i-tech
Developers of Selektope®

ECHA's Public Consultation on Derogation Conditions for Medetomidine: Guidelines for the Submission of Information

Background information

In the European Union (EU), biocides are regulated under the *Biocidal Products Regulation* (BPR).[1] Article 5(1) of the BPR sets so-called *exclusion criteria*: biocidal active substances meeting one of these criteria shall not be approved. Nonetheless, a biocidal active substance meeting one of the exclusion criteria may still be approved if it meets any of the ***derogation conditions*** set in Article 5(2) of the BPR.

Medetomidine, the biocidal active substance **used in I-Tech's antifouling substance Selektope®**, is currently undergoing a process for the renewal of its approval under the BPR. The approval of Medetomidine is essential to allow Selektope® to remain on the market. In a recently adopted opinion, the *Biocidal Products Committee* of the European Chemicals Agency (ECHA) has concluded that Medetomidine exhibits endocrine-disrupting properties, which is one of the exclusion criteria which may prevent a biocide from being approved. I-Tech, as well as a number of experts involved in the assessment, disagree with these conclusions, but these have now been formally recognised by ECHA.

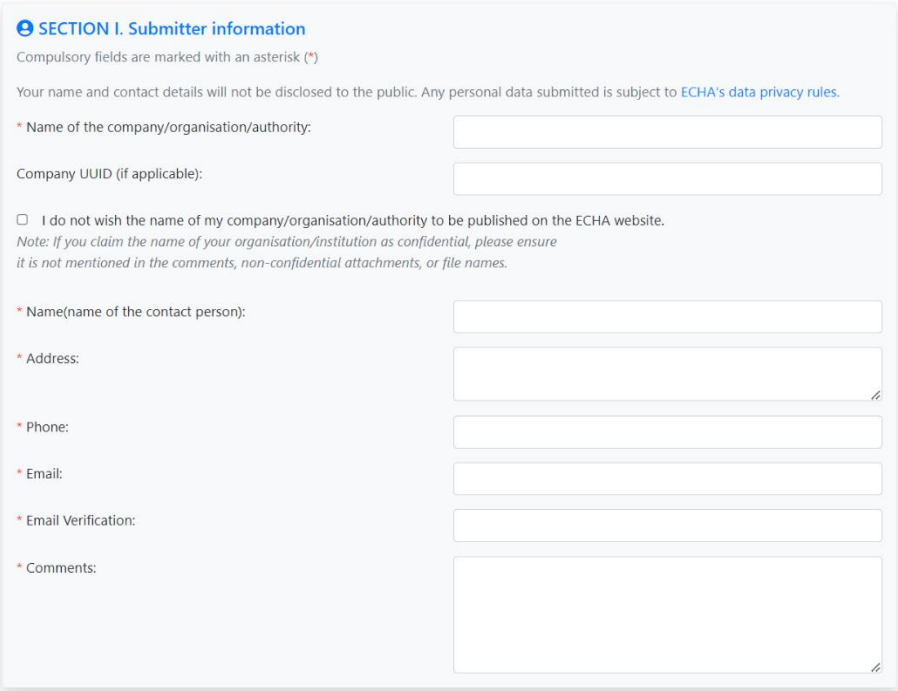
ECHA has now opened a **public consultation** to gather information on whether Medetomidine meets any of the derogation conditions. This consultation provides stakeholders with a valuable opportunity to present their views and evidence to ECHA, enabling them to advocate for the continued use of Medetomidine. By participating, stakeholders can contribute to a balanced assessment and ensure that their perspectives are considered in the decision-making process, in order to allow an essential biocide like Selektope® to remain on the market. Therefore, **we invite you to take part in the consultation following the steps outlined below. It will be possible to submit comments by 6 November 2024.**

To access the public consultation to submit your views, please use the following link, directing you to the official website of ECHA.

[1] Regulation (EU) No. 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products.

Step by Step Guide

I. Submitter Information

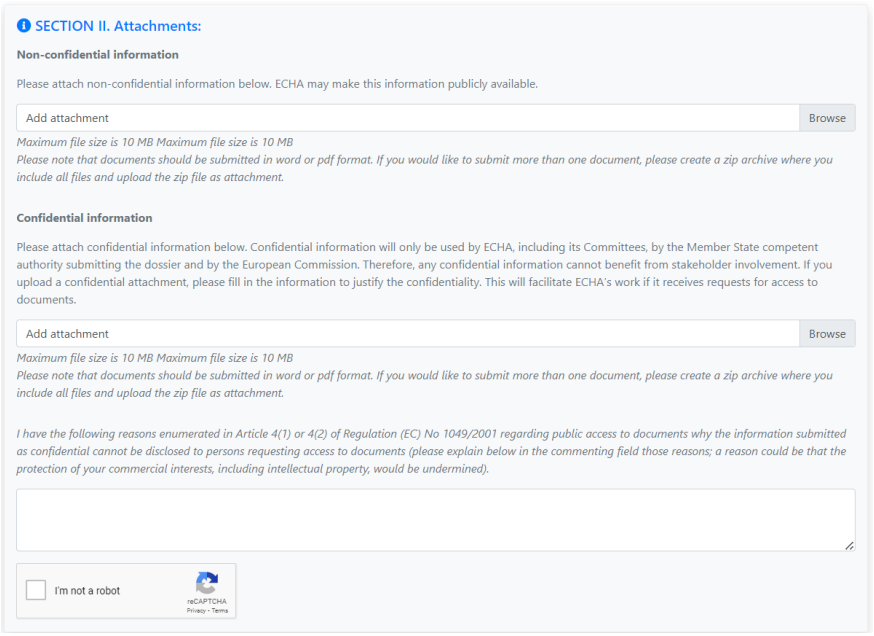


In this section, you will be asked to provide the name of your company as well as personal information.

If you wish to keep your submission anonymous, select the option '*I do not wish the name of my company/organisation/authority to be published on the ECHA website*' by ticking on the box. If you claim the name of your organisation as confidential, please ensure not to mention it elsewhere – i.e., in the comments, non-confidential attachments, or file names.

In the box for comments, you can include a summary of why you believe medetomidine meets derogation conditions, which you may explore in further detail in your attachments (see next section).

II. Attachments



In this section, you will have the opportunity to submit any documents that support your views and arguments. You can choose to submit these documents as either non-confidential or confidential. If you decide to submit confidential information, this will not be made available to the public and will only be used by ECHA, including its Committees, by the competent authority submitting the dossier (Norway), and Member State competent authorities for biocides as well as the European Commission.

According to Regulation (EC) No 1049/2001, persons requesting access to documents may still be allowed to consult information submitted as confidential, unless the owner of this information provides reasons why this should not be made available. If you do not wish your information to be disclosed in case of 'access to documents' requests, please provide reasons why in the box at the bottom; for example, this could be that the protection of your commercial interests, including intellectual property, would be undermined.

Please use referenced information as much as possible. Technical and scientific background to submitted information will have a higher impact on the process.

It would be relevant to attach documents regarding what alternatives are available for protection against barnacles, including technical reasons why Medetomidine is preferred and the financial consequences to a possible non-approval.

In addition, it is key to submit documents evidencing the belief that Medetomidine meets the derogation criteria set in Article 5 (2) of the BPR and therefore it may still be approved:

- Article 5 (2)(b): Evidence shows that the active substance is crucial for preventing or controlling a serious threat to human health, animal health, or the environment.
- Article 5 (2)(c): Not approving the active substance would cause more harm to society than the potential risks it poses to human health, animal health, or the environment

We believe that Medetomidine meets these criteria due to the following characteristics:

+ Targeted Impact: The active substance specifically targets barnacle larvae through a unique mode of action without harming them, minimising the risk for resistance development.
+ Proven Safety: Medetomidine has a well understood safety profile and meets stringent antifouling safety standards for humans and the environment. There are substantial safety margins and no risk for toxicity, including endocrine disruption, from antifouling products when risk mitigation measures are followed.
+ Minimal Environmental Impact: Medetomidine allows for effective and sustainable antifouling, with much lower biocides concentration in paints compared to alternatives. Medetomidine helps minimise the spread of invasive species while also protecting marine ecosystems.
+ Reduced Emissions: The active substance contributes to improved vessel efficiency, leading to lower fuel consumption and greenhouse gas emissions. Efficient fouling protection is essential to achieve both European and global CO_2 emission goals for the shipping industry.

After that, simply click on submit to complete the procedure and share your comments with ECHA.

Submit