

SAFETY DATA SHEETS

This SDS packet was issued with item:

078944900

N/A



FERA

Diagnostics
and Biologicals

Hazard Communication Standard: Safety Data Sheet

NAME OF THE VETERINARY DIAGNOSTIC PRODUCT

UTid® In-clinic Culture plates (Veterinary use).

PHARMACOLOGICAL/CHEMICAL PROPERTIES

Schedule B (or USHTS) Number: 3821.00.0000 – Miscellaneous chemical products

Chemical properties:

All Prepared Culture plates contains nutrients such as peptones, amino acids, yeast extract, minerals, vitamins and agar solidifiers. Unlike traditional media, they contain chromogenic substrates or chromogens.

CAS number: 9002-18-0

The plates are prepared media, pre-packed and ready for use by the end user.

List of excipients:

- a) **The UTid® In-clinic Culture plates** consist of four chambered plate containing four selective chromogenic agars. This unique agar combination provides a comprehensive scheme for identifying the various infectious agents.

Media III selective media for the isolation of Gram-negative pathogens: Composition in g/L - Agar 15.0; Peptone and yeast extract 17.0; color mix; pH 7.0 +/- 0.2.

Color (Media III): Tan to beige

Media III selective media for the isolation of Streptococcus ssp.: Composition in g/L – Agar 15.0; Peptones & growth factors 22.0; Salts 7.5; Color mix; Total 46.9 g/L; pH 7.3 +/- 0.2.

Color (Media III): White/Cream to light gray

Media II selective media for the isolation of Staphylococcus ssp.: Composition in g/L- Agar 15.0; Peptone and yeast extract 40.0; Salts 30.0; color mix; pH: 7.3 +/- 0.2

Color (Media II): Tan/beige to gold

Media I selective media for the isolation of fungi: Composition in g/L – Agar 15.0; Peptones & growth factors 22.0; Salts 7.5; Color mix; Total 46.9 g/L; pH 7.3 +/- 0.2.

Color (Media I): Blue/green.



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Nature and composition of immediate packaging:

At this time, all Culture plates herein described are produced, sterilized and packed at a commercial bacterial culture media laboratory located in the Northeast United States; inspected by the Food and Drug Administration for compliance with the current Good Manufacturing Practices regulations for Medical Devices and Diagnostic Products, CFR 21, Part 820. Plates are made to order and packed inside a customized Foil Zip Sealed, 4.5 mils thick Mylar® bags, with 100cc oxygen absorbers and sterile desiccant paper.

Contain no greater than 50 ml or 50 g for each individually packaged unit.

Culture plates are used for culturing animal samples only. If kept sterile and sealed does not contain or spread infection and diffuse disease for animals or humans.

We also declare and confirm that the Culture plates specified in this document do not contain any substances, materials or articles that can be classified as dangerous.

MARKETING AUTHORISATION HOLDER

FERA Diagnostics and Biologicals, Corp.

950 Danby road, suite 206

Ithaca, NY

14850

MARKETING AUTHORISATION NUMBER

Centre for Technology Licensing (CTL) contract number: C2016-12-10768

DATE OF FIRST AUTHORISATION OF THE AUTHORISATION

16 October 2020

DATE OF REVISION OF THE TEXT

Approved: January 30th, 2021