CHEM+POUR® FLEXIBLE PACKAGING TECHNICAL GUIDE

lifecycle Biotechnologies

www.lifecyclebio.com

CHEM+POUR
A Novel Approach to Reagent Fills

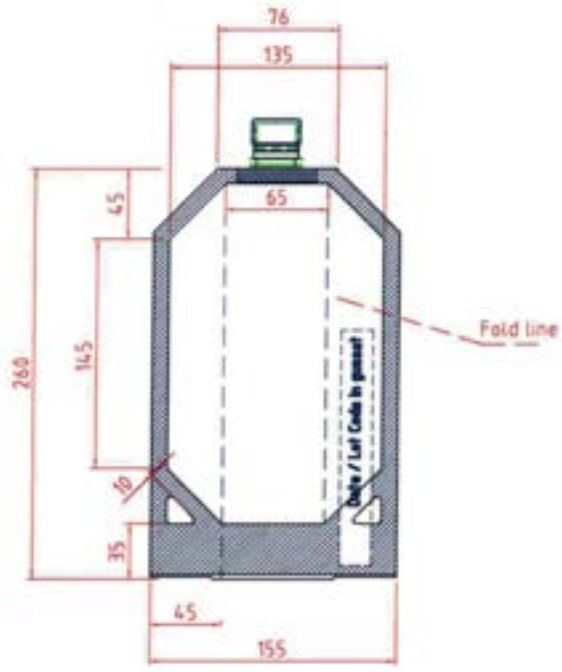
Table of Contents Page

Lifecycle's CHEM+POUR flexible reagent bags were designed around a growing need of performance packaging with sustainability aspects and economical enough for industrial applications for both 4L and 1L fills. Accordingly, Lifecycle has developed a dedicated fill line around these bags and with increased batch volume capacity to meet both internal and client needs.

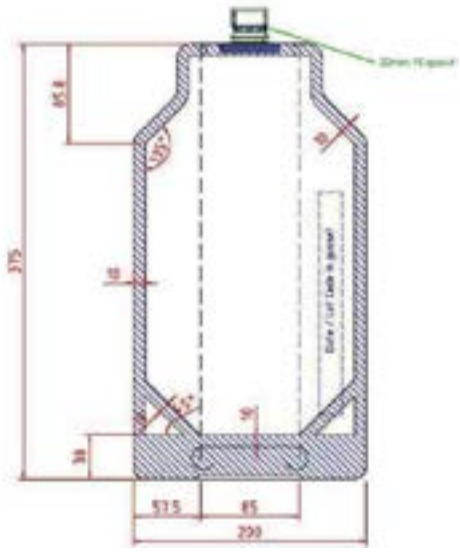
The multi-laminate bags are panel-constructed to stand without support and include viewing window for content and volume determinations. Although they are manufactured with composite polymeric layers, Lifecycle developed a recycling program to limit their environmental impact. For most life sciences applications, CHEM+POUR will replace glass or plastic bottles with improved performance, safety and sustainability.

This guide will help Lifecycle's clients understand our enthusiasm around this package and answer most technical and application questions to help make the decision to move use CHEM+POUR.

CHEM+POUR 1L, 3068I



CHEM+POUR 4L, 3064I



CHEM+POUR
Physical Properties

CHEM+POUR bags are constructed in unique, space saving manner so they stand freely without support, much like a rigid bottle. The bag film structure consists of multiple polymeric layers to provide the necessary strength and performance to withstand the rigors of sterilization, filling, shipping and product use, with familiar low density polyethylene. The pour spouts also constructed of polyethlene. Side panels consisting of the same film structure without the printed layer that allows for clear viewing of the contents.

The CHEM+POUR film properties are given below. For many applications, such as cleanroom reagents and hazardous chemicals, filled CHEM+POUR bags are packaged within a secondary LDPE overwrap for added protection that approximates gas transmission rates near to glass bottles.

Property	***Typical Values***
Laminate Thickness	0.2 mm
Basis Weight	191 g/m2
Seal Strength	10 Kg/15mm
Oxygen Transmission	2.7 cc/100in^2/day
Moisture Transmission	0.2 g/100 in^2/day

CHEM+POUR
Chemical and Biocompatibility

Reagent	Max Conc.	Compatibility
Acetic Acid	10%	R
Acetic Acid	25%	L
Dimethyl Sulfoxide	10%	R
EDTA	500mM	R
Ethyl alcohol	80%	R
Ethyl alcohol	90%	NR
Hydrochloric Acid	6N	R
Hydrogen Peroxide	10%	R
Isopropyl Alcohol	80%	R
Isopropyl Alcohol	99%	NR
Methyl alcohol	80%	R
Methyl alcohol	90%	NR
Phosphate Buffer	100mM	R
Phosphate Buffered Saline	10X	R
Sodium Azide	5%	R
Sodium Chloride	0.9%	R
Sodium Hydroxide	5N	R
Sodium Hypochlorite	6%	R
Sulfuric Acid	200mM	R

CHEM+POUR bags were designed to be sterilized by gamma irradiation for aseptic fills on Lifecycle's automated fill lines. Through our experience, we have found our bags to be compatible with most reagents and chemicals used in for Life Sciences applications. The table to the left includes several that have been specifically evaluated in our laboratories.

R Recommended. No change observed, nor visible indication of chemical attack after more than 12 months.

L Limited or short-term Use. Some visible changes in physical properties evident.

NR Not Recommended

Irradiated and filled CHEM+POUR bags were evaluated by FTIR, HPLC, DSC and direct cytotoxic effects following incubation at 57°C for 96 hours. The table to the right summarizes the data indicating a very low level of package extractables that could either interfere with assays or impact cellular growth with reagents packaged in CHEM+POURs.

Method	Results
Fourier-Transform Infrared Spectroscopy Scans	Scans indicate no change after 96 hours
Cytotoxicity by Minimal Essential Elution Assay USP <87>	No cell lysis or intracytoplasmic granules evident after 96 hours
High Performance Liquid Chromatography Transition (ACN-Water)	The number of transmission peaks remained the same after incubation
Differential Scanning Calorimetry	Conforms with polyethylene standards following incubation

CHEM+POUR Manufacturing

Initially developed for proprietary products, Lifecycle developed high-speed, aseptic filling and packaging capabilities employing this unique package. We offer custom filling for strategic clients in the life sciences laboratory and production spaces seeking a better alternative to traditional plastic or glass.

Lifecycle has added additional filling capacity for CHEM+POUR:

- Up to 12,000L batch size
- Aseptic fill volumes between 250mL and 4L supported by USP <71> testing.
- Able to fill acids, bases and solvent-based products

CHEM+POUR is the ideal replacement for rigid bottles since the space-saving design and flexible nature take up less space on production shelves. An added practical benefit is users don't experience the "glug" associated with rigid bottles since the bags collapse as the are emptied.

CHEM+POUR Sustainability

Life Sciences packaging is a paradox because we must balance purity and safety against cost. Most single use containers cannot be recycled since residue or the multi-layer construction are not accepted at most recycling center. Renewed awareness to the large volumes of plastic pollution entering the environment as a planetary threat is a concern with most business leaders. We developed CHEM+POUR to answer some of these problems.

<ANSWER 1: WEIGHT>

Does it seem trivial that the average 4L CHEM+POUR weighs only 49 grams while a 4L round handle jug is 140 grams? A typical pallet shipment of filled product contains 144 units. That translate to 20Kg of plastic bottle waste verses 7Kg for the CHEM+POUR, not to mention the shipping cost savings you will see!

<ANSWER 2: VOLUME>

The square stand-up design of the CHEM+POUR means 25% higher shipping density over bottles, meaning shipping costs savings while requiring less space on your shelves. Where a few bottles will fill your trash can, the same number of spent CHEM+POURs will only require a fraction of the space!

<ANSWER 3: CRADLE-TO-GRAVE-DESIGN>

Where most recycle programs won't accept used CHEM+POURs, we want them back so they won't end up in the landfill. We will send you a drum container and, once filled, just sent it back to us. We shred them and include them in the plastic stream that make those very drum containers. All we ask is you rinse them out as any bottle. It's pretty simple.

We Are Lifecycle

Our story began in 1978 and these 42 years of experience have made us who we are today

❑Highly Experienced Staff

Integrated Production, Chemists, Scientists, Engineers, QA/QC/Reg, Sales & Marketing and Administrative Professionals to solve your problems

❑Capabilities

- 10L - 12,000L batch capacity with aseptic filling and bagging
- Automated, semi-automated and manual fill available
- Large part PE & PP blow molding
- Process, formulation and assay development
- Global regulatory, sourcing and logistics management
- Full analytical chemistry support
- Personalized, technical and immediate customer support

Lifecycle Biotechnologies Headquarters

❑Locations

- Loveland, CO: Reagent Manufacturing
- Cleburne, TX : HQ, Reagent and Plastic Production, Laboratories and Innovation Center
- Cleburne Texas: (Coming late 2021) Innovation Center & Laboratories

For more information about Lifecycle Biotechnologies, our products, and our manufacturing capabilities, please contact us.

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