

PRODUCT SAFETY INFORMATION

Directions: Please complete this form electronically and add your company name to the header section on page two. All questions must be answered on this form BEFORE any materials or components can be accepted at Lyophilization Technology Inc. Any costs for meeting these requirements will be submitted to the Client Company for their review and approval prior to beginning the project.

GENERAL INFORMATION:

Company Name:

Address:

Contact Name:

Contact Phone #:

Contact Email:

Medical/Safety Contact Name:

Medical/Safety Contact Phone #:

Medical/Safety Contact Email:

Is the contact above monitored 24 hours a day:

Yes

No

Medical/Safety Contact should be someone qualified to discuss the material with emergency services in the event of a spill, exposure, or accident.

PRODUCT INFORMATION:

Product Name:

Product Strength:

Product Type/Category
(cephalosporin, antibiotic, cytotoxic,
biologic, etc.):

API Storage Conditions (check one):

CRT 2°C – 8°C -20°C ± 10°C -70°C ± 10°C

Drug Product Storage Conditions:

CRT 2°C – 8°C -20°C ± 10°C -70°C ± 10°C

SAFETY INFORMATION:

Permissible Exposure Limit (PEL):

Occupational Exposure Limit (OEL):

Toxicology Endpoints (NOEL,
NOAEL, LOEL, other) include
species and duration

Comparator Drugs

Product Name:

Biological Safety Level (BSL):

DEA Controlled Substance:

Yes

No

Schedule #:

Hazardous Material:

Yes

No

Class:

Packing Group (check one)

I

II

III

N/A

UN#

Hazardous Waste:

Yes

No

Applicable Waste Codes:

Protect From (list)

(light, heat, etc.):

HANDLING INFORMATION:

Recommended Engineering

Controls (list):

Recommended PPE (list):

Cleaning Agent:

Decontamination Agent(s):

(include contact time)

Special Equipment for Handling:

Waste Disposal Procedure:

Remaining API (check one):

Return

Dispose

Return Address:

Product Name: _____

ATTACHMENTS: Check the appropriate box.

<input type="checkbox"/>	SDS attached
<input type="checkbox"/>	SDS not available, alternate safety information attached
<input type="checkbox"/>	Other (list): _____

Form completed by: _____

Title: _____

Date: _____

To be completed by LTI Personnel:

Reviewed By: _____ Date: _____