## SARTURIUS

## From DSP Buffers to Dangerous Goods: One Single Source

#### Your Benefits:

- Highly concentrated solutions can help reduce your footprint and warehousing when diluted at the point of use
- Proven chemical compatibility with Flexsafe® film
- One single vendor to qualify for the sourcing of buffers & dangerous goods



# Overcoming Large Volume Handling of Dangerous and Hazardous Solutions

In the manufacturing of biopharmaceuticals purification steps are critical to the process; therefore the equipment and consumables used must be of the highest quality standards. To ensure a robust supply chain, we have capabilities to produce all the formulations required for the wide variety of applications in downstream processing:

- Media & Buffer pH adjustment
- Chromatography column cleaning and storage
- Purification | Diafiltration | Polishing

- Virus Clearance & Inactivation
- Equipment cleaning
- Membrane flushing & regeneration

Media & Buffers Specialists will help you select the best formulations to minimize the burden of preparing large volumes of liquids including dangerous goods and optimize the associated transport logistics.



## Buffers in Biologics Manufacturing

All our liquid formulations are manufactured in ISO certified facilities following cGMP guidelines and are packaged in our robust Flexsafe® bags. The complete range of scalable Flexsafe® bags enables you to implement single-use bioprocessing throughout all steps of drug manufacturing, from process development to production – all using just one film.

- WFI Quality water
- Acids, Bases & Alcohols (HCl, NaOH, EtOH)
- Organic Solvents
- Phosphate- and Amine-based (PBS, Tris)

### Dangerous Goods Manufacturing Capabilities

Formulation	CAS Number	Max Concentration	Data available for compatibility with Flexsafe® bags**	Raw Material Grade*	Max Batch Size
Sodium Hydroxide	1310-73-2	19M   50%		EP and   or USP	5,000L
Ethanol	64-17-5	17M   99%		EP and   or USP	5,000L
Tween 80   Polysorbate 80	9005-65-6	100%		EP and   or USP	5,000L
Acetic Acid	64-19-7	17M   99%		EP and   or USP	5,000L
Citric Acid	77-92-9	4M   50%		EP and   or USP	5,000L
Hydrochloric Acid	7647-01-0	12M   37%		EP and   or USP	5,000L
Urea	57-13-6	8M		EP and   or USP	5,000L

 $<sup>^\</sup>star \;\; \text{Specifications including QC testing subject to customers' requirements and approval}$ 

<sup>\*\*</sup> Customized compatibility and stability studies can be offered

# UN-Certified Secondary Packaging for Dangerous Goods Transportation

	Volumes	Secondary Packaging	Labeling	Shipping Validation
Flexsafe® 2D bags	10L   20L	UN-Certified cardboard boxes	Product & CLP*	ADR**
Flexsafe® 3D bags	50L 100L  200L	UN-Certified PE drums	Product & CLP*	ADR**

<sup>\*</sup> EU Regulation and Global Harmonized System impose specific requirements for Classification, Labeling and Packaging of dangerous goods

### Ordering Information

Below are our standard, off-the-shelf product references

Product Description	Primary Packaging	Volume	Dangerous Good   CLP	Order Number   EMEA & Asia	Order Number   Americas
NaOH 1M	Flexsafe®	20L	Yes	CFB3FA7006	CFB3FA7006
WFI-Quality Water	Flexsafe®	20L	No	CFB3FA3006	CFB3FA3106
WFI-Quality Water	Flexsafe®	200L	No	CFB3FA3009	CFB3FA3109

### Your Customized Formulations

Our Buffer & Media Specialists will support you to create the solution that perfectly matches your expectations. For critical raw materials, you can either request specific suppliers or rely upon our established global network of qualified suppliers. Customized primary and secondary packaging and release assays are also available upon request to our specialists.

For more information, please contact your Sartorius Sales Representative or send your contact details to:

Europe | Asia: CellCultureMedia.EU@sartorius.com America: CellCultureMedia.NA@sartorius.com

<sup>\*\*</sup> ADR: International Carriage of Dangerous Goods by Road

# Sales and Service Contacts

For further contacts, visit www.sartorius.com

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