

## CONTAINER HAVING VORTEX BREAKER AND SYSTEM

## CROSS-REFERENCED TO RELATED APPLICATIONS

This application claims the benefit of U.S. Provisional Patent  
5 Application No.: 61/130,349, filed on May 30, 2008, the entire contents of  
which are incorporated by reference herein.

## FIELD OF THE INVENTION

This invention relates to a disposable container having a vortex breaker  
10 at its outlet and to a system utilizing the container.

## BACKGROUND OF THE INVENTION

Prior to the present invention, fluids have been processed in systems  
that utilize stainless steel containers. These containers are sterilized after use  
15 so that they can be reused. The sterilization procedures are expensive and  
cumbersome as well as being ineffectual at times.

In order to provide greater flexibility in manufacturing and reduce the  
time needed to effect valid regeneration, manufacturers have begun to utilize  
disposable sterilized bags that are used with each product batch. An example  
20 of use of these disposable bags is in a system for producing proteins by  
biological processing wherein the protein is derived from growing cells and  
then recovered. A problem occurs at the bag outlet where the fluid is removed  
from the bag. When the fluid is removed, one or more conical shaped vortices  
are formed from a conical column of gas present in the bag. This is  
25 undesirable since a vortex will cause mixing of the fluid with gas which  
results in undesirable foaming. A vortex will also entrain air into the protein  
filled fluid. This is undesirable since air can denature protein. Air  
entrainment into the flow stream also causes problems with processing  
equipment such as gages, sensors, pumps and filters.

30 Accordingly, it would be desirable to provide a disposable container  
for fluids having means for minimizing or preventing foaming at the container  
outlet.

## SUMMARY OF THE INVENTION

A disposable container for a fluid having an inlet and an outlet is provided having a device for minimizing or preventing foaming of fluid at the outlet.

5           A system is also provided that utilizes the container with a unit operation down stream of the container such as a normal flow filtration (NFF) unit or the like whereby treated fluid is recovered. For example, the effluent from the container can be directed through clarification depth filters, pre-filters or microporous membrane filters. Examples of specific unit operations  
10 include clarification, buffer and media preparation and virus removal.

The outlet is provided with a vortex breaker comprising a solid surface that initially directs fluid away from the outlet. Openings are provided adjacent the solid surface which permits fluid to enter the outlet. The initial direction of fluid away from the outlet minimizes or prevents the formation of  
15 one or more vortices at the outlet.

## BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a schematic view of a system of this invention.

Figure 2 is a perspective view of a vortex breaker positioned adjacent  
20 an outlet of the container of this invention.

## DESCRIPTION OF SPECIFIC EMBODIMENTS

The disposable container of this invention is formed of monolayer or multilayer flexible walls formed of a polymeric composition such as  
25 polyethylene, including ultrahigh molecular weight polyethylene, linear low density polyethylene, low density or medium density polyethylene; polypropylene; ethylene vinyl acetate (EVOH); polyvinyl chloride (PVC); polyvinyl acetate (PVA); ethylene vinyl acetate copolymers (EVA copolymers); blends of various thermoplastics; coextrusions of different  
30 thermoplastics; multilayered laminates of different thermoplastics; or the like. By "different" it is meant to include different polymer types such as polyethylene layers with one or more layers of EVOH as well as the same polymer type but of different characteristics such as molecular weight linear or branched polymer of fillers and the like. Typically medical grade and

preferably animal-free plastics are used. They generally are sterilizable such as by steam, ethylene oxide or radiation such as beta or gamma radiation. Most have good tensile strength, low gas transfer and are either transparent or at least translucent. The container is provided with an inlet, and an outlet.

- 5 The outlet is provided with a vortex breaker positioned adjacent the outlet and secured to the inside surface of the container such as by heat sealing or with an adhesive. Optionally, the vortex breaker can be molded into the outlet structure. In a preferred embodiment, the disposable container is positioned within a solid support container for ease of filling and emptying the container  
10 of fluid.

Referring to Figure 1, the container of this invention 10 having inlet 9 and containing fluid 12 includes a vortex breaker 14 secured to the inner surface 16 of the container 10 at outlet 11. A pump 18 is provided to direct the fluid 12 through the outlet 11 to a downstream unit operation such as a  
15 filtration unit 20 as shown. An example of a process utilized with the system of this invention is the production of proteins derived from growing cells which are lysed to release cellular protein. The protein then is isolated by filtration to separate cell debris from the protein. The filtrate is directed through conduit 22 to a point of use or to be further treated.

- 20 Referring to Figure 2, a vortex breaker 30 of this invention is shown. The vortex breaker comprises a solid surface 32 that can be any shape including circular, as shown or polygonal. The base 34 is sealed to the inner wall 16 of container 10. The vortex breaker 30 is positioned adjacent outlet 11. The solid surface 32 is supported by supports 36 attached to solid surface 32  
25 and base 34. The vortex breaker 30 initially causes fluid to be directed away from outlet 11 as indicated by arrows 38 and 40 and then is directed to outlet 11 through the spaces between supports 36 as indicated by arrows 37 and 39. By operating with this vortex breaker, formation of vortices is minimized or prevented. The vortex breaker may also be formed as part of the outlet 11.

## CLAIMS

What is claimed:

1. A disposable container for a fluid which comprises:
  - 5 a closed volume formed of flexible walls,
  - an inlet through one of said walls,
  - an outlet through one of said walls,
  - and a vortex breaker positioned adjacent said outlet and secured to an inner surface of said walls, said vortex breaker adapted to direct fluid
  - 10 initially away from said outlet and then through said outlet.
2. A fluid processing system which comprises:
  - the container of Claims 1,
  - a unit operation downstream of the container and
  - 15 one or more conduits to effect flow from said container to said unit operation.
3. The container of Claim 1 wherein said vortex breaker comprises a solid surface secured to a base by spaced apart solid supports.
- 20 4. The system of Claim 2 wherein said vortex breaker comprises a solid surface secured to a base by spaced apart solid supports.