

TECHNICAL DATA SHEET

DESCRIPTION 0.1% PEPTONE WATER + 0.1% POLYSORBATE 80 - FLUID D USP, BOTTLED

 $\textbf{SGL PRODUCT CODE} \hspace{0.1in} 4824$

Diluent described in the United States Pharmacopeia (USP) <71>. The diluent is primarily used as a general rinse or diluent to test a wide variety of samples typically containing lecithin or oil as part of the USP <71> sterility test.

FORMULATION

Typical product composition*:

WEIGHT / VOLUME
1.0 g
1.0 ml
1000 ml

*Product may be adjusted and/or supplemented to meet performance criteria

QUALITY CONTROL SPECIFICATION

PHYSICAL TESTS	SPECIFICATION CRITERIA
Appearance	Clear, pale straw coloured liquid
pH at 20-25°C	7.1 ± 0.2

STERILITY TESTS	SPECIFICATION CRITERIA
Incubation at 20-25°C for 14 days	No growth detected
Incubation at 30-35°C for 14 days	No growth detected

Additional specification testing may be performed as requested by the customer.

Manufactured in compliance with ISO 9001 (Ref No FM37824).