

# **EU BPR Regulatory Update**

December 2024

There is still time to place Citriodiol®-based insect repellent products on EU national markets.

## **Updated Timeline**

Citrefine's support of the Citriodiol® dossier (generic name Eucalyptus citriodora oil, hydrated, cyclized (EC Oil (H/C))) continues with two early working groups attended in 2024.

Ongoing delays in ECHA's review schedule and recent communications with our eCA mean the estimated Product Authorisation deadline for Citriodiol®-based product dossier submissions is now November 2027, giving customers the time and opportunity to continue to place products on the EU market. Please see our <u>updated timeline</u> on our website.

New deadline for submission of Citriodiol®-based

Product Authorisation (BPR) dossiers: November 2027

This delay beyond 2024 is possible after the European Commission extended the end of the BPR's Review Programme from December 31st 2024 to December 31st 2030.

#### Take Action Now to Maintain *Existing* Citriodiol® Registrations

Many biocidal product registrations issued by Member States under transitional rules were set to expire at the end of the BPR Review Programme, which until recently was December 31, 2024. This includes Citriodiol®-based products registered under PT19. Now that the Review Programme has been extended, it is important to check in with the local authority to confirm that any registrations your company holds for Citriodiol®-based products are automatically extended beyond this date. These registrations may expire if not proactively renewed before year end. This can be the case even if you are a sub-registrant and Citrefine has extended the master registration.

ACTION →→→ Review existing Citriodiol®-based product registration deadlines and take steps to ensure they remain valid for 2025 and beyond.



# Next Steps to Avoid the "Market Freeze"

If you are considering adding a new Citriodiol®-based insect repellent product to your product line in Europe within the next 6 years, you need to start the process to avoid being frozen out of the market. The "market freeze" is the time immediately after Union listing of EC Oil (H/C) (est. Nov 2027) when your company will no longer be allowed to use the quicker / simpler registration process allowed under member state national rules to place a repellent product on the market. Instead, you would:

- First have to apply for authorisation of the product under the more intensive and more costly BPR rules,
- Then go through the lengthy evaluation process (typically 3+ years) and
- Only after the product is evaluated and approved, be able to launch the product.

In other words, if you miss this Nov 2027 deadline you will be frozen out of the European market until approval of your product authorisation dossier, which could be 2031 or beyond.

ACTION  $\rightarrow \rightarrow \rightarrow$  If your company wants to manufacture and/or launch its <u>own</u> dermally applied or spatial insect repellent (like a plug-in device or diffuser) before 2031, take steps now to notify or register the product in any EU countries where you plan for the product to be sold. Note: the time taken to gain the national approval must also be taken into account to ensure the approval is received before the start of the freeze period.

#### **How Citrefine Can Help**

If you need a letter of intent to supply, information about active substance endpoints to complete internal safety assessments, or a letter of access to the same for national product registrations, Citrefine can support this process. Bridging arguments to our product data may also be possible depending on your formulation. Contact us to put in place a supply agreement that facilitates this data access.

ACTION  $\rightarrow \rightarrow \rightarrow$  If your company wants to manufacture and/or launch <u>one of Citrefine's</u> dermally applied products included in our Biocidal Product Family (BPF) before 2031, contact us for support.

Citrefine has developed a full product dataset with robust efficacy data to support registration during the transitional phase and under the BPR. We can provide access to active substance and product data to support your product launch. NOTE: Even with a complete dataset, transitional registrations in some countries can take 2 or more years, so don't delay if you want to avoid the "market freeze"!



| 1. Citrefine's Biocidal Product Family - updates shown in yellow highlight |             |  |
|--|-------------|--|
| Format   | Citriodiol® | Comments   |
| Pump Spray   | 30%         | Our representative product in EC Oil (H/C) dossier   |
|  |             | This successful product is an alcohol-based pump spray with high levels of                     |
|  |             | efficacy against <i>Culex</i> , <i>Aedes</i> and <i>Anopheles</i> genera of mosquitoes, midges |
|  |             | and ticks.   |
| Compressed Gas<br>& Bag-on-Valve<br>Aerosol                                |             | Nitrogen compressed gas propellant using EcoValve (or equivalent)                              |
|  |             | technology; no bag insert required OR  |
|  |             | Nitrogen compressed gas propellent using bag-on-valve technology.                              |
|  |             | NEW efficacy testing supports the use of this formula as a fabric spray to                     |
|  |             | repel <i>Culex</i> mosquitoes and ticks (not combined with on skin use).                       |
|  |             | FURTHER ongoing efficacy testing aims to support use of this formula as a                      |
|  |             | surface treatment to repel bedbugs.  |
| Pump Spray   | 10%         | Hydro-alcoholic spray with child-friendly scent specifically formulated for                    |
|  |             | daily application to hair to repel head lice. Additional efficacy testing is                   |
|  |             | expected to be complete by end of 2024.  |
| NEW  | 10%         | Hydro-alcoholic spray for application to dogs' coats to repel ticks. Preliminary               |
|  |             | efficacy testing is complete.  |
| Emulsion Spray   | 19.9%       | This non-flammable mosquito and tick repellent product shows strong levels                     |
|  |             | of efficacy, low alcohol content and a pleasant feel on the skin.                              |
|  | 15%         | Product to be used as fly and tick repellent for application to horses. Field                  |
|  |             | testing for flies and tick testing is complete.  |
|  | 9.9%        | This alcohol-free mosquito and tick repellent product has no hazard                            |
|  |             | classification, a gentler scent and supports a moisturizing claim.                             |
| Roll-on/Lotion   | 30%         | This is a lotion product which has high levels of efficacy against <i>Culex</i> , <i>Aedes</i> |
|  |             | and Anopheles mosquitoes as well as ticks with two unique methods of                           |
|  |             | application.   |

All products are supported by 3-year stability data and, where relevant, in standard and recycled content packaging. NEW products and uses above are still under development. Inclusion in the final BPF is dependent on success of this development. Please be in touch for details as to where each project stands today.



## Welcome to our new customers

Welcome to our new customers who have now joined us from Limaru. Citrefine now supply direct to our customers and no longer distribute via Limaru. We look forward to working with all our customers more closely to best support the future of your Citriodiol®-based products in your business. We hope that the instructions provided by our Operations team have been helpful. As an importer, you may already be aware of your obligations to also notify the hazards of the imported chemicals to the Classification and Labelling (C&L) inventory. However, if you have any questions, feel to contact us.

# New efficacy standards under the BPR:

Many authorities continue to require efficacy data to meet the new <u>BPR guidance standards</u> for PT19 product registrations or renewals at the national level. In doing so, the authorities require the claimed application rate to be an amount at which the product passes human health risk assessment. Efficacy data supporting Citrefine's BPF has been conducted to this new standard and these studies are available to Citriodiol® customers to support their new or amended national registrations.

#### **New product uses - Spatial repellents**

Due to increasing interest in spatial repellents, we have carried out preliminary efficacy and risk assessments to determine Citriodiol®'s suitability for use in both indoor and outdoor spatial repellent devices such as in candles and plug-in devices. If you have an interest in this type of product, please get in touch and we would be happy to share our findings and work with you to help bring these types of products to market.

#### **Regulatory webinar January 2025**

We are pleased to be hosting a webinar in January 2025. This will be the first in a series of webinars, with this first one focusing on the how to notify repellent products in France during the transitional phase and options for linking these products the Citrefine Biocidal Product Family (BPF) to avoid the market freeze.

We will be sending further details about this along with a link to register for the webinar shortly. Register your interest here.



To learn more about bringing Citriodiol®-based products to market in Europe, please contact a member of our regulatory affairs team listed below:

Genevieve Faherty Leanne Webster

Regulatory Affairs Director Senior EU Regulatory Affairs Manager

Claire Stewart EU Regulatory Affairs Officer genevieve.faherty@citrefine.com leanne.webster@citrefine.com claire.stewart@citrefine.com

Questions specific to product classification or Safety Data Sheets can be directed to:

Eva Racz

Regulatory Affairs Manager

eva.racz@citrefine.com