



EU BPR Regulatory Update

Winter 2024

The **OPPORTUNITY** for your company to take advantage of the recent expansion of Citrefine’s Biocidal Product Family has been **EXTENDED** as has the time available to place your Citriodiol® products on the national markets in Europe.

Updated Product Authorisation Timeline

Despite the inclusion of a draft CAR opinion for Eucalyptus citriodora oil, hydrated, cyclized (EC Oil (H/C) or Citriodiol®) on R4BP3, further delays have slowed down EC Oil (H/C)’s progression to Union Listing. It is no secret that a bottleneck of active substances and Union-wide product and biocidal product families (BPFs) await final evaluation. Recent communications from our eCA indicate a full Working Group to review the EC Oil (H/C) dCAR will not take place before March 2025. We have pushed back our estimated Product Authorisation timeline to reflect this delay. See [updated timeline](#) attached.

**New estimated deadline for submission of Citriodiol®
Product Authorisation dossiers: April 2027**

Next Steps

This new timeline allows customers an additional year to register products under the transitional scheme with national authorities while preparing dossiers for Product Authorisation. Unlike other PT19 repellents for which full Product Authorisation dossiers are the only route to market, EC Oil (H/C) products can be placed on the market in a far more cost effective and faster way. For example, in countries that require only notifications at the national level (e.g. Germany and France), products can be placed on the market almost immediately. And for Member States that do require a data submission, the data requirements are substantially lower now than they will be at Product Authorisation stage (for example, at Product Authorisation an environmental risk assessment will be mandated whereas now, only a handful of countries require this). In other words, now is the time to take the next step and register your Citriodiol® products so you can continue selling these products with claims permitted on your national label throughout the market freeze (when the product dossier is evaluated under the BPR).



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1. Citrefine's Biocidal Product Family		
Format	Citriodiol®	Comments
Meta SPC 1 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 mosquitoes, including tropical use, and ticks.
Meta SPC 2 Compressed Gas & Bag-on-Valve Aerosol		Nitrogen compressed gas propellant using EcoValve (or equivalent) technology; no bag insert required.
		Nitrogen compressed gas propellant. Bag-on-valve technology.
		NEW efficacy testing supports the use of this formula as a fabric spray to repel mosquitoes (not combined with on skin use). Potential for tick claim.
		New efficacy testing supports use of this formula as a surface treatment to repel BEDBUGS. Additional efficacy testing is ongoing to support claims around preventing spreading of these pests.
NEW	10%	Hydro-alcoholic spray specifically formulated for daily application to hair to repel head lice. Efficacy testing in ongoing.
NEW	10%	Hydro-alcoholic spray for application to dogs' coats to repel ticks. Efficacy testing in ongoing.
Meta SPC 3 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. Fly field testing is complete.
Meta SPC 4 Emulsion Spray	9.9%	This alcohol-free mosquito and tick repellent product has no associated hazard classification, a gentler scent and supports a moisturizing claim.
Meta SPC 5 Roll-on/Lotion	30%	This is a lotion product with high levels of efficacy against mosquitoes and ticks and two unique methods of application.

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.



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New efficacy standards under the BPR:

Many Member State authorities are now requiring efficacy data to meet the new [BPR guidance standards](#) for PT19 product registrations or renewals at the national level. In so doing, the authorities will look to ensure that the claimed application rate is the same as the application rate used in the human health risk assessment. If you are joining the BPF family, you can be reassured that the data Citrefine is generating to support the final product range in the BPF is being conducted to this new standard with application rates tied to the human health and environmental risk assessments including the endpoints set forth in the current dCAR. These studies are available to customers to support their new or amended national registrations.

To learn more about EC Oil (H/C)'s evaluation timeline, new claims or available products within the BPF, please contact a member of our regulatory affairs team listed below.

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Note that our Senior European Regulatory Affairs Manager, Leanne Webster, is currently on maternity leave.