Press Release
24 May 2023 17:00:00 CEST

Expert panel suggests changed classification of Selektope

Within the context of a re-registration process in EU, an advisory panel of experts from the European chemical agency ECHA has recommended that Medetomidine, the biocidal active substance used in Selektope, should be classified as an endocrine disruptor for humans. Selektope is used as an antifouling substance in underwater hull paints.

> ***Although the immediate commercial effects of the suggestion are limited, we are both disappointed and surprised by the reasoning of the expert group, says CEO, Philip Chaabane. We do not share the opinion that, based on the existing regulations, Medetomidine should be defined as an endocrine disruptor for humans. We will therefore continue to make our case for a renewed approval at every step of the way.***

Selektope is an antifouling agent, developed by the Swedish bio-technology company I-Tech, which is used in underwater hull paints to prevent the growth of barnacles. It was first developed as a medicinal substance and by the turn of the millennium, its antifouling properties were discovered. The continued development of Selektope was then financed, among others, by The Swedish foundation for strategic environmental research, Mistra, the Swedish Energy Agency and the EU Eco-Innovation Project.

Customers are the global paint manufacturers that supply the shipbuilding industry in Asia, the most important selling point is the substance contribution to stronger protection against marine fouling, which in turn reduces ships' fuel consumption and greenhouse gas emissions. By adding Selektope in underwater hull paint the total amount of biocides and heavy metals used in antifouling coatings can also be reduced. Today, the product is used on more than 1,000 ships worldwide.

Since its first commercialisation, Selektope has been integrated into the product portfolio of six of the world's nine largest paint manufacturers, and the substance is included in the development process of several more.

When I-Tech applied for approval in 2009, some of the current evaluation criteria were not included. In 2016, Selektope, with the active substance Medetomidine, was approved by ECHA after previously being approved in Japan, Korea and China.

The changed recommendation comes after the company, according to the rules, applied for an active substance renewal in 2021. Since the first approval the regulation have changed and now include assessment of whether a substance may be an endocrine disruptor, which ECHA's advisory panel of experts now considers Medetomidine to be.

In its response to the expert panel's comment, I-Tech states that:

- The legally binding Commission Delegated Regulation[1] setting out the scientific criteria for the determination of ED properties, makes clear that ED with respect to humans is only established if there is (i) an adverse effect in an intact organism or its progeny, (ii) an endocrine MoA i.e. it alters the function(s) of the endocrine system; and (iii) the adverse effect is a consequence of the ED MoA. I-Tech has explained how adversity has not been demonstrated in the available evidence (effects absence of further testing).
- Guidance on the identification of ED substances under the BPR[2] states that, "*[i]n the absence of internationally validated test methodologies, no specific guidance can be given here on how to identify potential links between such [endocrine] effects to non-EATS endocrine modalities*.
- It is well known and extensively documented that Medetomidine, at pharmacological concentrations, activate alpha2-adrenoreceptors. This is the desired pharmacological response for which Medetomidine has been used for the last 20 years and sedative effects are reversible upon removal of medetomidine exposure. Other post-sedative effects are considered not to be a direct action of medetomidine. Most notably, there is no clear direct effect of Medetomidine on an endocrine organ or tissue and whilst the function of the endocrine response may be moderated, the actual function is not fundamentally altered and cannot be considered adverse.

I-Tech will continue to vigorously defend its position in the subsequent stages of the renewal process for Medetomidine. We do not agree that Medetomidine can be lawfully characterised as an active substance with ED properties for humans.

There are multiple opportunities for I-Tech to defend Medetomidine, as it goes through its evaluation for renewal under the BPR:

i. a public consultation on whether Medetomidine can be substituted for alternative substances; [3]
ii. development of a non-legally binding opinion by the ECHA Biocidal Products Committee ("BPC"), which is a peer review assessment of the draft report produced by the Norwegian evaluating authority on approval of the substance/PT combination;[4]
iii. a public consultation on derogation to the BPR exclusion criteria for a substance identified as ED;[5]
iv. development of a legally binding European Commission implementing regulation on the active substance/PT combination approval (with or without conditions), or an implementing decision on non-renewal under the Examination Procedure.[6]

The full evaluation and decision-making process is scheduled to be completed by 30 June 2025, though this could be extended.[7]

[1] Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528 /2012.
[2] Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528 /2012 and (EC)No 1107/2009, p. 11.
[3] Article 10 BPR: see https://echa.europa.eu/public-consultation-on-potential-candidates-for-substitution

[4] Article 14(3) BPR
[5] Article 5(2) BPR: see https://echa.europa.eu/derogation-to-the-exclusion-criteria-current-consultations
[6] Article 14(4) BPR: see Article BPR https://commission.europa.eu/law/law-making-process/adopting-eu-law/implementing-and-delegated-acts/comitology_en
[7] COMMISSION IMPLEMENTING DECISION (EU) 2022/1495 of 8 September 2022 postponing the expiry date of the approval of medetomidine for use in biocidal products of producttype 21 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

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About I-Tech AB
I-Tech is a biotechnology company that has developed the product Selektope®, an active agent that prevents barnacle attachment on submerged surfaces such as ships and boat hulls, but also other marine installations. By increasing the resistance to barnacle growth in marine paint systems (e.g. antifouling coatings), fuel and maintenance costs are reduced. I-Tech has obtained the necessary regulatory approvals for Selektope® and has several of the world's largest manufacturers of marine antifouling coatings as customers. The company's share is listed for trading on Nasdaq First North Growth Market in Stockholm with Erik Penser Bank as Certified Adviser. For more information visit our website www.i-tech.se.

This information is information that I-tech is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2023-05-24 17:00 CEST.

Attachments
Expert panel suggests changed classification of Selektope