

PUBLIC

Information obtained during the consultation on potential candidates for substitution from 3 November 2023 until 4 January 2024.

Substance name: Medetomidine (RS)-4-[1-(2,3-dimethylphenyl)ethyl]-1H-imidazole (Racemic)

Product type: 21

Intended use: Anti-fouling products containing medetomidine are to be used on hulls of vessels such as commercial and government ships, super-yachts and pleasure craft, to surfaces such as outdrives, outboard legs, propellers and stern gears of pleasure craft, and to structures and objects subject to immersion. All surfaces are treated while they are out of the water.

EC number: -

CAS number: 86347-14-0

eCA: Norway

Comment 1	2024/01/04 11:45
Country	Sweden
Name of organization/institution	I-Tech AB
General information	Analysis of alternatives have been made using the ECHA template and is submitted as attachments in word and pdf format.
Product Type	21
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	

PUBLIC

Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	<p>Alternatives to medetomidine are of consideration due to concerns raised regarding possible endocrine disruptive properties for humans and non-target organisms and well as being classified as both toxic and very persistent. The biocidal alternatives for both commercial and leisure vessels cannot be fully compared regarding endocrine disruptive properties, since neither of the substances have been fully assessed regarding those endpoints. It can however be highlighted that there are discussions ongoing and a full comparison will not be possible until both substances has been through the renewal process for BPR. The degradation profiles of the two biocidal alternatives are slightly better than medetomidine when considering current classifications. Considering actual environmental fate the substances have more similar properties, copper compounds do not degrade in the environment and tralopyril could form a metabolite classified as very persistent. Thus substitution is not guaranteed to offer a benefit to human health or the environment. The non-chemical alternatives all have lower assessment scores, especially when focusing on the technical feasibility and fouling protection for commercial vessels. The hazards for humans and the environment varies between the non-chemical products but they all pose a risk of contributing to transport of invasive species in the marine environment. The increased emissions from commercial vessels with poor fouling protection have not</p>

PUBLIC

	<p>been taken into consideration during this assessment, but it is a significant factor to have in mind when deciding on suitable alternatives for fouling prevention. The conclusion for both use type is that none of the analysed alternatives can be considered as suitable alternatives to substitute the use of medetomidine as technology for protection against barnacle fouling when considering impacts of increased GHG emissions and the transfer of invasive species.</p>
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	Public.zip
Attachments (confidential information)	██████████
Justification for confidential attachment	