at 30-35 °C	50-200 %
			44-48 h at 20-25 °C	50-200 %
<i>Aspergillus brasiliensis</i>	16404	10-100	70-74 h at 20-25 °C	50-200 %
<i>Escherichia coli</i>	8739	10,000-100,000	70-74 h at 30-35 °C	No growth

Please refer to the actual batch related Certificate of Analysis.



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Literature

EU GMP Medicinal Products for Human and Veterinary use (2008): Annex1 Manufacture of Sterile Medicinal Products.

European Pharmacopoeia 8.0 (2014): 2.6.12. Microbial examination of non-sterile products (total viable aerobic count); 2.6.13. Microbiological examination of non-sterile products (test for specified micro-organisms)

Guidance for Industry (2004): Sterile Drug Products Produced by Aseptic Processing - Current Good Manufacturing Practice.

Japanese Pharmacopoeia 16th edition (2011): 4.05 Microbial Limit Test.

PDA Technical Report No. 13 (2014 Revised): Fundamentals of an Environmental Monitoring Program.

United States Pharmacopoeia 38 NF 33 (2015): <61> Microbiological Examination of Non-Sterile Products: Microbial Enumeration Tests; <62> Microbiological Examination of Non-Sterile Products: Test for Specified Microorganisms.

Ordering Information

Product	Cat. No.	Pack size
Sabouraud Dextrose (4%) Agar (SDA) w. Chloramphenicol	1.46394.0006	6 x 200 ml bottle
Sabouraud Dextrose Agar (SDA) w. Chloramphenicol	1.46298.0020	20 x 18 ml tube
Sabouraud Dextrose (4%) Agar (SDA) w. Chloramphenicol	1.46466.0006	6 x 400 ml bottle

Merck KGaA, 64271 Darmstadt, Germany
Fax: +49 (0) 61 51 / 72-60 80
mibio@merckgroup.com
www.merckmillipore.com/biomonitoring

Find contact information for your country at:
www.merckmillipore.com/offices
For Technical Service, please visit:
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