

- To: To whom it may concern
- From: JiHyeon(Veronica) Moon in PLM Transducer
- CC: Reginald Rumwell, Satchi Panda
- Date: Apr 15<sup>th</sup>, 2019
- Subject: Prolystica® 2X Concentrate Enzymatic Presoak and Cleaner with Siemens transducers

*Completed*  
*Apr 15, 2019*

This memo confirms the compatibility of Prolystica® 2X Concentrate Enzymatic Presoak and Cleaners with Siemens probes.

#### ■ Executive Summary:

Enzymatic products, Prolystica® 2X Concentrate Enzymatic Presoak and Cleaners and Enzol Enzymatic Detergent, are respectively manufactured from STERIS Corporation and Advanced Sterilization Products. Since Prolystica® 2X Concentrate Enzymatic Presoak and Cleaners is an equivalent with Enzol Enzymatic Detergent by having protease enzyme and being a neutral pH solution, this memo justifies that Siemens transducers approved for use with Enzol Enzymatic Detergent can be used with Prolystica® 2X Concentrate Enzymatic Presoak and Cleaners.

#### ■ Analysis

Both Prolystica® 2X Concentrate Enzymatic Presoak and Cleaners and Enzol Enzymatic Detergent have protease, or also called subtilisin, with 0.1-1 % and neutral pH, therefore these two products are considered to be equivalent. A neutral or near-neutral pH detergent solution provides the best material compatibility and good soil removal. Enzymes added to neutral pH solutions assist in removing organic material. Please, refer to the picture 1 & 2.

With this reason, Prolystica® 2X Concentrate Enzymatic Presoak and Cleaners will be updated on the Transducer Disinfectant Compatibility Matrix(P/N 11335653) without performing an actual long-term soaking test.



### SAFETY DATA SHEET

#### 1. Identification of the Substance and Company

**Prolystica® 2X Concentrate Enzymatic Presoak and Cleaner**  
**Product No. 1C33 & 20D3**

#### 3. Composition/Information on Ingredients

Hazardous Component(s)	% By Wt.	CAS No.	EU No.	Symbol	R Phrases	Oral LD <sub>50</sub>	LC <sub>50</sub>
Ethanolamine	1 – 5	141-43-5	205-483-3	Xi	R36/37/38	1.07 ml/kg (female rat)	ND
Protease (Subtilisins)	0.1 – 1.0	9014-01-1	232-752-2	Xi, Xn	R37, R38, R41, R42	>2g/kg b.w. (rat)	ND
Ethoxylated Alcohol surfactant	1 – 5	68439-46-3	NA	Xn	R22, R41, R51	>500 – 2000 mg/kg (rat)	ND
Polyalkylene glycol	1 – 5	9003-11-6	NA	NA	NA	>4000 mg/kg (rat)	ND
Glycerine	1 – 5	56-81-5	200-289-5	ND	ND	12600 mg/kg (rat)	>570 mg/m3/1H (rat)

#### 9. Physical and Chemical Properties

**Solubility in Water:** Complete **Specific Gravity:** 1.060

**Physical State/Appearance/Odor:** Liquid/slightly hazy – yellow to amber/floral odor

**pH (neat):** Approximately 7.5 – 8.5

**pH (1% w/w solution):** 7.0 – 9.0

**Odor Threshold, Vapor Pressure, Vapor Density, Evaporation Rate, boiling Point and Freezing Point:** Not Available

**Coefficient of Water/Oil Distribution:** Not Applicable

Picture 1. Chemical composition of Prolystica® 2X Concentrate Enzymatic Presoak and Cleaners

# SAFETY DATA SHEET



Version 1.54	Revision Date: 2018/06/21	SDS Number: 100000011189	Date of last issue: 2018/05/19 Date of first issue: 2015/04/24
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## SECTION 1. IDENTIFICATION

Substance name : ENZOL Enzymatic Detergent  
ASP

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Chemical nature : Liquid

### Hazardous components

Chemical name	CAS-No.	Concentration (%)
disodium tetraborate decahydrate	1303-96-4	>= 1 - <= 5
subtilisin	9014-01-1	>= 0.1 - <= 1

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : Bottle, liquid

Colour : clear, violet

Odour : mint-like

pH : 7.8 - 8.8

Flash point : > 93 °C

Solubility(ies)

Water solubility : soluble

Picture 2. Chemical composition of Enzol Enzymatic Detergent

## ■ Conclusion

Prolystica® 2X Concentrate Enzymatic Presoak and Cleaners manufactured from STERIS Corporation is enzymatic cleaner. With this justification memo and technical information, customers can use Prolystica® 2X Concentrate Enzymatic Presoak and Cleaners to clean a transducer before disinfecting or sterilization. Compatible probes, which are expected to use with Prolystica® 2X Concentrate Enzymatic Presoak and Cleaners are the same as the validated probes with Enzol Enzymatic Detergent, checked "C" in the matrix. This will be updated on the Transducer Disinfectant Compatibility Matrix(P/N 11335653).

■ **Related Document**

Transducer Disinfectant Qualification Protocol, P/N 5931980.

■ **Attachment**

1) Technical Information\_Prolystica® 2X Concentrate Enzymatic Presoak and Cleaners



Prolystica 2X  
concentrate\_Enzym



Prolystica 2X  
concentrate\_Enzym

2) Technical Information\_Enzol Enzymatic Detergent



ENZOL Enzymatic  
Detergent\_MSDS\_v



Enzol\_Leaflet.pdf