

24 January 2020

**Subject: Environ® LpH® and Environ Vesphene® Family of Disinfectants**

Dear Valued Customer:

We have important information to share with you. We are expecting an impact to the future availability of our Environ LpH and Environ Vesphene family of products. The European Union's Biocidal Products Committee (BPC) is expected to issue an opinion recommending non-approval of chlorophene (ortho benzyl para chlorophenol, or OBPCP) as an active ingredient in any private area and public health area disinfectants (Biocidal Product Type 2).

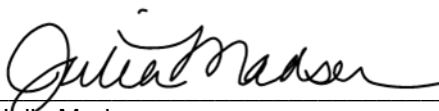
Despite the best efforts of our European supplier and STERIS to address the concerns of the BPC, it appears that the BPC will issue a non-approval recommendation. While the opinion has not been published, we are confident that this regulatory action is imminent. This will directly impact the continued availability of Environ LpH and Environ Vesphene formulations. Therefore, we have chosen to notify our Customers in advance of the opinion to allow time to plan for this change.

We anticipate these products to be available for sale for approximately another twelve months (March 2021). In addition, these products may be used for six months after the stop sale date (September 2021).

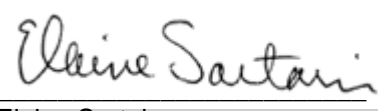
Our entire team is here to support your transition to a new disinfectant program. Your local Account Manager and Technical Services team will be reaching out to discuss plans to help you meet your individual needs. As a result of this forthcoming regulatory action, we have shifted our resources into developing bridging documentation to support a smooth transition from existing formulas to non-chlorophene based formulas with similar characteristics and performance.

We value our Customer partnerships and understand how important supply security and product quality are to you. We have maintained these products for over 15 years and will continue to support future formulas with the same level of commitment. We apologize for the inconvenience this will cause you and we will do everything we can to help you move forward.

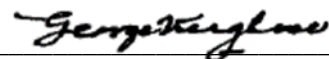
Best regards,

A handwritten signature in black ink, appearing to read "Julia Madsen".

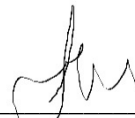
Julia Madsen  
Vice President and General Manager

A handwritten signature in black ink, appearing to read "Elaine Sartain".

Elaine Sartain  
Vice President Marketing

A handwritten signature in black ink, appearing to read "George Verghese".

George Verghese  
Senior Director Technical Service

A handwritten signature in black ink, appearing to read "Frédéric Bar".

Frédéric Bar  
Area Sales Director, Europe

For questions, please contact us at: [lifesciences@steris.com](mailto:lifesciences@steris.com) or contact your local Account Manager.

Attachments:

1. Notification: Impact to Future Availability of Environ LpH and Environ Vesphene II Family of Disinfectants
2. Frequently Asked Questions

24 January 2020

**Notification: Impact to future availability of Environ® LpH® and Environ Vesphene® Family of Disinfectants**

The European Union's Biocidal Products Committee (BPC) is expected to formally reject the use of chlorophene (ortho benzyl para-chlorophenol, or OBPCP) as an active ingredient in any private area and public health area disinfectants (Biocidal Product Type 2). Chlorophene is an active disinfectant ingredient in the Environ LpH and Environ Vesphene family of products.

Therefore, the continued availability of these chlorophene containing products is at risk. We anticipate being able to continue selling the following products through March 1, 2021.

Product Name	Product Number	Package Size
Environ LpH se Disinfectant	641208EC	4 x 3.78 L bottle
Environ LpH st Disinfectant	641129EC	144 x 59.1 mL pouch
Environ Vesphene se Disinfectant	641408EC	4 x 3.78 L bottle
Environ Vesphene st Disinfectant	641329EC	144 x 59.1 mL pouch

We have allocated our resources to develop bridging documentation to support a transition from existing formulas to other STERIS disinfectants with very similar characteristics and performance. Your local Account Managers will be reaching out to you to support you through this transition.

Please forward this notification to others within your organization who are responsible for change control.

Best regards,

A handwritten signature in blue ink, appearing to read "Jon McCabe", written over a horizontal line.

Jon McCabe  
Sr. Global Product Manager  
Formulated Chemistries, STERIS Life Sciences

Attachments

1. Environ LpH and Environ Vesphene Family of Disinfectants
2. Frequently Asked Questions

24 January 2020

## Frequently Asked Questions (FAQs)

Notification: Impact to future availability of Environ® LpH® and Environ Vesphene® Family of Disinfectants

### 1. What products are affected?

Product Name	Product Number	Package Size
Environ LpH se Disinfectant	641208EC	4 x 3.78 L bottle
Environ LpH st Disinfectant	641129EC	144 x 59.1 mL pouch
Environ Vesphene se Disinfectant	641408EC	4 x 3.78 L bottle
Environ Vesphene st Disinfectant	641329EC	144 x 59.1 mL pouch

### 2. Are there other names for chlorophene?

Chlorophene is also referred to as 2-benzyl-4-chlorophenol (IUPAC nomenclature), clorofene, ortho-benzyl-para-chlorophenol, o-benzyl-p-chlorophenol, and OBPCP.

### 3. Why is STERIS required to phase out disinfectants containing chlorophene?

During the Biocidal Product Regulation (BPR) review of active ingredient dossiers, the Biocidal Product Committee concluded that chlorophene would not be approved for continued use in disinfectants sold for use in the EU.

### 4. When will STERIS stop selling these products?

We will sell these products for as long as possible. We anticipate the stop-sell date will be 1 March 2021.

### 5. How will STERIS allocate products to Customers?

It is imperative that you work closely with your STERIS Account Manager on your plans. We will allocate product to our Customers by the following priority:

- a. Existing purchase orders
- b. Purchase order forecasts provided to STERIS
- c. Historical purchases
- d. Purchase orders submitted within two months prior to the date we must stop selling.

### 6. When will we have to stop using the products?

End users may continue to use these products until 1 September 2021.

### 7. What are our options for replacing products?

- a. Revalidate with STERIS quaternary ammonium disinfectants
  - i. Vesta-Syde® SQ Disinfectant is a concentrated formula and is available in the same package sizes as the Environ products: 3.78 L bottles and 59.1 mL pouches
  - ii. Vesta-Syde SQ Ready To Use Disinfectants is available as a 1:64 or 1:128 dilution.

8. What would STERIS recommend for a new surface disinfection program?  
STERIS has a full range of products for surface disinfection. Please work with your local Account Manager to select the products that best meet your contamination control needs.
  
9. Are there any benefits of quaternary ammonium disinfectants over phenolic disinfectants?  
In our experience, STERIS quaternary ammonium disinfectants and phenolic disinfectants perform very similarly for most Customers and in most situations. The primary advantages of STERIS quaternary ammonium disinfectants over STERIS phenolic disinfectants is increased use-dilution stability and global availability.
  
10. What is the long-term future of phenolic disinfectants?  
STERIS believes phenolic disinfectants can offer advantages over other disinfectants for some Customers or in some situations. Based on discussions with our suppliers, we expect phenolic active ingredients to be available in the United States and around the world for the foreseeable future. STERIS will continue to offer phenolic disinfectants as an option to our Customers outside of the EU because of their potential advantages and to meet our Customer needs.
  
11. How does STERIS keep current with the changing regulations?  
We have an experienced, global team of regulatory specialists who monitor the laws in each of the countries where we offer products. Our team is supplemented by regulatory consultants who ensure we are prepared for any changes in local laws. We continually invest in our expertise to ensure we can maintain a reliable supply of products to you. STERIS has maintained these formulations and our regulatory compliance for over 15 years of evolving regulations.