



Bioclear™ 11: an alternative film for Cellbag™ bioreactors

Designed for WAVE Bioreactor™ systems

November 2014

Imagination at work

Agenda

Background

Bioclear™ 11 film description

Cellbag™ offering

Comparison to Bioclear 10 film

Summary



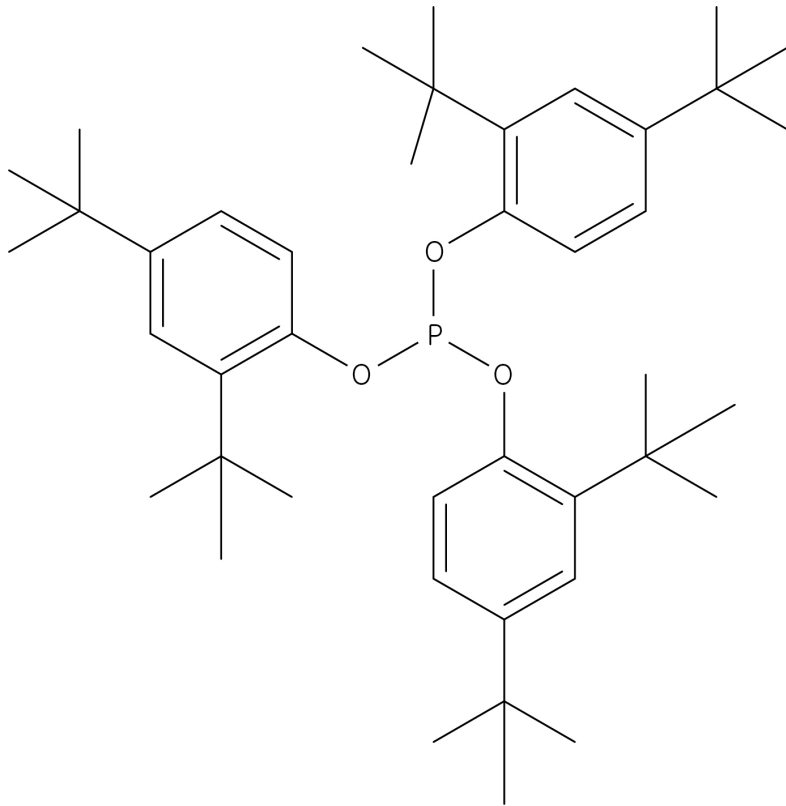
Background



Bioclear™ 11 film: a response to industry needs



The industry experienced inhibited cell growth in certain applications



Tris-(2,4-di-tert-butylphenyl)-phosphite (TBPP), often referred to under the trade name Irgafos™-168

Many bioreactor films are brought under scrutiny

Industry published on the topic¹:

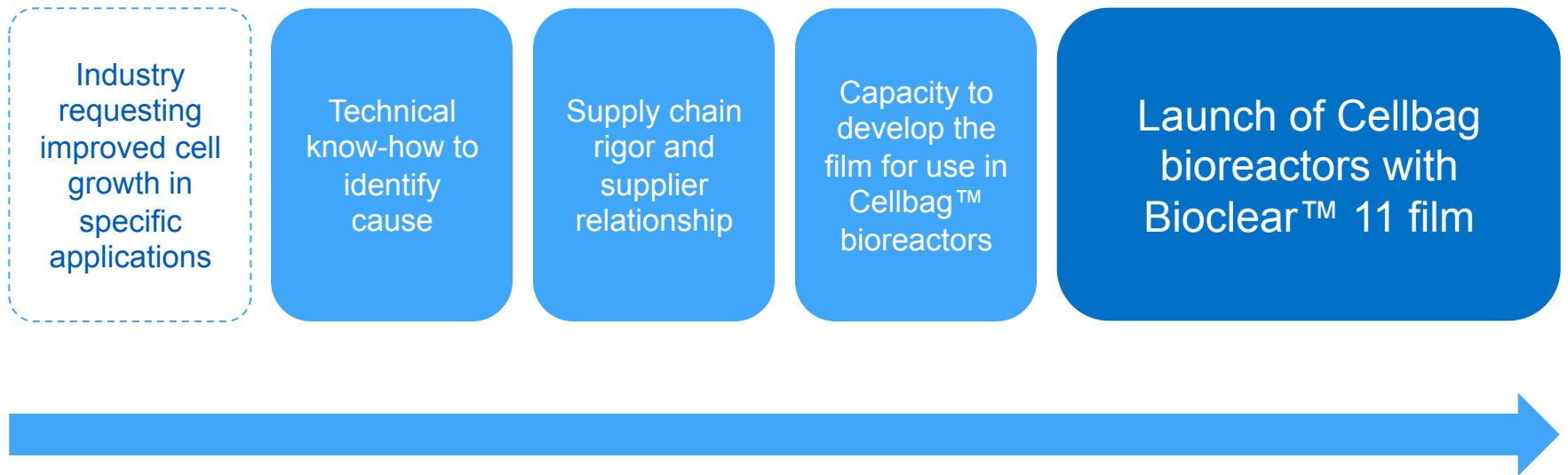
Root cause identification: TBPP degradation product is harmful to cells

GE Healthcare Life Sciences has resolved this issue by introducing Bioclear™ 11 film

¹Hammond M. *et al.* Identification of a leachable compound detrimental to cell growth in single-use bioprocess containers. *PDA J. Pharm. Sci. and Technol.* **67**, 123-134 (2013).



GE Healthcare worked with a supplier to develop a low-antioxidant film



Bioclear™ 11 film description



GE Healthcare launches Cellbag™ bioreactors with Bioclear™ 11 film



The Bioclear 11 film

- offers improved cell growth in cell-sensitive applications compared to Bioclear 10 film
- is a low-antioxidant film
- is developed for use in Cellbag bioreactors
- is available in standard and custom Cellbag bioreactor formats



The Bioclear™ 11 film is a low-antioxidant version of the Bioclear 10 film



Consistent robust film design

Same materials as Bioclear 10 film, but with changes in the outer low-density polyethylene layer.

- Achieved overall low levels of TBPP* by completely removing it from the outer film layer where most of it resides

Procured from same supplier

Maintained physical attributes

*Often referred to under the trade name Irgafos™-168



Cellbag™ offering



Cellbag™ bioreactor designs available in multiple formats

	Bioclear™ 11 film
Products	45 new standard products with same design as Bioclear 10 film
Bag types	Basic, Oxywell2, screw cap, perfusion, ReadyMate™, optical pH, and DOOPT II
Cellbag sizes	2L to 200 L Cellbag bioreactors, standard and custom
M*Bag sizes	20 L and 50 L M*Bag mixing chambers, standard and custom
Hardware compatibility	No change

[For a complete list of product numbers, please click here](#)



Comparison to Bioclear™ 10 film



Product documentation

The Bioclear™ 10 to Bioclear 11 film change:

- change control might be required for the end user
- does not affect GE Healthcare documentation or regulatory aspects
- has the same certificate of quality
- has the same regulatory support documentation offered for products used in regulated environments

Access regulatory support files and more at
www.gelifesciences.com/rsf



Manufacturing processes



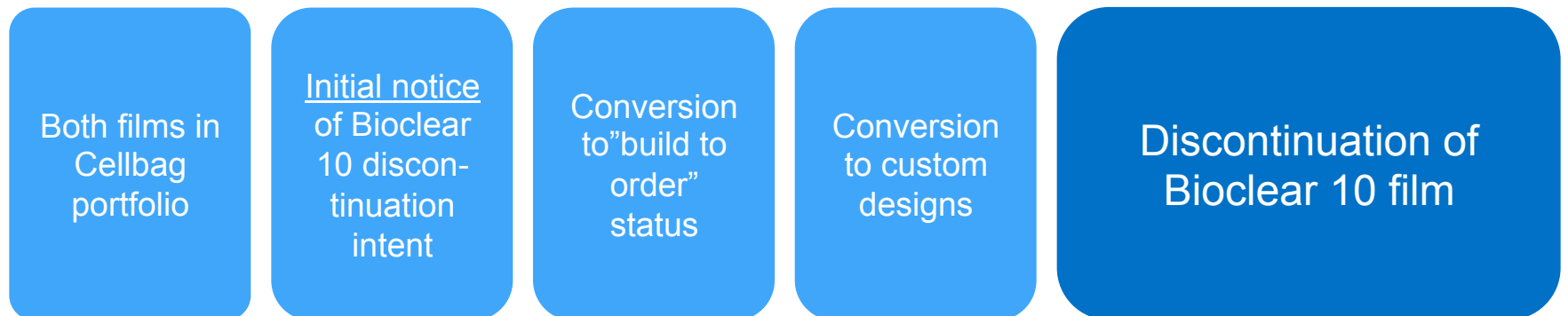
The Bioclear™ 10 to Bioclear 11 film change:

- does not affect the film or the bag manufacturing processes



We will continue to supply Cellbag™ bioreactors with Bioclear™ 10 film for now

Ample time for discontinuation change control will be provided



Future investment will be made in the Bioclear 11 film (R&D, market support, etc.)



Summary



Bioclear™ 11 film: for improved cultivation of specific cell lines in Cellbag™ bioreactors



Developed by GE Healthcare with dedication to product quality and supply-chain rigor

Response to industry observations

Result of a close collaboration with customers

Available now!



www.gelifesciences.com

GE, imagination at work, and GE monogram are trademarks of General Electric Company.

Bioclear, Cellbag, ReadyMate, and WAVE Bioreactor are trademarks of GE Healthcare companies.

Irgafos is a trademark of BASF SE.

ReadyMate is covered by US patent number 6,679,529 B2 owned by Johnson & Boley Holdings, LLC and licensed to GE Healthcare companies.

© 2014 General Electric Company – All rights reserved. First published Nov. 2014.

All goods and services are sold subject to the terms and conditions of sale of the company within GE Healthcare which supplies them. A copy of these terms and conditions is available on request. Contact your local GE Healthcare representative for the most current information.

GE Healthcare Bio-Sciences AB
Björkgatan 30
751 84 Uppsala
Sweden



