ANALYSIS OF ALTERNATIVES

to biocidal active substances meeting the substitution criteria under the Biocidal Products Regulation

Legal name of submitter: I-Tech AB

Date: 4th January December 2024

Substance candidate for substitution: Medetomidine CAS 86347-14-0

Trading name: Selektope

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FIGURES

LIST OF ABBREVIATIONS

Acute Tox:	Acute Toxicity
AEL:	Acute Exposure Levels
B:	Bioaccumulation
BPD:	Biocidal Products Directive 98/8/EC
BPR:	Biocidal Products Regulation (EU) 528/2012
CAR:	Competent Assessment Report
CAS:	Chemical Abstracts Service
CCS:	China Classification Society
CDP:	Controlled Depletion Copolymer
C:	Celsius
CfS:	Candidate for Substitution
CLP:	Classification, Labelling and Packaging Regulation (EC) No 1272/2008
CO2:	Carbon dioxide
Cu2O:	Copper oxide or cuprous oxide
DIY:	Do It Yourself
DNV:	Det Norsk Veritas
ECHA:	European Chemicals Agency
EC:	European Commission
eCA:	evaluating Competent Authority
ED:	Endocrine Disruptive
EEA:	European Economic Area
EU:	European Union
FRC:	Fouling Release Coating3
GHS:	Globally Harmonized System of Classification and Labelling of Chemicals
GHG:	Green House Gas
g/L:	grams per Litre
HSE:	Health Safety environment
IAS:	International Accounting Standards
IMO:	International Maritime Organization
IPBES:	Intergovernmental Platform on Bio-diversity and Ecosystem Services
IUPAC:	International Union of Pure and Applied Chemistry
ISO	International Organization for Standardization
kPa:	kilopascal
LPG:	Liquid Petrol Gas
LNG:	Liquid Natural Gas
MAMPEC:	Marine Antifouling Model to Predict Environmental Concentrations

MISTRA:	The Swedish Foundation for Strategic Environmental Research
mN/m:	Millinewton/Meter
MSCAs:	Member State Competent Authorities
N:	Nitrogen
NH:	Nihonium
n.a:	not applicable
NIS:	Non-Indigenous Species
NOx:	Nitrogen Dioxide
OECD:	Organization for Economic Co-operation and Development
Pa:	Pascal
PEG	Poly Ethylene Glycol
PBT:	Polybutylene terephthalate
PAR:	Product Assessment Report
P:	Persistent
PH:	Potential of Hydrogen
PFAS:	Per-and Polyfluoroalkyl Substances
PT 21:	Product Type 21
R&D:	Research & Development
ROVs:	Remotely Operated Vehicle
RQ:	Risk Quota
Sintef:	Stiftelsen for industriell og teknisk forskning (The Foundation for Industrial and Technical Research)
SFE:	Surface Free Energy
SPC:	Self-Polishing Co-polymer
STP:	Sewage Treatment Plants
STOT SE:	Specific Target Organ Toxicity Single Exposure
STOT RE:	Specific Target Organ Toxicity Repeated Exposure
TNsG:	Technical Notes for Guidance
TOC:	Total Organic Carbon
T:	Toxic
TBT:	Tributyl Tin
UV:	Ultraviolet
VI:	Viscosity Index
vP:	very persistent
vPvB:	very persistent and very bioaccumulative
vPvM:	very persistent and very mobile
w/w:	weight /weight

DECLARATION

The applicant is aware of the fact that evidence might be requested by ECHA or the relevant Member State Competent Authority to support information provided in this document.

Also, we request that the information redacted in the public version of the analysis of alternatives is not disclosed. We hereby declare that, to the best of our knowledge as of today, 4th of January 2024, the information is not publicly available, and in accordance with the due measures of protection that we have implemented, a member of the public should not be able to obtain access to this information without our consent or that of the third party whose commercial interests are at stake.

Signature:

Philip Chaabane CEO, I-Tech AB

Date, Place:

04th of January 2024, Mölndal, Sweden

1. SUMMARY:

The intended use of medetomidine as an active substance in antifouling coatings is to protect submerged hulls of deep sea- and coastal vessels and other parts of stationary under water installations from biofouling.

The outcome of using medetomidine is significantly reduced or no hard fouling on submerged surfaces. This directly influences vessel drag during the sailing period meaning less shaft power usage for the main engine, resulting in less GHG/NOx emissions into air including minimized transfer of invasive species globally. Additionally, the protection from hard fouling provided by medetomidine also protects steel & aluminium constructions from damage and the need for regular maintenance or reduced lifetime.

The end- or consequential users are mainly paint manufacturers which market their antifouling coatings, containing medetomidine, to Ship Owners, Ship Managers, Shipyards, Offshore companies and professional applicators within the commercial shipping industry including the leisure yacht market.

Medetomidine effectively repels hard fouling by binding to octopamine receptors in invertebrates and activating a reversable physiological response which results in increased mobility of the shell-building organisms, predominantly barnacles. The physical reaction of the organisms prevents them from settling on the surface. The physical effect is reversible and exposed larvae transferred to clean environments have been shown to settle and transform into juvenile adults.

The number of active biocidal substances serving the European market is limited, especially under PT 21, Antifouling products. This Analysis of Alternatives will list all supplementary- or alternative biocides in antifouling coatings. Biocides with the same mode of action and/or the same efficacy as medetomidine are not present on the market.

I-Tech AB together with industry partners, consultants and other industry peers took various steps to identify different chemical- and non-chemical alternatives to actively benchmark the mode of action, the efficacy, the formulation criteria including micro- and macro-economic backgrounds. Additionally, I-Tech AB has engaged with independent expert consultants including direct customers to gather their views on the alternatives for medetomidine.

Based on the research conducted, over 15 years knowledge of the EU biocidal market and stakeholder contributions this Analysis of Alternatives concludes that for commercial vessels the loss of medetomidine from the market could have negative impacts on:

- the diversity of the market
- emissions from the shipping industry
- transfer of invasive species

For leisure vessels the decision is less clear cut as alternative methods could be feasible, with additional costs and increased ecosystem risks such as transport of invasive species on reduced levels.

The concerns regarding human health or the environment associated with medetomidine are not irrelevant to the two chemical alternatives included in the analysis and thus substitution is not guaranteed to offer a benefit to human health or the environment. An inadequate chemical diversity against barnacle fouling could also lead to resistance occurrence, which might spread afterwards across the target organism population.

2. SCOPE OF THE ASSESSMENT AND OVERVIEW OF THE APPROACH

As outlined in Table 1, the analysis of alternatives presented in the following sections concerns biocidal (chemical) and non-biocidal coatings and technologies that have been identified as potential alternatives to the use of medetomidine in antifouling applications. The scope of the analysis of alternatives covers the two uses of medetomidine in the European Economical area (EEA).

- Use type 1 is protection against barnacles in antifouling coatings or other technologies used on commercial vessels.
- Use type 2 is protection against barnacles in antifouling coatings or other technologies used on leisure vessels.

Protection against fouling is an area where much research is done, both due to the increasing requirements to reduce carbon dioxide (CO_2) emissions from commercial vessels (IMO, 2023) and the need to reduce the risk of spreading invasive species (IMO, 2023). The focus on research of new technologies which limits emission from shipping even further is beneficial for both the antifouling- and the shipping market, however development and verification of technologies are long-term projects, especially for technologies intended for use on commercial vessels where the requirements are extra high regarding efficacy and service-life. For this assessment the alternatives have been limited to biocidal and non-biocidal coatings and technologies currently approved and available on the market in EEA.

Shipping and leisure boating is a global industry, but the use of antifouling substances and coatings are regulated differently in different areas. The geographical scope is here the EEA market, covering countries which fall under the remit of the EU Biocidal Products Regulation ((EU) 528/2012) (EU, 2012). It should be noted that some of the consequences and risks described in the analysis may have global implications, such as emissions of CO_2 to air or transport of invasives species between continents.

Table 1 Overview of analysis scope

Scope of alternatives	Approved biocidal active substances and authorised biocidal products Non-biocidal coatings and technologies
Uses within scope	Use type 1: protection against barnacles in antifouling coatings or other technologies used on commercial vessels Use type 2: protection against barnacles in antifouling coatings or other technologies used on leisure vessels
Geographical scope	EEA

The assessment has followed the guidance outlined in *ECHA (2023) Analysis of alternatives to biocidal active substances for applicants and authorities: a recommended framework guidance*, adapted based on data availability.

The approach can be summarised as:

Task 1 – Longlisting of alternatives

An initial list of biocidal and non-biocidal alternatives for the assessment were identified through review of publication from the scientific community, governmental organisations, non-governmental organisations and trade magazines but also communication with trade organisations, biocide-suppliers, coating producers, ship owners, ship managers & shipyards.

Criteria for longlisting was kept intentionally broad to not eliminate any options from the alternative without an initial assessment. Market availability in EEA was a criteria for biocidal and non-biocidal coatings due to the long development cycles of these technologies. Non-coating technologies were added to the longlist of alternatives without this requirement. In total 14 alternative technologies were identified for commercial vessels (use type 1) and leisure vessels (use type 2).

Task 2 – Shortlisting of alternatives

The 14 alternatives identified as alternative technologies in task 1 were compared to the selection criteria for shortlisting the alternatives for in-depth analysis. To be eligible for in-depth analysis a technology was required to provide full hull protection against barnacles and be available on the EEA market for the use type of interest. 5 alternative technologies for use type 1 and 7 for use type 2 were selected for a full analysis of alternative.

Task 3 - Hazard assessment

Derivation of risk scores for medetomidine, the biocidal alternatives and the non-biocidal coatings alternatives have been based on the Global Harmonised System (GHS) Column model. Classification from safety data sheets is used to score human, environmental and physical-chemical hazards. Very high danger is 1, high danger 2, moderate danger 3, low danger 4 and negligible danger 5.

Endocrine Disruption (ED) is currently not included in the scoring model but is considered very high danger for human health. Persistence (P) or Bioaccumulation (B) is not included separately, but was for this assessment considered a high danger (including PFAS substances).

Non-coatings alternatives usually lack safety data sheets and the hazards posed were therefore generally not assessed. Consideration for this lack of hazard scoring is made at comparison of the available alternatives.

Task 4 - Exposure assessment

The exposure assessment for the biocidal alternatives included in this analysis have been based on data included in the coatings described in the EU BPR dossiers (section Intended uses and Efficacy or Summary of risk assessment) for the use type discussed.

Table 2 Exposure levels as % biocide and corresponding score from 1-5

Exposure level (% biocide)	Score

Below 5	5
Below 10	4
Below 20	3
Below 30	2
30 and above	1

Human exposure has been based on the risk quota for combined exposure, using normal personal protection equipment for application of the coating.

Table 3 Summary of exposure considerations

Use Type	Exposure type	Exposure
Use type 1	Primary	Professional operators: • mixing and loading into reservoirs (potman), • application of the product by airless spraying (spray man) or brush and roller (chandler), • removing coating containing the product by sand blasting, grit filling, cleaning of spraying equipment • cleaning paint brushes
Use type 1	Primary	Professional operators and non-professionals: • mixing and loading into reservoirs (potman), • application of the product by brush and roller (chandler), • removing coating containing the product by sand blasting, grit filling, cleaning of spraying equipment • cleaning paint brushes

For professionals, exposure to antifouling paints is normally irregular with long intervals between exposures. The most realistic worst case exposure scenario is that a painter may be exposed regularly, and then not to the same active substance (TNsG [2002], part 2, page 121 for professional spraying of antifouling products, and subsequent technical discussion by Member States). Human exposure to Use type 2 also occur during application and maintenance activities. Use type 2 coatings are generally applied to the hull by brush and roller, either by a non-professional in a marina or a professional in a smaller boatyard. To keep exposure at safe levels non-professional users should wear gloves and normal clothing (maximally 50% penetration).

For this assessment, environmental emissions from the use phase (service life) of coatings in Use type 1 and 2 have been considered. Activities like application and maintenance for Use type 1 takes place in an industrial setting, shipyards, with strict rules regarding minimising environmental pollution. The service-life of an antifouling coating for use type 1 is generally 3-

5 years depending on the coating system and the vessel type, although some products are specified for las long as 7.5 years.

Application and maintenance activities for use type 2 are performed on hard surfaces and the ground is protected by protective material such as tarpaulin. Some emissions of paint flakes to sewage treatment plants (STP) could occur but is not considered significant in the risk assessment procedure for approval of antifouling substances or coatings according to the BPR. In many European areas, leisure vessels are removed from the water during the winter months and therefore leisure coatings have a service-life of one year, being renewed before launching the vessel in spring/summer.

Emissions from the service-life are calculated with a modelling program called Marine Antifouling Model to Predict Environmental Concentrations, MAMPEC (Deltares, 2023) using standardised emissions scenarios agreed for use by the EU Member State Competent Authorities. Environmental exposure has been based on environmental exposure risk quotas for water and sediment inside a standardised OECD harbour.

Table 4 Risk quotas for human and environmental assessment and scoring used for exposure assessment

Exposure assessment RQ	Score
RQ below 1	5
RQ below 5	4
RQ below 10	3
RQ below 15	2
RQ 15 and above	1

Technologies that do not have any release of substances has not been assessed for exposure. Consideration for this lack of exposure scoring is made at comparison of the available alternatives.

Task 5 - Technical feasibility assessment

The technical feasibility assessment for medetomidine and the potential alternatives was performed using the qualitative scoring matrix presented below. All alternatives, including medetomidine, was compared to a standard antifouling coating containing biocides to achieve protection against hard fouling during a 3–5-year service life for use type 1 and a standard biocidal antifouling coating approved for non-professional application for use type 2. Each substance or technology was scored against the five technical feasibility criteria to allow for a comparison of technical feasibility.

Table 5 Technical feasibility assessment scoring criteria

Technical feasibility criteria	Scoring criteria	Score
Technical readiness	Proven proof of concept	1 point

	Successfully tested at full scale	2 points
	Commercially available	3 points
Is the alternative available in sufficient quantities	No (strong availability concerns)	1 point
	Possible availability concerns	2 points
	Yes (no availability concerns)	3 points
Are changes to the processes/ equipment for use required	Significant changes	1 point
	Moderate changes	2 points
	No (i.e. a drop-in replacement/ minimal changes)	3 points
Efficacy towards target organisms	Concentration/ time required higher	1 point
	Concentration/ time required comparable	2 points
	Concentration/ time required lower	3 points
Ecosystem effects such as resistance concerns or risk for transport of invasive species transport for non-biocidal technologies	Yes (proven)	1 point
	Possible concerns (concern raised but not yet proven)	2 points
	No	3 points

Task 6 - Economic feasibility assessment

The economic feasibility assessment for medetomidine and alternatives was performed using the qualitative scoring matrix presented below. Medetomidine and all potential alternatives were compared to a standard antifouling coating containing biocides to achieve protection against hard fouling during a 3–5-year service life for use type 1 and 1 year for use type 2.

Table 6 Economic feasibility assessment scoring criteria

Indicator	Overall score

Price per litre	Significant lower – 5 Lower – 4 Comparable – 3 Higher (not disproportionate) – 2 Significantly (disproportionate higher) - 1
Cost of equipment	Significant lower – 5 Lower – 4 Comparable – 3 Higher (not disproportionate) – 2 Significantly (disproportionate higher) - 1
Application rates /maintenance	Significant lower – 5 Lower – 4 Comparable – 3 Higher (not disproportionate) – 2 Significantly (disproportionate higher) - 1
Risk management	Significant lower – 5 Lower – 4 Comparable – 3 Higher (not disproportionate) – 2 Significantly (disproportionate higher) - 1

3. ANALYSIS OF THE SUBSTANCE FUNCTION(S), TYPES OF USES, TECHNICAL REQUIREMENTS AND MARKETS FOR THE PRODUCTS

This section presents an overview of the substance identification, properties (Section 3.1) and function (Section 3.2), uses (Section 3.3), technical requirements (Section 3.4) and market for medetomidine.

In summary, medetomidine is an antifouling active substance used in coatings applied 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.

The function of medetomidine in the antifouling coatings is to protect the coated surfaces from hard fouling, predominantly barnacles. Medetomidine containing coatings have two use types, coatings for commercial vessels (use type 1) and coatings for leisure vessels (use type 2).

3.1. CfS active substance identification and properties

This section presents the substance identifiers, physical properties, human health and environmental hazards, and a description of the outcomes of the risk assessment for medetomidine that is used as the basis for comparison with the potential alternatives.

Table 7 Substance identification

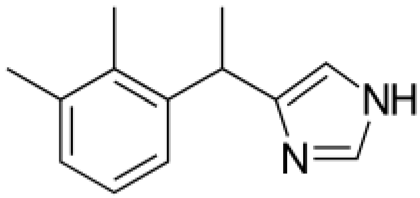
Main constituent(s)	
ISO name	Medetomidine
IUPAC or EC name	(RS)-4-[1-(2,3-dimethylphenyl)ethyl]-1H-imidazole (Racemic)
EC number	811-718-6
CAS number	86347-14-0
Index number in Annex VI of CLP	613-321-00-1
Minimum purity / content	99.5 % (w/w)
Structural formula	

Table 8 Physical properties

Property	Result	Test method applied or description in case of deviation
Aggregate state at 20°C and 101.3 kPA	Solid	Visual inspection
Physical state (appearance) at 20°C and 101.3 kPA	Crystalline powder	Visual inspection
Colour at 20°C and 101.3 kPA	White to light brown	Visual inspection
Odour at 20°C and 101.3 kPA	Odourless	Observation
Melting / freezing point	110-116°C	OECD 102

<table>
<tr><td>Boiling point at Granulometry</td><td>Decomposes at temperatures above 150°C</td><td>OECD 103</td></tr>
<tr><td>Vapour pressure</td><td>1. 86 x 10^{-4} Pa at 45 °C
8.3 x 10^{-6} Pa at 25 °C
3.5 x 10^{-6} Pa at 20 °C</td><td>OECD 104</td></tr>
<tr><td>Henry's law constant</td><td>8.3 x 10-6 Pa m3 mo1·1 at 25 °C and pH 7.9</td><td>calculated</td></tr>
<tr><td>Surface tension</td><td>63.5 mN/m (90 % saturated solution at 20 °C)</td><td>OECD 115 ring method</td></tr>
<tr><td>Water solubility at 20 °C</td><td>9.86 g/L at pH 5
0.425 g/L at pH 7
0.153 g/L at pH 9</td><td>EC A.6, OECD 105, flask method</td></tr>
<tr><td>Partition coefficient (n-octanol/water) and its pH dependency</td><td>
<table>
<tr><td>pH</td><td>Temperature (ºC)</td><td>Log P</td></tr>
<tr><td rowspan="3">5</td><td>10</td><td>1.1</td></tr>
<tr><td>20</td><td>1.2</td></tr>
<tr><td>30</td><td>1.3</td></tr>
<tr><td rowspan="3">7</td><td>10</td><td>2.5</td></tr>
<tr><td>20</td><td>2.6</td></tr>
<tr><td>30</td><td>2.6</td></tr>
<tr><td rowspan="3">9</td><td>10</td><td>3.1</td></tr>
<tr><td>20</td><td>3.1</td></tr>
<tr><td>30</td><td>3.0</td></tr>
</table>
</td><td>EC A.8, OECD 107</td></tr>
<tr><td>Thermal stability and identity of breakdown products</td><td>No significant change of melting point or the melting enthalpy after storage. It is considered chemically stable.</td><td>OECD 113 (accelerated storage for two weeks at 54 ºC).</td></tr>
</table>

Reactivity towards container material	n.a	n.a
Dissociation constant	7.1	OECD 112 (titration method)
Viscosity	n.a	n.a
Stability in organic solvents used in biocidal products and identity of relevant degradation products	Stability in 1-methoxy-2-propanol, benzyl alcohol, p-xylene, o-xylene, acetone, ethyl acetate, methanol, acetonitrile, methyl isobutyl ketone, 2-methoxy-1-methylethyl acetate, iso-butanol and n-butanol. Medetomidine was determined to be stable (less than 5% degradation after 14 days at 54°C) in all solvents with the exception of methyl isobutyl ketone (8% degradation observed).	Visual method

Classification

Table 9 Hazard classifications according to the CLP Regulation (ECHA, Committee for risk assessment - Opinion proposing harmonised classification and labelling at EU of Medetomidine, 2015).

Hazard Class and Category Code(s)	Hazard statement Code(s)
Acute Tox. 2	H300
Acute Tox. 2	H330
STOT SE 1	H370 (eye)
STOT SE 3	H336
STOT RE 1	H372
Aquatic Acute 1	H400
Aquatic Chronic 1	H410

Medetomidine is classified as very persistent (vP) and toxic (T) but not bioaccumulative (B). It does not meet the classification requirements for PMT substances (ECHA, Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, Evaluation of active substance assesment report Medetomidine Product type 21, 2015).

Medetomidine is proposed to be classified as an endocrine disruptor, having endocrine disrupting properties with respect to humans and non-target organisms. The BPR renewal dossier containing the proposal is currently under review by the member states, schedules for working group meeting in March 2024 and Biocidal Products Committee opinion available end of June 2024.

Risk score

This section presents the outcomes of the risk assessment for medetomidine which shall be used as the baseline against which potential alternatives shall be compared.

3.1.1.1.1 Hazard assessment - medetomidine

The hazard assessment for medetomidine has followed the methodology outlined in Section 2. The outcome of the hazard assessment is presented in Table 10.Table 10 and gives a total hazard assessment score of 8. Based on the Column model a human health hazard score of 2, 1 for very high danger of acute toxicity (Acute tox 2) and 1 for very high danger of chronic toxicity (ED), is given. The environmental and animal health score is based on medetomidine having aquatic acute and chronic toxicity, resulting in a score of 1.

Medetomidine does not have any physical-chemical hazard classifications and therefore receives a hazard score of 5.

Table 10 Hazard assessment score

Substance name	Human health	Environment inc animals	Phys-chem	Overall score
Medetomidine	2	1	5	8

3.1.1.1.2 Exposure assessment - medetomidine

Humans are exposed to use type 1 coatings during application and maintenance activities. The coatings are applied predominantly by airless spray by professional operators at shipyards. To ensure that operator exposure to medetomidine is kept within acceptable levels (AEL) personal protection equipment is used (gloves, double coveralls with maximally 1% penetration and respiratory protection equipment with protection factor 40).

Exposure from medetomidine to humans and the environment are driven by the amount of the substance in the coatings and the exposure routes. The exposure routes taken into consideration for the use types have been agreed by the EU Member State Competent Authorities and are used as basis for approvals according to the EU BPR. Data has been taken from the EU BPR approval dossier for medetomidine issued by ECHA in 2016.

The exposure assessment for medetomidine has followed the methodology outlined in Section 2. The outcome of the exposure assessment is presented in Table 11.

Table 11 Exposure assessment score Use type 1

Substance name	Exposure (% in EU BPR approval dossier)	Human exposure score (RQ professional spray and cleaning)	Environmental exposure (RQ for OECD harbour, water+sediment)	Overall score (RQ sum/exposure)
Medetomidine	0.1 – score 5	0.99 – score 5	1.53 – score 4	14

Table 12 Exposure assessment score Use type 2

Substance name	Exposure (% in EU BPR approval dossier)	Human exposure (RQ non-professional combined exposure)	Environmental exposure (RQ for OECD marina, water+sediment)	Overall score
Medetomidine	0.1 – score 5	0.82 – score 5	6.82 – score 3	13

Table 13 Risk score medetomidine

Use type	Hazard score	Exposure assessment score	Risk score
Use type 1	8	14	22
Use type 2	8	13	21

3.2. Description of the function provided by the CfS active substance

3.2.1. Function and mode of action

Medetomidine binds to octopamine receptors in invertebrates and activates a physiological response; this results in increased motility of larvae from shell-building organisms, e.g. barnacles and tubeworms. The increased motility inhibits settling behaviour of the larvae and the effect is receptor specific. The effect is reversible and exposed larvae transferred to clean environments settle and transform into juvenile adults (Dahlström M, 2000).

Since medetomidine acts as a non-lethal deterrent on target organisms and its effect is fully reversible, resistance development is unlikely to occur. Medetomidine affects the octopamine receptor, a neurotransmitter receptor, in the target organism. Since this has a deterrent effect the target organisms will only be exposed under short periods of time. The benefits of resistance development will be low due to the short-term exposure and the presence of plenty of habitats without medetomidine. Alterations of a receptor leading to resistance development are therefore regarded as not likely to occur. Neither is it regarded as likely that more sensitive individuals of the target species will have a negative selection pressure exerted on them.

3.2.2. Efficacy towards the target organism(s)

The efficacy towards the main target organism, barnacles, is observed from 0.24 µg/L, unspecific effects are seen in concentrations above 0.24 mg/L. The lower concentration corresponds to approximately 0.05% (w/w) of medetomidine in antifouling coatings. The assessment of the biocidal activity of the active substance in the Competent Authority Report for medetomidine (2015) demonstrates that it has a sufficient level of efficacy against the target organism(s) and the evaluation of the summary data provided in support of the efficacy of the accompanying product, establishes that the product may be expected to be efficacious. Concentrations in coatings up to 0.1% (w/w) were considered acceptable for use type 1 and 0.13% (w/w) for use type 2 from risk assessment perspective in the current BPR approval.

3.2.3. Functionality delivered by the substance

The main functionality delivered by medetomidine use in antifouling coatings is to significantly reduce or a complete elimination of barnacle fouling on submerged surfaces, meaning mostly the hull of ships/vessels. This direct influence of less hard fouling on a hull is a reduction in resistance between water and hull surface, leading to reduced drag (shaft power usage from the main engine) during sailing periods (voyages). A hull with soft fouling can have an increase in drag with 17% and medium amounts of hard fouling increased drag with 44% while a heavily fouled hull can have as much as an 69% increase (Schultz, 2011). Therefore, if hull resistance and subsequent drag is kept low it results in less fuel consumption and less greenhouse gas (GHG) emissions. Economically the ship's operator uses less fuel consequently, regardless of diesel, heavy fuel, liquefied petroleum gas (LPG), liquefied natural gas (LNG), methanol, ammonia, hydrogen or other alternative fuel sells like batteries or diesel – electric/electrical power sources.

Medetomidine enables especially ocean-going vessels to perform their services efficiently with less maintenance such as underwater cleaning, less disruptive stops for drydocking and cleaning and reduce the transport of invasive species around the globe which minimizes the disruption of local ecosystems (CoatingsWorld, 2021) (Jose A. Fernandes, 2016). The protection medetomidine brings against hard fouling can last for over 5 years, the exact service-life and formulation of the coating is dependent on the particular formulation of the coating per coating manufacturer (Chugoku Marine Paints, 2023). The vessels need medetomidine as one ingredient within the antifouling coating and in combination with other biocides, medetomidine can contribute to the protection against soft- and hard-fouling by optimising the performance of other biocides (stakeholder communication). Medetomidine is available in commercial products both as the sole active substance against hard fouling and in combination with both other actives for hard fouling, if extra protection and/or a more diversified biocide matrix for lower overall biocidal loadings is needed. The end users and consequential users are mainly paint manufacturers which market their antifouling coatings to Ship Owners, Ship Managers, Shipyards, Offshore companies and professional applicators within the commercial shipping industry including the leisure vessel market.

Products for commercial vessels (use type 1)

The functionality delivered by medetomidine containing products for commercial vessels

- Full barnacle protection in system intended for commercial vessels with service-life of 3 to 5 years.
- Approved for use on commercial vessels in EU.
- Idling possible without barnacle fouling for 45 days

Products for leisure vessels (use type 2)

The functionality delivered by medetomidine containing products for leisure vessels

- Barnacle protection in system for leisure vessels with a service-life of 1 year.
- Approved for use on leisure vessels in EEA/EU
- Approved for non-professional application (do-it-yourself, DIY).

3.3. Intended uses and products

3.3.1. Overview of the intended uses of the active substance

The intended use of medetomidine is to protect hulls of deep sea and coastal vessels and submerged parts of stationary installations from fouling by larvae of shell-building organisms such as acorn and stalked barnacles, and tube-building polychaetes such as marine tubeworms.

The result of medetomidine containing coatings is significantly reduced or no barnacle fouling, depending on product formulation. This directly influences vessels drag during the sailing periods resulting in less GHG emissions into air. A case study comparing a premium medetomidine coating with another premium biocidal coating showed that 375 tonnes of fuel could be saved yearly per vessel, corresponding to 1000 tonnes of CO_2, saved, due to less fouling (CoatingsWorld, 2021) (ShipManagement, 2021). Based on that study it can be calculated that 1 tonne of medetomidine used in antifouling coatings can reduce GHG emissions from ships with 3.473.703 tonnes, in comparison with a standard biocidal antifouling coating. In comparison with a premium coating the saving would be 644 318 tonnes instead.

Antifouling coatings are not only used to reduce the added resistance between water and hull, less fouling on a hull also reduces the risk of transport of alien invasive species (AIS). Shipping vessels has been a well-known source of invasive species for many years but until recently it was assumed that ballast water was the main source. In 2017 the International Maritime Organization (IMO) put the spotlight on hull fouling as an important source of AIS (Karayannis, 2016) and the problem has since then only gained attention (Weber & Esmaeili, 2023) (Jesica Goldsmit, 2018) (Katie E. Costello, 2022). The IPBES Assessment on Invasive Alien Species and their Control addresses one of the most important direct drivers of biodiversity loss (IPBES Global Assessment, 2019) and was adopted at IPBES-10 (28 August - 2 September 2023 in Bonn, hosted by the USA). The full assessment and its summary for policy-making were published and presented to the press on Monday, 4 September 2023.

It's important to note that the use of antifouling coatings is not limited to large vessels; even smaller boats and watercraft used for various purposes employ these coatings to protect their hulls from fouling (Katie E. Costello, 2022). Additionally, the formulations of antifouling coatings have evolved over time to address environmental concerns and comply with regulations, leading to the development of more sustainable alternatives.

Product type and intended uses

Medetomidine is approved for use as an antifouling active substance in product type 21 (PT21), antifouling products (approval start date 01/01/2016, approval end date 30/06/2025). Antifouling coatings 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.

Coatings containing Medetomidine have two use types, coatings for commercial vessels (use type 1) and coatings for leisure vessels (use type 2).

Antifouling coatings are often categorized by different technologies. One of the most often used method is to distinguish antifouling coatings by the binder system. The binder system influences significantly the release mechanism of biocides.

Coatings for commercial vessels containing medetomidine are based on the following technologies;

- **Eroding/ablative systems:** The binder system is based on rosin a natural product which is eroded over time and while being eroded releases the biocides to the surface where it is active.

- **Self polishing coating Systems (SPC):** generally show a better performance. The main binder system are so called self-polishing polymers which initially are not water soluble but which convert after a hydrolysis reaction to a water soluble polymer. The combination of erosion and the conversion from insoluble to soluble binder system is called self-polishing. Self-polishing is more controlled than the pure erosion process in ablative system and thus releases the biocides in a more controlled manner to the coating surface. The two systems being used with medetomidine are silyl acrylate polymer-based coatings and metal acrylate polymer-based coating systems. Medetomidine is used along side the two other hard fouling agents to resits the higher fouling pressure in certain trades and/or is used as the sole active against hard fouling for a significant reduction of biocidal loading as the main benefit without compromising performance.

Coatings for leisure vessels containing medetomidine are based on the following technologies;

- **Hard matrix systems with biocides:**. In these systems the paint thickness will remain constant over the lifetime and the biocides are slowly dissolved out of the paint film. Due to the increased diffusion the biocide concentration on the surface is being reduced over time. These systems are mainly used for high-speed boats.
- **Hard matrix systems without biocides:**. In these systems the paint thickness will remain constant over the lifetime and these systems mainly used for leisure boats that are not permanently immersed into the water.
- **Ablative systems:** With or without biocides is this antifouling system most often used for leisure boats. This coating is soft and worn away as the boat hull moves through the water.
- **One component silicone:** Biocide free silicone coating systems are available for yachts.

3.3.1.1.1 Use type 1: commercial vessels

Medetomidine is used for barnacle protection in antifouling paint intended for commercial vessels, with a service-life of between 3 years to 5 years (typical docking period) and under in-water inspection even 7 years. In water inspections (the vessel does not need to dock meaning it is not dry) are allowed by technical classification companies (DNV, Bureau Veritas, Lloyds) (every vessel needs to have a classification approval mainly for safety on board).

There are currently no medetomidine containing antifouling coatings intended for commercial vessels authorised for use under the BPR but there are products currently under evaluation for use in several member states.

Two medetomidine containing antifouling coatings intended for commercial vessels have been approved under transitional legislation in Greece, Portugal & Spain.

Table 14 Justification for medetomidine use by type of user - use type 1

Type of user	Reason for use
All commercial vessels (Cargo-, Container and other Ship Operators)	Reduce drag and maintain fuel efficiency including emissions to air. This is crucial for cost savings and adhering to environmental regulations globally. In countries like New Zealand and Australia bio-fouled vessels are not allowed to enter.

Cruise Liners, Ferries and Passenger Vessels	Enhance the aesthetic appeal of their vessels and to ensure a smooth and efficient journey for passengers
Naval Forces and military	Maintain their operational effectiveness. Fouling can significantly impact the speed and manoeuvrability of these vessels
Offshore-, Tugs, Port operating vessels, Oil and Gas Industry	Prevent the accumulation of marine growth, which can compromise the integrity of the structures
Commercial Fishing	Ensure that their equipment remains in good condition and to avoid the negative impacts of fouling including the fishing gear
Research vessels, Scientific- and Research Organisations	Ensure accurate data collection and maintain the performance of scientific instruments

3.3.1.1.2 Use type 2: Leisure vessels

Medetomidine is used for barnacle protection in antifouling coatings intended for leisure vessels with a service-life of 1 year. Medetomidine is approved for antifouling coatings for use on leisure vessels and can be applied as a DIY product according to the current approval from 2016. However, due to uncertainties related to approval criteria of leisure products under the BPR (human and environmental risk assessment) no products have been submitted for evaluation by coatings manufacturers. The short service-life for this use type can be explained by the differences in maintenance of leisure vessels around Europe, depending on the need to remove the vessel from water during winter or not. Generally leisure vessels in countries surrounding the Baltic Sea and the North Sea are removed during winter and following extended time on land the antifouling coating needs to be re-applied to ensure functionality. Vessels in countries in the southern parts of Europe are generally not remove for winter and would therefore benefit from a longer service-life.

One medetomidine containing antifouling products intended for leisure vessels have been approved under transitional legislation in Greece and Malta.

Table 15 Justification for medetomidine use by type of user - use type 2

Type of user	Reason for use
Leisure Boat Owners - re-creational boats, yachts, and sailboats	Protect vessels from fouling organisms. This helps maintain the boat's performance by reducing drag and maintains fuel efficiency, reducing emissions to air. This is crucial for cost savings and avoiding transport of invasive species. Extensive fouling can also reduce the manoeuvrability of a leisure vessel.

3.3.2. Market and supply chains

The antifouling market technical description

Table 16 Antifouling coating technologies

Antifoulings	FRC
SPC	Silicone
Matrix	Hard
Eroding/Ablative	

Technically, the market is divided into Antifoulings and Fouling Release Coatings (FRC). Antifoulings include active ingredients and leach out to prevent the attachment of fouling organisms and are mostly grouped into Self Polishing Antifouling (SPCs), Matrix- and Eroding/Ablative antifouling coatings. FRCs act via a very smooth (slippery) surface to which the organisms do not find anchorage/settling on. The function is based on a combination of smoothness, surface properties, fouling release effect from hydrophobic surface properties and the fouling prevention mechanism coming from the hydrophilic properties.

Hydrophilic and hydrophobic are two terms used to describe the behaviour of substances in contact with water. Hydrophilic substances are attracted to water, while hydrophobic substances repel water. For example, if you drop water on a hydrophilic surface, it will spread out evenly. Some examples of hydrophilic substances include glass, salt, sugar, cellulose, and starch. On the other hand, if you drop water on a hydrophobic surface, it will form droplets. Examples of hydrophobic substances include fats, oils, alkanes, and powdered makeup.

The antifouling market commercial description

Table 17 Market categorisation of antifouling technologies

Low grade	Medium	Premium	Efficacy	Price
SPC, Hard/Matrix, Ablative			Low	Low
	SPC, Hard/Matrix		Medium	Medium
		SPC, Silicone	High	High

Commercially, the antifouling market is categorised in Low-**,** Medium- and Premium grade antifouling. Low grade antifouling content usually less complex- and less expensive ingredients which is reflected on to less efficacy and lower price per litre and/or square meter. The medium market performs on medium level whereas the Premium grade performs the best with highest prices per litre and/or square meter.

Table 18 Overview of coating types

	Antifoulings	FRC
Mechanism	Work by releasing biocides or other substances into the surrounding water, which inhibit or even kill fouling organisms	Use a low-friction surface to prevent fouling organisms from attaching to the hull. When the ship moves through the water, the low adhesion allows the fouling organisms to be easily removed. A combination of smoothness, surface properties, the fouling release effect comes from hydrophobic surface properties and there is the fouling prevention mechanism coming from the hydrophilic properties.
Pros	Effective in preventing biofouling. Particularly useful in areas with high fouling pressure. Easy to apply, even with temperatures below 5 C.	Non-biocidal Provides a smooth surface that reduces drag and increases fuel efficiency. Can be more effective over the long term than fouling defence coatings.
Cons	Environmental concerns related to the release of biocides. Sometimes limited effectiveness over time as the biocides are depleted.	May be less effective in areas with high fouling pressure. Initial cost can be higher compared to fouling defence coatings. Easily exposed to mechanical damages. If damaged, they lose their Antifouling properties. More sensitive to application temperatures below 5 C.

It is important to note that FRCs are often combined with co-biocides in very low concentrations to increase efficacy, particularly for idle- or static conditions in which FRCs (silicone-based coatings without biocides) have their weaknesses. A typical silicone-based coating needs water movement, current or speed through water for organisms not to settle. The efficacy of silicones is triggered by an extreme smooth (slippery) surface. The surface is to smooth for organisms to settle whereas a biocidal SPC for example, does not allow organisms to settle via the active ingredients. In addition, some new SPCs products (CF Premium) using medetomidine show it is possible to reduce the biocide loading to similar low levels yet maintaining performance.

Market sectors for biocidal products.

The market for biocidal antifouling products (both for Antifoulings and FRCs) can be described as an oligopoly as there are a limited number of chemical manufacturers are holding approvals for a small number of active substances for PT21 under the EU BPR. This means that a limited number of active substances, for a limited number of antifouling coatings from paint manufacturers are available on the market. Especially for hard fouling prevention, only 3 ingredients are available: copper-based compounds, tralopyril and medetomidine. As outlined in Section 3.3.1, the primary application areas for antifouling include different applications sectors. Each of these sectors have unique requirements and preferences for antifouling products.

3.3.2.1.1 Market trends

Paint manufacturers, end users and other shipping industry representatives and consultants have observed a growing trend towards a greener industry, meaning a clear shift towards the development and use of more sustainable antifouling coatings. This includes the use of biocide-free or low-biocide alternatives. This has not only been driven by regulatory standards, but by the general consensus of authorities, industry and the public to reduce negative impact to the environment and human health from exposure to hazardous substances. The main driving forces in antifouling development include optimal efficacy to reduce fuel consumption and GHG emissions to adhere to upcoming IMO requirements (IMO, IMO STRATEGY ON REDUCTION OF GHG EMISSIONS FROM SHIPS, 2023), but also reduced biocidal release into sea water to follow the European Green Deal and Chemical Strategy for Sustainability.

Intended use 1: Commercial Shipping:

Table 3. Biocides approved by the European BPR (exception diuron and zinc pyrithione which are in the approval process) and their toxicity (Amara et al. 2018).

Name	Brand name	Target species	Mode of action
Cu_2O		Broad-spectrum antifouling agent	Competitive binding to metal ligands, creation of reactive oxygen species, interaction with nucleic acids (Borkow and Gabbay 2005)
DCOIT	Sea-Nine™ 211 N. Rocima™ 200	Broad-spectrum antifouling agent targeting soft fouling	Creation of radicals causing intracellular oxidative stress (Chapman and Diehl 1995)
Diuron		Diatoms and algae	Photosynthesis inhibitor (Jung et al. 2017)
Chlorothalonil		Hard fouling organism, crustaceans, and invertebrates	Inhibition of thiol-dependent proteins and enzymes (Tillman et al. 1973)
Dichlofluanid (DCF)	Preventol®	Macro algae, diatoms, and invertebrate fouling organisms	No information about toxic mechanism of DCF and its degradation products (Jung et al. 2017)
Zinc/Copper pyrithione	Zn/Cu Omadine	Broad-spectrum antifouling agent targeting soft fouling	Inhibiting several cellular processes, such as ATP balance, membrane transport, and protein synthesis (Dahllöf et al. 2005)
Tralopyril	Econea®	Broad-spectrum antifouling agent targeting hard fouling	Interfering with mitochondrial function (Vilas-Boas et al. 2022)
Zineb		broad-spectrum antifouling agent targeting soft and invertebrate fouling organisms	Inhibitor of metabolic pathways through thiol interactions within proteins and enzymes (Hunter and Evans 1990)
Medetomidine	Selektope	Barnacle larvae	Receptor stimulation, causing hyperactive swimming behaviour (Dahlström et al. 2000)

Intended use 2: Leisure Yachting

The general public use antifouling coatings for their leisure boats, which are either applied by professional applicators at smaller boat yards, or as DIY products applied by the boat owners themselves. This varies from country to country, with leisure boat owners in Northern Europe and the Mediterranean mostly hiring third-party professionals, whereas leisure boat owners in Western Europe, including Germany and Poland, tending to have a larger proportion of DIY users.

The market is characterized by the presence of major players in the coatings industry, as well as smaller companies specialising in marine coatings.

European countries with significant maritime activities, such as Denmark, Finland, Germany, Greece, the Netherlands, Norway, Poland and Sweden are key contributors to the antifouling market.

The main producers of antifouling products for commercial vessels are provided in Table 19 , with a summary of the technology used and authorisation status.

Table 19 Availability of biocidal antifouling products commercial Shipping market:

Manufacturer	**Biocidal Product Name**	**Technology**	**Authorisation status**	**Authorisation end date**
Antifoulants				
Akzo Nobel	Intersmooth	Cu/Silyl acrylate SPC, Self Polishing systems		
	Interspeed	CDP Controlled Depletion Polymer		
	Interswift	Blend of Intersmooth and Interspeed		
Chugoku Marine Paint	Seaflo Neo	CF Z and CF Premium: CU-free Zn acrylate SPC SL M and SL Z: Silyl methaacrylate SPC		
	Sea Grandprix	500: Zn acrylate SPC 1000L: Silyl acrylate SPC		
	Sea Premier	1000:Zn acylate SPC 3000: Silyl methacrylate SPC		
Hempel	Atlantic+	Acrylic SPC		
	Dynamic	Silyl acrylate SPC		

	Globic+	Nano-acrylate SPC 9000: Nano-acrylic SPC 9500 S: Nano-acrylic SPC		
	Olympic+	Acrylic SPC		
	Oceanic	Zn carboxylate SPC		
Jotun	Sea Force EU	Ion exchange SPC	BPR	2033-09-21
	Sea Mate	Silyl acrylate SPC		
	Sea Quatum EU	Silyl methacrylate SPC	BPR	2033-09-21
	Sea Ouantum Spectrum			
Nippon Paint	A-LF Sea	100: ZB acrylate SPC 250: 400, 600: Cu-silyl-acrylate SPC		
	Aquaterras	Biocide-free amphilicmicro-domain SPC		
	Fastar	Amphilic nano-domain silyl acrylate SPC		
	Ecoloflex	Original: CU acrylate SPC		
PPG	ABC	SPC		
	Amercoat	CDP		
	Sigma Alphagen	SPC		
	Sigma Ecofleet	SPC		
	Sigma Nexeon Sigma Nexeon 750?	Cu-free ZN acylate SPC Plus S launch Q1 2024		

	Sigma Sailadvance	Zn methacrylate SPC		
Fouling release (FR) coatings				
Akzo Nobel	Intersleek	Biocide-free fluoropolymer		
AST Inc	SLIPS Dolphin	Biocide-free		
Chugoku Marine Paint	Bioclean (Bioclean+ BioClean Flex)	Biocide-free (Biocidal)		
Hempel				
	Hempaguard X7	Biocidal silicone hydrogel (Actiguard)		
	Hempasil X3	Biocide-free enhanced hydrogel		
Jotun	SeaQuest	Biocide-free silicone		
	SeaQuest Endura	Biocidal silicone		
PPG	Sigmaglide	Biocide-free pure PDMS		

(SPC: self-polishing copolymer, CDP: controlled depletion polymer; CSP: controlled surface-active polymer)

Examples of leading EU medium sized and small producers for the leisure yacht market are Boero including Veneziani, Stoppani (Lechler), DeIssel, Nautix and Epifanes.

Boero including their daughter company Veneziani have a revenue of € 90 million with leisure yachting coatings only. Stoppani (Lechler) has as example €22,2 million. Those examples alone are a significant economic weight. The European marine coating market in total will surpass €1.7 billion by 2025:

According to the Graphical Research, in its new forecast analysis, the "Europe Marine Coatings Market" is estimated to surpass $2 billion by 2025. Sturdy demand for marine coating products to increase the vessel's life by preventing it from biofouling and corrosion will propel the Europe marine coating market size by 2025. For instance, many manufacturers in countries such as the U.K., Belgium, Spain etc. are producing new coatings with foulrelease technology that is useful in substantial fuel savings, especially for large cargo ships. Companies are developing eco-friendly coatings such as metal-free anti-fouling agents to help sustain the aquatic life and control the oceanic pollution, which would positively drive the Europe marine coating market size by 2025. (Source: www.grandviewresearch.com)

3.3.3. Application methods and rates, risk mitigation measures for each intended use (how is the active substance used in the biocidal products, treated articles/end-products)

For professionals, exposure to antifouling paints is normally irregular with long intervals between exposures. The most realistic worst case exposure scenario is that a painter may be exposed regularly, and then not to the same active substance (TNsG [2002], part 2, page 121 for professional spraying of antifouling products, and subsequent technical discussion by Member States). Human exposure to Use type 2 also occur during application and maintenance activities. Use type 2 coatings are generally applied to the hull by brush and roller, either by a non-professional in a marina or a professional in a smaller shipyard. To keep exposure at safe levels non-professional users should wear gloves and normal clothing (maximally 50% penetration).

For this assessment, environmental emissions from the use phase (service life) of coatings in use type 1 and 2 have been considered. Activities like application and maintenance for use type 1 takes place in an industrial setting, shipyards, with strict rules regarding minimising environmental pollution. The service-life of an antifouling coating for use type 1 is generally 3-5 years depending on the coating system and the vessel type, although some products are specified for las long as 7.5 years (90 months).

Application and maintenance activities for use type 2 are performed on hard surfaces and the ground is protected by protective material such as tarpaulin. Some emissions of paint flakes to sewage treatment plants (STP) could occur but is not considered significant in the risk assessment procedure for approval of antifouling substances or coatings according to the BPR. In many European areas, leisure vessels are removed from the water during the winter months and therefore leisure coatings have a service-life of one year, being renewed before launching the vessel in spring/summer.

Table 20 Overview of use

Product Type	**Use type 1**	**Use type 2**
Where relevant, an exact description of the authorised use	Marine	Marine
Target organism(s) (including development stage)	Barnacles (larval stage) Tube-building polychaetes such as marine tubeworms (larval stage)	Barnacles (larval stage) Tube-building polychaetes such as marine tubeworms (larval stage)
Field of use	Outdoor use	Outdoor use
Category(ies) of users	Professional users	Professional users Non-professional users
Application method(s)	Airless spray Brush (rarely)	Brush Roller Airless spray can (stern drives)

3.4. Description of the technical requirements that must be achieved by the product(s)

Table 21 Summary of technical requirements for antifouling products by use type

	Use type 1	**Use type 2**
Technical requirements	Full barnacle protection in system intended for commercial vessels with service-life of 3 to 5 years. Approved for use on commercial vessels in EU. Idling possible without barnacle fouling for 45 days	Barnacle protection in system for leisure vessels with a service-life of 1 year. Approved for use on leisure vessels in EU Approved for professional and non-professional application (DIY).

Marine fouling protection coatings have to fulfil several requirements. These range from their efficacy against fouling organisms to their workability in application. Paints must be stable and have a shelf life of at least 1 year and they must be applicable with standard application technologies. These technologies include roller and brush, especially for yachts and do it yourself applications, and airless spray for larger commercial vessels. Most applications happen outside in shipyards. Coatings must be able to be applied all year round and under all atmospheric conditions. It should be noted that not all technologies, especially silicone-based technologies, can be applied at temperatures below 5 degree Celsius. Table 21 provides an overview of the technical requirements that must be met by all antifouling products that are to be applied to commercial vessels (use type 1) and leisure vessels (use type 2). These technical requirements apply to products containing medetomidine and other biocidal or non-biocidal alternatives.

For antifouling coatings there is no generally accepted standard to evaluate the technical performance of coatings. There is the ISO 21716 standard which was developed for the screening of efficacy for antifouling coatings as a bioassay, but it is explicitly not designed to evaluate performance . A common assessment method for the performance of antifouling coatings is the ISO 19030 which measures a vessel's hull performance in service between two docking intervals (ISO, 2016). This method cannot be used to measure the performance of coatings as the performance is measured indirectly via the performance of the vessel. The standard methodology to evaluate antifouling coatings are static immersion tests which are then rated by standard methods like the widely used rating system from the US Naval Ships Technical Manual fouling rating (USNavy, 2006).

The main certification requirements for antifouling coatings are a tin free certificate (IMO, 2001) which demonstrated that the antifouling coating adheres to the convention prohibiting antifouling systems containing tin and cybutryne and the approval of Classification Societies. Classification Societies are organisations which develop and apply technical standards for the design, construction and survey of ships and which carry out surveys and inspections on board ships Worldwide there are more than 50 classification societies but only 11 classification societies are presently recognised by the European Commission. Each Classification Society has its own way of approving coating systems, for example the China Classifications Society (CCS) demands a static performance test against proven systems (CCS, 2011).

Most attempts to develop a standardised laboratory method to evaluate the performance of antifouling have failed, therefore the standard way to test performance remains to be testing in marine environments by exposure of test samples to real life conditions. One drawback to this method is that the fouling conditions can vary by season and on an annual basis, which means that results will vary depending on when immersion of samples occurs. This requires a comparison of positive and negative samples to be made under varying conditions. The variation between geographical locations is of course also a challenge, since both fouling pressure and species differ significantly.

3.4.1. Technical feasibility assessment

3.4.1.1.1 Technical feasibility assessment - medetomidine

The technical feasibility assessment for medetomidine has followed the methodology outlined in Section 2. The outcome of the technical feasibility assessment is presented in Table 22. The technical feasibility assessment for medetomidine represents both Use type 1 and 2.

Table 22 Technical feasibility assessment - medetomidine

Substance name	Technical readiness	Availability	Changes required for use	Efficacy	Ecosystem effects	Overall score
Medetomidine	3	3	3	3	3	15

3.4.2. Economic feasibility assessment

3.4.2.1.1 Economic feasibility assessment - medetomidine

The economic feasibility assessment for medetomidine has followed the methodology outlined in Section 2. The outcome of the economic feasibility assessment is presented in Table 23. The economic feasibility assessment for medetomidine represents both Use type 1 and 2.

Table 23 Economic feasibility assessment - medetomidine

Substance name	Price per litre	Cost of equipment	Application rates / maintenance	Risk management	Overall score
Medetomidine	3	3	3	3	12

3.5. Summary of medetomidine assessment scores

The assessments of medetomidine regarding risk, exposure, technical feasibility and economic feasibility have been combined to product an overall qualitative score. The score will be used for comparison to the potential alternatives identified for in depth analysis.

Table 24 Overall assessment score for medetomidine

Use type	Hazard score	Exposure assessment	Technical Feasibility	Economic Feasibility	Overall score

Use type 1	8	14	15	12	49
Use type 2	8	13	15	12	48

4. ANNUAL TONNAGE

Medetomidine has limited sales in EU, resulting from the lack of authorised coatings containing medetomidine under BPR. Medetomidine is a new active substance according to BPR and is therefore not allowed to be sold unless products are approved according to BPR or transitional legislations. The approval process for antifouling coatings is struggling with sever delays which has negatively impacted new active substances such as medetomidine. The sales of medetomidine in EU is expected to increase once coatings currently under evaluations are approved.

The annual tonnage sold in EU are <1 tonne per year.

5. IDENTIFICATION OF POTENTIAL ALTERNATIVES

This section covers the methods used to identify and then refine the potential alternatives to medetomidine under the two intended uses.

5.1. Description of efforts made to identify possible alternatives

A broad data gathering approach was used to identify all possible alternatives within the scope. This included the use of a stakeholder consultation, use of I-Tech's internal research and development data and data searches to compliment this information. The following sections cover the approach and scope of each data gathering activity and an overview of the results.

5.1.1. Stakeholders' involvement

I-Tech's commercial focus lies within the EU-27 and therefore all partners and clients within this region, especially those exploring different alternatives chemically and non-chemically, were consulted.

The different consultation activities included meetings/interviews, written communication (e-mails), digital- and in-person meetings. When discussing the alternatives, open ended questions were used to avoid influencing the stakeholder. The initial questions focused on the stakeholders' knowledge on alternatives for biocides within the maritime industry generally and then specifically alternatives for low biocidal antifouling focussing on hard fouling. When talking with stakeholders within the paint sector, questions focused on alternatives for antifouling and non-chemical alternatives, such as pro-active and re-active cleaning as complementary technology as one example only.

The stakeholders with relevance for this consultation have been organised into stakeholder categories: stakeholder role in relation to I-Tech AB or in the sector generally; the technology relevant to the stakeholder and thus the topic of engagement. For more detailed stakeholder involvement, their categories, the type of meeting/communication conducted and the contact details for each stakeholder - please see Annex II.

Table **25** A list of the stakeholders relevant

Chugoku Marine Paints, Ltd.	Direct customer	Antifouling alternatives
Hempel AS	Direct customer	Antifouling alternatives
Jotun AS	Direct customer	Antifouling alternatives
PPG Industries	Direct customer	Antifouling alternatives
American Chemet Corporation	Peer	Antifouling alternatives
Arxada AG	Peer	Antifouling alternatives
Cosaco GmbH	Peer	Antifouling alternatives
Janssen PMP	Peer	Antifouling alternatives
LANXESS Deutschland GmbH	Peer	Antifouling alternatives
Nitto Chemical Indusry Co., Ltd	Peer	Antifouling alternatives
Nordox AS	Peer	Antifouling alternatives
Hapag Lloyd AG	Indirect customer	Antifouling alternatives
Stena AB	Indirect customer	Antifouling alternatives
Stolt-Nielsen Tankers	Indirect customer	Antifouling alternatives
CEPE	Association	Antifouling alternatives
Word Coating Council	Association	Antifouling alternatives
Intertanko	Association	Antifouling alternatives
Verband Deutscher Reeder	Association	Antifouling alternatives
SNAME, GR	Association	Antifouling alternatives
The Royal Institute of Naval Architects	Association	Antifouling alternatives
Mærsk Mc-Kinney Møller Center for Zero Carbon Shipping	Foundation	Antifouling alternatives
Safinah Group	Independent consultant	Antifouling alternatives
Limnomar	Independent consultant	Antifouling alternatives
Dr. Brill & Partner	Independent Laboratory	Antifouling alternatives

Bellona	NGO	Antifouling alternatives
Wärtsilä,FI	Industry stakeholder	Air Lubrication Technology
Fleet Cleaner,NL	Industry stakeholder	Pro-active cleaning
Hull Wiper,UAE	Industry stakeholder	Pro-active cleaning
Hasytec,GER	Industry stakeholder	Ultrasonic and Electrochemical Systems
Outokumpu,FI	Industry stakeholder	Biofouling-Resistant Materials /steel
Ocean Innovations, USA	Industry Stakeholder	Ultraviolet

As shown above, I-Tech AB considered as many experts as possible. Direct customers like leading and smaller paint manufacturer have been contacted as well as ship owners, shipyards, ship managers, applicators plus some associations including NGOs, foundations or ministries. The communication and meetings varied from digital- via personal meetings to E-Mail or phone conversations (see Annex II).

As examples for questions discussed, some examples from the interviews:

- What do you think about biocides in antifoulings?
- What do you think of reducing the biocidal load of antifoulings?
- Are you satisfied with the efficacy of antifoulings or more direct,
- Is the market ready for none–biocidal or none-chemical alternatives only?

I-Tech AB additionally asked independent bodies where one of them agreed to issue an alternatives assessment which refers to alternatives in the market generally (see ANNEX III)

Two out of 3 direct EU customers of I-Tech's issued statements whereof one provided reference vessels (See ANNEX IV & V).

All stakeholders basically agreed that the vision long term could probably be reduced biocide in combination with other technologies. Short- and medium term, low biocidal solutions in combination with supplementary solutions like cleaning or other alternatives are the way forward. No chemical- and technical solution can contribute to solve the complex challenge of biofouling. Vessel types, different trading pattern, different idling periods, different water temperatures, different fouling pressures per European region and waters, different efficacies per biocide and/or other substances and technologies are all solving the biofouling challenge.

5.1.2. Research and development

The research and development of medetomidine as an antifouling substance has been a long journey. The Marine Paint project, in which the development of medetomidine to an antifouling substance took place, was a Swedish multidisciplinary research project at the University of Gothenburg and Chalmers University of Technology, initiated in 2003. The funding organisation MISTRA, The Swedish Foundation for Strategic Environmental Research (MISTRA, 2023) had a specific requirement on the project: Marine Paint should not generate fundamental research regarding antifouling substances. The aim instead was for the research to result in an actual product with the potential to reduce the environmental footprint of antifouling products used on ships and leisure boats. I-Tech (Interface Technologies) was founded as a company shortly after the project start to ensure that the results from the project would be utilised in the best way to fulfil the goal set by MISTRA. The Marine Paint project ended up running from 2003 to 2011 and received approximately €8 million in public funding and generated more than 60 scientific publications.

Quite early it was decided that the substance would be submitted for evaluation according to the European Biocidal Products Directive (EU BPD 98/8), now updated to a regulation (Biocides Products Regulation (BPR), EU 528/2012) (ECHA, 2023). Without a regulatory approval in EU the goal of the Marine Paint project would not be met.

To fulfil the information requirements for a BPD dossier I-Tech had to be creative, generating a data-set covering phys-chem, efficacy, toxicology, and ecotoxicology would cost more than the any start-up could afford. Since medetomidine and dexmedetomidine were approved as pharmaceutical substances much of the regulatory data focusing on phys-chem and toxicology could be bought from the US FDA registration owner. These studies became the backbone of the EU dossier in combination with scientific studies from Marine Paint and a few standard regulatory studies to ensure that all data requirements were met. I-Tech submitted the dossier to the British competent authority Health and Safety Executive (HSE) in April 2009 and medetomidine was finally approved for use in EU in 2016, 7 years after the dossier submission.

Two persons from the original research program are still working at I-Tech and the knowledge around medetomidine and the functionality as an antifouling substance has continued to grow.

EU has also seen medetomidine as a promising innovation and granted funding to I-Tech for its further commercialisation on medetomidine through EcoInnovation (€600 000) in 2012. The aim of the programme was to reduce the environmental impact and make better use of resources (EC, 2023).

Due to medetomidines efficacy against barnacle fouling there is a continued belief that medetomidine can deliver outstanding barnacle protection as in ingredient in antifouling coatings, especially in a market that focus on reduced emissions to air from commercial shipping and reduced biocidal loadings. I-Tech is currently focusing its R&D capabilities on how to reduce emissions of medetomidine into the environment by controlling the release with different binder systems and still keep the current efficacy. I-Tech is also looking into ways of reducing human exposure when handling medetomidine in production of antifouling coatings.

I-Tech is currently a 12-person company focusing solely on the development and sales of medetomidine (I-Tech, 2023).

Protection against fouling is as previously described an area where much research is done by active substance suppliers, antifouling coatings manufacturers, other materials suppliers and the scientific community. The initial interest in this research area was triggered by the ban of using tributyltin (TBT) as an antifouling biocide (IMO, 2001) and has been maintained due to the increasing requirements to reduce carbon dioxide (CO_2) emissions from commercial vessels (IMO, 2023) and the need to reduce the risk of spreading invasive species (IMO, 2023). The focus on research of new technologies which limits emission from shipping even further is beneficial for both the antifouling- and the shipping market. However, the result of approximately 30 years of research has not resulted in many new commercialized technologies, biocidal or not. The development and verification of technologies are long-term projects requiring substantial funding. This is especially true for technologies intended for use on commercial vessels since the requirements are very high regarding both efficacy and service-life. Many of the ideas and discoveries published in scientific publications never reach farther than the R&D stage. One common limitation is that new substances discovered through research that have efficacy against fouling organisms are classified as biocide and require approval according to BPR for use in EU. Few stakeholders are today willing to invest the substantial sums needed to take a new antifouling biocide to the market.

5.1.3. Data searches

- Literature type
  - Scientific literature and academic journals in the field of antifouling, coatings technology and environmental science
  - Academic reports and conference proceedings
  - Trade journals and magazines
  - Regulatory information and legislations for EU
- Data sources
  - Google
  - Google scholar
  - Science Direct (full text access)
  - PubMed
  - ResearchGate
  - ECHA website
  - IMO website
- Keyword examples
      - CO_2 emissions and fouling
      - Alternative fouling protection
      - MSDS for antifouling products on the EU market (December 2023)
      - Antifouling biocides and approved products (December 2023)
      - Environmental effects of antifouling
      - Environmental effects of foul release coatings
      - Environmental effects of copper antifouling
      - Tralopyril and PFAS
      - Invasive species antifouling
      - Fouling leisure vessels

5.2. Identification of alternatives

Alternatives have been identified through review of scientific research, stakeholder communication and extensive knowledge internally regarding the antifouling market in EU. Identified alternatives have been refined according to criteria for antifouling function and market presence. Remaining alternatives were reviewed and compared to medetomidine regarding risk, technical- and economic feasibility and availability. The alternatives have been categorised according to the use type identified as relevant.

5.2.1. Screened alternatives and selection for further assessment

The selection criteria for the first assessment of alternatives was based on the functionality fulfilled by medetomidine.

- Chemical alternatives approved or pending (review program substances) for approval according to BPR, for intended use 1 and/or 2, with efficacy profile covering barnacles such as in Antifoulings. Fouling prevention via none-settlement solutions.

- Non-biocidal coating alternatives available on the EU market for use 1 and/or 2 such as FRCs, see 3.3.2. or fouling prevention via special surfaces.
- Non-chemicals antifouling system intended for use 1 and/or 2 such as Ultrasound e.g.
- Supplementary solutions such as under water cleaning for example.

Table 26: Initial list of chemical and non-chemical alternatives and outcome of the selection for further assessment

Intended use number	Alternative number	Name of the alternative	CAS or EC Number (where applicable)	Description of the alternative	Reason for selection/rejection for further assessment
1 and 2	1.	Copper flakes, dicopper oxide, Copper thiocyante	7440-50-8 1317-39-1 111-67-7	Broad spectrum antifoulant	Selection criteria 1: approved antifouling biocides according to EU BPR.
1 and 2	2.	DCOIT	64359-81-5	Broad spectrum antifoulant, used as co-biocide	Selection criteria 1: approved antifouling biocides according to EU BPR. Rejection criteria in-depth analysis: Co-biocide
1 and 2	3.	Tralopyril	122454-29-9	Broad spectrum antifoulant	Selection criteria 1: approved antifouling biocides according to EU BPR.
1	4.	Zineb	12122-67-7	Broad spectrum antifoulant, used as co-biocide	Selection criteria 1: approved antifouling biocides according to EU BPR. Rejection criteria in-depth analysis: Co-biocide
1 and 2	5.	Non-biocidal hard coatings	n.a	Extremely smooth, non-stick surface	Selection criteria 1: available on the EU market for use 1 and/or 2

1 and 2	6.	Silicone-based coatings	n.a	Low-friction, foul-release surface	Selection criteria 1: available on the EU market for use 1 and/or 2
1 and 2	7.	Hydrophobic coatings	n.a	Water-repellent surface by surface chemistry and micro texture	Rejection criteria: Not commercially available for full hull protection, only niche areas
2	8.	Ultrasonic systems	n.a	Sound waves disrupting fouling	Selection criteria 1: available on the EU market for use 2. Not commercially available for full hull protection for use 1, only niche areas. Risk of creating cavitation. Cavitation is the formation of partial vacuums in a liquid by a swiftly moving solid body (such as a propeller) or by high-intensity sound waves. Also : the pitting and wearing away of solid surfaces (as of metal or concrete) as a result of the collapse of these vacuums in surrounding liquid.
1 and 2	9.	Electrochemical systems	n.a	In situ generated biocides	Rejection criteria: No approved substances available in EU
1 and 2	10.	UV - light	n.a	Physical deterrent of fouling organisms	Rejection criteria: Not commercially available for full hull protection, only niche areas

2	11.	Biofouling-resistant materials	n.a	Vessel construction material resisting fouling	Selection criteria 1: available on the EU market for use 1 and/or 2
2	12.	Antifouling films/wraps	n.a	Adhesive film based on silicone technology	Selection criteria 1: available on the EU market for use 2
1 and 2	13.	Air lubrication technology	n.a	Reduction of frictional resistance	Selection criteria 1: available on the EU market for use 1 and/or 2 Rejection criteria in-depth analysis: No full fouling protection.
1 and 2	14.	Cleaning	n.a	Physical removal of fouling	Selection criteria 1: available on the EU market for use 1 and/or 2

The selection criteria for the in-depth analysis (in Section 0) of the identified alternatives includes the following:

- Chemical alternatives approved or pending (review program substances) for approval according to BPR for intended use 1 and/or 2, with full efficacy against barnacles demonstrated as single biocide in product, not co-biocide.
- Non-biocidal coating alternatives available on the EU market for use 1 and/or 2, available for full hull protection.
- Non-chemicals antifouling system alternatives commercially available on the EU market intended for use 1 and/or 2, available for full hull protection.

This eliminated alternatives were not investigated further due to meeting at least one of the following criteria:

- biocidal alternatives which do not deliver full protection against barnacles, the key function of medetomidine;
- coatings and other alternative technologies which cannot protect the full hull, for example alternatives that remove fouling but do not offer protection; and
- alternatives that are not available on the market, since alternatives should be able to substitute the use of medetomidine without unreasonable delay.

The 7 alternatives listed in Table 27 have been investigated in detail and the evidence on the suitability of each presented in Section 0.

Table 27: Shortlisted chemical and non-chemical alternatives for further assessment

Intended use number	Alternative number	Name of the alternative	CAS or EC Number (where applicable)	Description of alternative
1 and 2	1.	Copper flakes, dicopper oxide, copper thiocyante	7440-50-8 1317-39-1 111-67-7	Broad spectrum antifoulant, approved for use 1 and 2 according to EU BPR. Mode of action in all three copper compounds is generated by the cupric ion, Cu^{2+}.
1 and 2	3.	Tralopyril	133454-29-9	Broad spectrum antifoulant, approved for use 1 and 2 according to EU BPR.
1 and 2	5.	Non-biocidal hard coatings		Extremely smooth, non-stick surfaces available on the EU market for use 1 and 2.
1 and 2	6.	Silicone-based coatings		Low-friction, foul-release surface available on the EU market for use 1 and 2.
2	8.	Ultrasonic systems		Physical deterrent of fouling organisms available on the EU market for use 2.

2	12.	Antifouling films/wraps		Adhesive film based on silicone technology (low-friction, foul-release) available on the EU market for use 2
2	14.	Cleaning		Physical removal of fouling, available on the EU market for use 1 (proactive) and 2 (proactive and reactive). It should be mentioned that re-active cleaning of hard fouling under normal circumstances damages the coating film drastically and therefor influences the efficacy of the antifouling negatively. This is not an option for use type 1.

Through a broad stakeholder consultation supported by literature research and I-Tech's strong inhouse and historical experience in the sector 13 alternatives were identified and consequentially screen down to just 7 alternatives. These alternatives have then been investigated further as possible alternatives to Medetomidine through the information gathered from stakeholders and literature research, the findings of this investigation can be found in the following sections.

6. SUITABILITY AND AVAILABILITY OF POTENTIAL ALTERNATIVES

Following the screening and short-listing of available alternatives, the coatings and other technologies that fulfilled the criteria described in the previous section were reviewed and compared to medetomidine regarding risk, technical and economic feasibility and availability. The alternatives are all categorised according to the use type identified as relevant.

6.1. INTENDED USE 1 – Commercial vessels

As outlined in Section 3.3 and 3.4, alternatives to medetomidine should be approved for use and available for application to a number of commercial vessels, including, but not limited to, cargo containers, cruise liners, ferries and passenger vehicles, naval and military ships, offshore support vessels and structures, commercial fishing and aquaculture and research vessels.

Products for commercial vessels (Use type 1) should fulfil the technical requirements outlined in Table 21, notable:

- Full barnacle protection in system intended for commercial vessels with service-life of 3 to 5 years.
- Idling possible without barnacle fouling for 45 days

The following sections provide a summary of findings for potential chemical and non-chemical alternatives to medetomidine in Use type 1.

6.1.1. Chemical alternatives

Copper compounds

6.1.1.1.1 Substance ID and properties

Substance Name	**CAS #** **EC Number**	**Hazard Class and Category Code(s)**	**Hazard statement Code(s)**
Copper flakes	7440-50-8 231-159-6	Aquatic Chronic 2	H11
Dicopper oxide	1317-39-1 215-270-7	Acute Tox. 4 Acute Tox. 4 Eye Damage 1 Aquatic Acute 1 Aquatic chronic 1	H302 H332 H318 H400 H410
Copper thiocyanate	111-67-7 214-183-1	Aquatic Acute 1 Aquatic chronic l	H400 H410

None of the copper compounds are classified as PBT. Metallic compounds are not classified for persistence, due to their elemental status as they are unable to degrade (Jessica Briffa, 2020).

None of the compounds have been fully assessed for endocrine disruptive properties, this will be performed at renewal of the current approval which expires 31st of December 2025. The mode of action in all three copper compounds is generated by the cupric ion, Cu^{2+}. When copper from metallic copper, copper thiocyanate or cuprous oxide leaches into marine water in the presence of oxygen, the predominant form of the copper is the active substance, the cupric ion, Cu^{2+}. The cupric ion acts to retard settlement of the microscopic larvae of fouling organisms within a microlayer of water at the paint surface via two mechanisms:

(1) the ion retards organism's vital processes by inactivating enzymes such as superoxide dismutase;

(2) the ion acts more directly by precipitating cytoplasmic proteins as metallic proteinates (ECHA, 2016).

Products containing 37.5 - 42.5 % w/w Cu_2O have been proved efficacious against biofouling in European sea waters up to 25 months and in tropical sea waters up to 12 months, depending on film thickness and final product composition (ECHA, 2016). Copper thiocyanate demonstrated a sufficient activity for the approval of the active substance at 19.25 % w/w of active substance when considering use in European sea water (ECHA, 2016)).

6.1.1.1.2 Reduction of overall risk

This assessment of the reduction in overall risk follows the methodology outlined in Section 2.

Human health– Reduced risk based on EU hazard classification for human health. The copper-based substances have harmonised classifications for acute tox. 4 and eye damage 1. When using the Column model to compare, this results in a human health hazard score of 8. It should be noted that the copper-based substances have not yet been assessed for endocrine disruption and a full human health hazard comparison is therefore not possible at this stage due to a lack of data. The full assessment is expected to be completed during the renewal of the approvals for the active substances under the EU BPR, with current approvals valid until 31st of December 2025.

Animal health – Risk not significantly reduced. The cooper-based substances have harmonised classifications for having aquatic acute 1 and chronic 1 toxicity (very high danger) which results in a hazard score of 1. Factors not taken into consideration during hazard scoring are ongoing discussions around possible endocrine disrupting effects against non-target organisms, testing for endocrine disruptive properties towards amphibians is under discussion (ECHA, 2022).

Environment – Risk not significantly reduced. The scoring for this category is driven by the harmonised acute and chronic aquatic toxicity classification. However, a factor not taken into consideration is that metallic compounds are not classified for persistence, even though they do not degrade in the environment (ECHA, 2023).

The copper compounds do not have any physical-chemical hazard classifications and therefore receive a hazard score of 5.

Table 28 Hazard score (based on approval dossier for dicopper oxide (ECHA, 2016, ss. 10-11)

Substance name	**Human health**	**Environment inc animals**	**Phys-chem**	**Overall score**
Copper compounds	8	1	5	14

To assess the reduction in overall risk, a qualitative exposure assessment has been carried out according to the methodology in Section 2. The concentration of copper compounds in antifouling coatings of 40% w/w gives as score of 1, The human and environmental exposures are based on the risk quota (RQ) between exposure and safe exposure levels where for humans the RQ below 1 gives the highest score of 5 and for the environment the RQ of 1.08 gives a score of 4. The difference in exposure between medetomidine and the copper compounds are that a significantly higher amount of substance is used in the coating, 40% of copper compound compared to 0.1% of medetomidine. For human and environmental exposure, the scenarios used for assessment are standardised for assessment of antifouling coatings and no major differences can be identified.

Table 29 Exposure assessment based on exposure assessment in approval dossier for dicopper oxide (ECHA, 2016, ss. 19-58)

Substance name	**Exposure (% in EU BPR approval dossier)**	**Human exposure (RQ professional spray and cleaning)**	**Environmental exposure (RQ for OECD harbour, water+sediment)**	**Overall score**
Copper compounds	40 – score 1	0.9 – score 5	1.08 – score 4	10

The qualitative hazard and exposure assessments have been combined to produce a final risk reduction score, as per Section 2. The conclusion of this assessment suggests that the copper compounds score higher than medetomidine and so it could be considered that there is potential for a reduction in overall risk compared to medetomidine. As noted above, this assessment does not take into consideration endocrine effects on humans as there is a lack of data.

Table 30 Risk score for copper compounds Use type 1

Substance name	**Hazard score**	**Exposure assessment score**	**Risk score**
Copper compounds	14	10	24

6.1.1.1.3 Technical feasibility

The technical feasibility of copper based antifouling coatings as an alternative can be assessed according to 5 key aspects: technical readiness, availability, the changes required for use, the efficacy, and any issues of resistance. These are covered in detail in this section and then scored accordingly for comparison with medetomidine.

Copper based antifouling coatings are commercially available and widely used for commercial vessels in the EU and globally as the primary biocide to hinder fouling (Edith Arndt, 2021). Copper is approved for use in commercial coatings in EU and currently two products have been approved according to BPR. Minimal adaptations in the technology, application or regarding risk mitigation measures would be necessary to replace the potential candidate for substitution for use in coatings intended for commercial vessels, it is not uncommon to use copper and medetomidine together to maximize fouling protection (Chugoku Marine Paints, 2023).

Copper based antifouling coatings release copper ions which then act against a wide range of organisms as previously described. Copper has a very wide activity against different types of fouling species, including calcareous fouling and algae. Copper-only antifouling coatings often require a high concentration of copper to be efficacious against algae, with some commercial products containing up to 50% cuprous oxide in weight. According to stakeholders who contributed to the consultation, to increase performance and lower cost, copper-based antifouling products require a co-biocide, which are active against algae, to achieve full efficacy against fouling.

To deter barnacle larvae settlement, and perform a similar function to medetomidine, a release of 4.5 microgram/cm^2/day is needed for the copper antifouling coating. If that is achieved by commercially available products is not certain, averages below 4 microgram/cm^2/day has been reported (Aldis O. Valkirs, 2003). However, fouling pressure depends on many factors like nutrients, light, water temperature, water depth etc and as the fouling pressure varies, the required concentration of active substance may also vary. The risk for copper containing coatings to foul under idle conditions depends on the length of their idling periods and the risk of fouling, longer idling and higher fouling pressure gives a larger risk of fouling (Hoffman, 2023). Taking as example Suezmax tanker vessels (130.00 to 199.900 DWT) around 4 % of the fleet idle more than 30 days per year and during 2020 this value peaked at 8.5 % of the fleet (Hoffman, 2021).

To address these issues it is common to use additional biocides in antifouling paints to improve the antifouling performance of copper coatings. Another alternative is to use high concentrations, up to 70% copper containing coatings could be needed for full fouling protection in some cases

(Lindgren, Ytreberg, & Holmqvist, 2018). However, as mentioned by stakeholders during the consultation, such products are only available outside EU. An alternative to ensure full protection against hard fouling without increasing the concentration is to combine copper with medetomidine.

There are however some question marks regarding the use of copper and risks for resistance. The mode of action for copper outlined above is different to medetomidine and concerns have been raised as to the development of tolerance towards it. It has been reported that barnacles have developed tolerance against copper, with the invasive barnacle *Amphibalanus amphitrite* having tolerance observed in Florida by the Center for Corrosion and Biofouling Control since 2012 and by Weiss (1947). To test the theory that this barnacle preferentially settles on copper coated surfaces to avoid settlement competition by other sessile species, a series of two experiments and a literature review of historical copper toxicity tests on larval barnacles was conducted. The barnacle *A amphitrite* was preferentially used in many previous toxicity studies because it is readily available, has high fecundity, and is more sensitive to some toxicants than other species, including the native barnacle *A eburneus*. Copper tolerance in the barnacle *A amphitrite* has been observed through recruitment studies and observations in several parts of Florida. Though this barnacle is known to be sensitive to copper in the literature, the anomaly of its recruitment to copper coated surfaces is yet to be determined. Settlement studies of *A amphitrite* revealed a preference for settlement on inert surfaces without competing recruits, which is indicative of the literature sensitivity results but not the observed recruitment of this organism. Experiments were conducted to assess the effects of copper on larval development in the barnacle *A amphitrite*. Results showed that molting was a more sensitive endpoint than survival and that whole larval development assay was more sensitive than assays using a particular larval stage (Brinson, 2017) (Jian-Wen Qiu, 2005). *A amphitrite* is native to the south west Pacific Ocean and the Indian Ocean but can today found in most tempered European waters including the Mediterranean and the southern North Sea up to the Netherlands (HaV, 2021).

It has also been reported that in some regions (UK, Chile, Red Sea) algae have developed tolerance against copper compounds. A review article provided evidence that green and red macroalgae display several defences against copper to prevent, or at least reduce, stress and damage, among which are cellular exclusion mechanisms, synthesis of metal-chelating compounds, and the activation of the antioxidant system. The most important defence mechanisms identified in green and red seaweed involve: metal-binding to cell wall and epibionts; syntheses of metallothioneins and phytochelatins that accumulate in the cytoplasm; and the increase in the activity of antioxidant enzymes such as superoxide dismutase, ascorbate peroxidase, glutathione peroxidase and catalase, and greater production of antioxidant metabolites as glutathione and ascorbate in organelles and the cytoplasm (Alejandra Moenne, 2016).

When compared to medetomidine, the copper compounds score lower for technical feasibility (see Table 31) For technical readiness and availability copper compounds are market leader for antifouling coatings and no limitations can be identified regarding these criteria, they therefore received the highest score of 3. No major adaptations or changes to the product are necessary to replace medetomidine for the specified use and requirements for equipment, risk management measures and training needs are comparable. The reason for the lower score compared to medetomidine is efficacy, where the concentration needed to achieve the same effect as medetomidine is much higher (score 1) and risk for ecosystem effects such as resistance development, which was scored as 2 since its not proven in EU.

Table 31 Technical feasibility assessment score for copper compounds Use type 1

Substance name	Technical readiness	Availability	Changes required for use	Efficacy	Ecosystem effects	Overall score
Copper compounds	3	3	3	1	2	12

6.1.1.1.4 Economic feasibility

No specific economic advantage or disadvantage from using copper in antifouling coatings can be identified. For some premium antifouling coatings with high concentrations of copper, the amount of copper is slightly more costly than the required amount of medetomidine, while in some other premium antifouling coatings, copper is slightly less costly. An average cost of copper oxide at €8 per kg (market price November 2023) was the basis for determination of economic feasibility.

When compared to medetomidine, the copper compounds score the same for economic feasibility (see Table 32) due to similar price for product, same equipment needed for application, same type of application and requirements to manage risk.

Table 32 Economic feasibility assessment score for copper compounds Use type 1

Substance name	Price per litre	Cost of equipment	Application rates / maintenance	Risk management	Overall score
Copper compounds	3	3	3	3	12

6.1.1.1.5 Availability

The alternative substance is readily available for use in antifouling products, as it is the most commonly used active substance to prevent all types of biofouling. Currently 2 products for use type 1 containing the copper compounds assessed as alternatives are approved in EEA (Norway). Due to confidentiality, no data on the volumes of copper-based antifouling coatings placed on the EEA market or production capacity was available for comparison.

The only risk foreseen regarding availability of copper compounds are revised concentration limit or non-approval decision at the renewal procedure according to the BPR.

6.1.1.1.6 Conclusion on the suitability and availability of Copper compounds

The qualitative assessment of hazard and exposure for copper containing antifouling paints has concluded that there may be a reduction in the overall risk for humans due to the beneficial classification profile as non-toxic. However, risks for animals and the environment cannot be considered reduced in comparison to medetomidine due to the aquatic acute and chronic toxicity classification, the risk posed by no degradation of the compounds and the unclear outcome of the ongoing ED discussions.

In the technical feasibility assessment, the copper compounds get a slightly lower score than medetomidine due to the much higher concentration needed to achieve efficacy, 40% compared to 0.1% for medetomidine, and the risk for resistance development. The economic and availability assessments shows that there are no differences identified between the assessed copper compounds and medetomidine. The overall conclusion is that copper compounds has a slightly less favourable score regarding suitability than medetomidine, which scored 49, for the specified use type 1.

Table 33 Overall assessment score for copper compounds Use type 1

Substance name	**Hazard score**	**Exposure assessment**	**Technical Feasibility**	**Economic Feasibility**	**Overall score**
Copper compounds	14	10	12	12	48

Tralopyril

6.1.1.1.7 Identity and properties

Substance Name	CAS #	Hazard Class and Category Code(s)	Hazard statement Code(s)
Tralopyril	122454-29-9	Acute Tox. 2 Acute Tox. 3 STOT RE 1 STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1	H300, H330 H311 H372 (oral) H373 (inhalation) H400 H410

Tralopyril is not classified as PBT, only as T in the current approval.

Tralopyril's antifouling mode of action is generated by a disruption of ATP (adenosin triphosphate) production and energy production within the cells. This causes an energy metabolism dysfunction in exposed organisms and eventually death. This is a different mode of action compared to the fouling deterrent mode of action by medetomidine and the enzyme inactivation caused by the cupric ion, Cu^{2+} (ECHA, 2014) (ECHA, 2015) (ECHA, 2016).

6.1.1.1.8 Reduction of overall risk

This assessment of the reduction in overall risk followed the methodology outlined in Section 2.

Human health – Risk not significantly reduced based on EU hazard classification. Tralopyril has no harmonized classifications, however the human hazard classifications included in BPR approval dossier include acute tox. 2 and specific target organ toxicity for both oral and inhalation routes. When using the Column model to compare, this results in a human health hazard score of 3, 1 for very high danger of acute toxicity and 2 for high danger of chronic toxicity. It should be noted that tralopyril has not yet been assessed for endocrine disruption and a full human health hazard comparison is therefore not possible at this stage due to a lack of data. The full assessment is expected to be completed during the renewal of the approvals for the active substances under the EU BPR, with current approvals valid until 31st of March 2025.

Animal health – Risk not significantly reduced based on classification as having aquatic acute and chronic toxicity, same as medetomidine, giving a score of 1. A factor not included in this assessment is the scientific publications describing possible endocrine disruptive effects in fish (T-modality) where adverse effects on carbohydrate and lipid metabolism caused by mitochondrial dysfunction are indicated in Zebra fish (X Chen, 2021).

Environment – Risk not significantly reduced based on classification, the scoring is driven by the acute and chronic aquatic toxicity classification. An additional concern for the environmental hazard needs to be addressed here to make to comparison comprehensive, the degradation of tralopyril and the fulfilment of EU criteria as PFAS (per- and poly fluoroalkyl substance) (ECHA, 2023). The CF_3-group in the molecular structure of tralopyril, can result in formation of metabolites and/or degradation products that are extremely stable and potentially hazardous. Trifluoroacetic acid (TFA) is one of the possible major metabolites/degradation products, which is very persistent and very mobile in the environment (vPvM) (ECHA, 2023).

Tralopyril does not have any physical-chemical hazard classifications and therefore receives a hazard score of 5.

Taking the existing classifications and the ongoing discussion regarding PFAS tralopyril cannot be considered to have a more favourable hazard classification than medetomidine.

Table 34 Hazard assessment based on current EU BPR approval assessment (ECHA, 2014, s. 6)

Substance name	Human health	Environment inc animals	Phys-chem	Overall score
Tralopyril	3	1	5	9

To assess the reduction in overall risk, a qualitative exposure assessment has been carried out according to the methodology in Section 2. The concentration of tralopyril in antifouling coatings of 4% w/w gives as score of 5. The human and environmental exposures are based on the risk quota (RQ) between exposure and safe exposure levels where for humans the RQ below 5 gives a score of 4 and for the environment the RQ of 21.2 gives a score of 1. The major difference in exposure assessment between medetomidine and tralopyril is that the environmental exposure is much higher when considering water and sediment concentration inside an OECD harbour. The scenarios used for assessment of human and environmental are standardised for assessment of antifouling coatings and no major differences can be identified.

Table 35 Exposure assessment based on current EU BPR approval assessment (ECHA, 2014, ss. 19-48)

Substance name	Exposure (% in EU BPR	Human exposure (RQ professional	Environmental exposure (RQ for OECD harbour, water+sediment)	Overall score

	approval dossier)	spray and cleaning)		
Tralopyril	4 – score 5	1 – score 4	21.2 – score 1	10

The qualitative hazard and exposure assessments have been combined to produce a final risk reduction score, as per Section 2. The conclusion of this assessment suggests that tralopyril score lower than medetomidine and so it could be considered that there is unlikely to be a reduction in overall risk compared to medetomidine. As noted above, this assessment does not take into consideration endocrine effects on humans as there is a lack of data.

Table 36 Risk score tralopyril Use type 1

Substance name	Hazard score	Exposure assessment score	Risk score
Tralopyril	9	10	19

6.1.1.1.9 Technical feasibility

The technical feasibility of tralopyril antifouling coatings as an alternative has been assessed according to 5 key aspects: technical readiness, availability, the changes required for use, the efficacy, and any issues of resistance. These are covered in detail in this section and then scored accordingly for comparison with medetomidine.

Tralopyril has so far only found limited use in antifouling coatings in EU, it is unclear if this is because of technical or economic reasons. For commercial vessels it is mainly used in copper free coating systems sold in Asia, like NEXEON 750 or Seaflo NEO CF Z. None of the products have been approved in the EU according to the BPR and it is unclear if approval has been sought for the EU market since that is confidential information.

Tralopyril cannot be added to coating formulations as medetomidine is due to the high water solubility of tralopyril (0.17 mg/l at 20° Celsius). This high solubility can result in a fast release of tralopyril which limits the service-life and makes formulation more technically challenging. To control the release of tralopyril it is necessary to encapsulate the biocide (Kartal GE, 2022). In contrast to medetomidine, which is used in concentrations of only 0.1 %, tralopyril formulations have to be optimised for its use. As discussed with stakeholders, medetomidine can be added to a coating system without changing the formulation principle and thus improve hard fouling protection easily.

Tralopyril has a broad spectrum of activity against hard-shelled and soft-bodied invertebrate fouling organisms including barnacles, hydroids, mussels, oysters, polychaete tube worms, ascidians, bryozoans, and sponges. It is normally used in concentrations of up to 5 % in weight (MSDS NEXEON 750). To achieve protection against soft fouling organisms tralopyril, as medetomidine, is normally combined with a co-biocide like copper pyrithione, zinc pyrithione or DCOIT.

No resistance issues have been reported for tralopyril, likely due to the mode of action which is uncoupling mitochondrial oxidative phosphorylation. Development of resistance against this mode of action can be considered unlikely and rare for a variety of reasons; a lack of target site for mutation, the need for combined mechanisms in order to enable detoxification or uptake decrease, and a steep concentration-dependence in uncoupling phosphorylation (ECHA, 2014).

When compared to medetomidine, the tralopyril scores lower for technical feasibility (see Table 37). For technical readiness and availability tralopyril is proven commercially. However, lack of approved antifouling coatings under BPR makes availability difficult to assess for all biocides. Since this is not specific for tralopyril no limitations can be identified regarding the availability of substance and tralopyril therefore received the highest score of 3. Adaptations or changes to the product is necessary to replace medetomidine for the specified use and therefore is scored as 2. The requirements for equipment, risk management measures and training needs are comparable. The reason for the lower score compared to medetomidine is efficacy, where the concentration needed to achieve the same effect as medetomidine is much higher (score 1, 5% compared to 0.1% Regarding risk for ecosystem effects, tralopyril scored 3 since no indications of resistance development has been published.

Table 37 Technical feasibility assessment score tralopyril Use type 1

Substance name	**Technical readiness**	**Availability**	**Changes required for use**	**Efficacy**	**Ecosystem effects**	**Overall score**
Tralopyril	3	3	2	1	3	12

6.1.1.1.10 Economic feasibility

An analysis of the economic feasibility has been made using a hypothetical coating and compared the square meter price between medetomidine and tralopyril. No specific economic advantage or disadvantage with using tralopyril in antifouling paint can be identified based on cost per litre of coating. Cost of tralopyril assumed to €73 per kg (Report Biocides in Antifouling Paint, 2021). Unfortunately access to newer information regarding cost of tralopyril is not publicly available.

When compared to medetomidine, the tralopyril scores the same for economic feasibility (see Table 38) due to similar price for product in end-product, same equipment needed for application, same type of application and requirements to manage risk.

Table 38 Economic feasibility assessment score for tralopyril Use type 1

Substance name	**Price per litre**	**Cost of equipment**	**Application rates / maintenance**	**Risk management**	**Overall score**
Tralopyril	3	3	3	3	12

6.1.1.1.11 Availability

The alternative substance is readily available for use in antifouling products. However, as described in the Section 6.1.1.1.9 there are some limitations regarding the use profile, inclusion of tralopyril in coatings today containing medetomidine will not be possible without - reformulation.

If there is sufficient supply of tralopyril to cover use of medetomidine in EU is unknow, production volumes are not publicly available. Lack of approved antifouling coatings under BPR makes availability difficult to assess for all biocidal products. Since this is not specific for tralopyril no clear limitations can be identified regarding the availability. Other risks foreseen regarding availability of the substance is a revised concentration limit or non-approval decision at the renewal procedure according to the BPR.

6.1.1.1.12 Conclusion on the suitability and availability of tralopyril

The qualitative assessment of hazard and exposure for tralopyril containing antifouling paints concludes that there is unlikely to be a reduction in the overall risk for humans, animals or the environment in comparison to medetomidine. Hazard classifications for humans, animals and the environment are comparable to the hazards posed by medetomidine, especially when considering the fulfilment of PFAS criteria.

In the technical feasibility assessment, tralopyril has a slightly lower score than medetomidine due to the higher concentration needed to achieve efficacy and that medetomidine can be added into most coating formulations without adjustment, something that is not possible with tralopyril. The economic and availability assessments shows that there are no differences identified between tralopyril and medetomidine. The overall conclusion is that tralopyril has a less favourable overall score regarding suitability than medetomidine, score 49, for the specified use type 1.

Table 39 Overall assessment score for tralopyril Use type 1

Substance name	**Hazard score**	**Exposure assessment**	**Technical Feasibility**	**Economic Feasibility**	**Overall score**
Tralopyril	9	10	12	12	43

6.1.2. Non-chemical alternatives

Hard non-biocidal coatings

6.1.2.1.1 Identity and properties

Example product	Hazard Class and Category Code(s)	Hazard statement Code(s)
Hard Bottom Paint, Biltema	Carc. 2 STOT SE 2 STOT SE 3 Aquatic chronic 2	H351 H336 H335 H411

Hard non-biocidal coatings are usually based on epoxy or vinyl technology, creating a smooth hard surface which does not prevent biofouling. The fouling protection is instead achieved if the coating is subjected to regular in-water cleaning, which can be done without damaging the integrity of the coating (Barnes, 2023). The properties of hard non-biocidal coatings in this assessment are based on the example product: Hard bottom paint (Biltema) (Biltema, 2023). It is expected that other hard non-biocidal coatings would score similarly.

6.1.2.1.2 Reduction of overall risk

This assessment of the reduction in overall risk follows the methodology outlined in Section 2 to keep consistency with the comparison of all alternatives.

Human health – Risk slightly reduced based on hazard self-classification of example product (Hard bottom paint, Biltema). The basis for this assessment is the product classification as carcinogenic category 2 and the specific target organ toxicity, which gives an acute score of 4 (small danger) and a chronic score of 2 (high danger) for human health hazards.

Animal health – Risk comparable, based on the product classification of aquatic chronic category 2 which gives a score of 1 – very high danger. This is the same hazard score as for medetomidine.

Environment – Risk not significantly reduced, the scoring is driven by the chronic aquatic toxicity classification.

The coatings do not have any physical-chemical hazard classification and therefore get a hazard score of 5, negligible danger.

Table 40 Hazard assessment score for hard non-biocidal coatings Use type 1 based on product classification (Biltema, 2023)

Technology	**Human health**	**Environment inc animals**	**Phys-chem**	**Overall score**
Hard non-biocidal coatings	6	1	5	12

An exposure assessment has not been performed for hard non-biocidal coatings since there is no biocidal content to base the exposure assessment on. The lack of exposure assessment score will be taken into consideration at comparison of alternatives 6.1.3.

Table 41 Risk score hard non-biocidal hard coatings for Use type 1

Technology	**Hazard score**	**Exposure assessment score**	**Risk score**
Hard non-biocidal coatings	12	n.a	n.a

6.1.2.1.3 Technical feasibility

The technical feasibility of hard non-biocidal coatings as an alternative technology has also been assessed according to 4 key aspects: technical readiness, availability, the changes required for use and the efficacy. Resistance will not be discussed here as this is not relevant to non-biocidal coatings however other implications of this approach, such as the transfer of species, are discussed below.

Hard non-biocidal coatings are available on the EU market and can are applied in similar fashion as generic biocidal antifouling coatings therefore few changes would be needed. However, one major difference is that the coating type do not prevent the occurrence of fouling of surfaces, they instead rely on regular cleaning of the attached fouling (Esmaeili, 2023) or continuous proactive cleaning. The degree of fouling and the forces required for a sufficient cleaning effect are of high importance, cleaning in the biofilm stage will be quite less abrasive than in the macrofouling stages. There is still a lack of publications on the durability of cleaned coatings, cleaning in intervals down to one week has been published for pure epoxy coatings. No visible wear were detected after 120 days. Even if it can be assumed that some abrasion takes place also on hard coatings, a service-life of 5 years for a hard coating in combination with washing is possible (B. Waterman, 2019). However, regional and local restrictions, planning and executing regular in-water cleaning operations can be challenging for ships not operating on a fixed route (Barnes & Guy, 2020), which is one key issue with this coating type. Due to the hard surface of the coating, they are one of the only coating systems suitable for ships trading in waters prone to ice formation (Barnes, 2023).

The lack of fouling protection offered by hard non-biocidal coatings makes vessels coated with the technology at risk of functioning as vectors for transport of invasive species (Aylin Ulman, 2019). IAS is considered to be one of the greatest threats to the world's coastal and marine ecosystems. The impacts of IAS, including through disruption to fisheries, biofouling of coastal industry and infrastructure and interference with human amenity, have been estimated at several hundred million dollars per year. The main vectors for unintentional transfer are ships' ballast water, biofouling of mobile marine structures and aquaculture (GloFouling, 2023).

When compared to medetomidine, hard non-biocidal coatings score lower for technical feasibility (see Table 42). Technical readiness is scores the same as for medetomidine, 3, since there are commercially available products. Availability of alternatives in sufficient quantities is questionable since there is not a commonly used coating type for use type 1, it is therefore scored as a 2. Significant changes, score 1, are required for use of hard non-biocidal coatings, not for application of the coatings, however a very different maintenance practice will be needed to avoid fouling. The alternatives available when using a hard non-biocidal coating are proactive or reactive cleaning of the hull. Due to the lack of fouling protection in the coating system the efficacy is scored as 1 and ecosystem effects such as risk for transport of invasive species is therefore also set to 1.

Table 42 Technical feasibility assessment score for hard non-biocidal coatings Use type 1

Technology	**Technical readiness**	**Available alternatives**	**Changes required for use**	**Efficacy**	**Ecosystem effects**	**Overall score**

Hard non-biocidal coatings	3	2	1	1	1	8

6.1.2.1.4 Economic feasibility

The cost for hard non-biocidal coatings does not limit the technology as an alternative to medetomidine containing antifouling products. However, cleaning of hard non-biocidal coatings, both proactive and reactive, will be an additional cost compared to using a medetomidine containing coating which does not require any cleaning during the service-life. The procedure of proactive cleaning and the effects on running cost of a ship has been reported to only increase the cost marginally, when cost for the coating and proactive cleaning robot is not taken into consideration (Schultz, 2011). This is a relatively new method to maintain a clean hull and much less readily available than the more common practice of reactive cleaning. According to the IMO the cost for in-water hull cleaning (reactive cleaning) of a commercial vessel is in the range of €4500 to € 45 000 (IMO, GreenVoyage2050, 2012). For a fouled hull this is the only option to avoid a very large increase in fuel cost. A hull with soft fouling can have an increase in drag with 17% and medium amounts of hard fouling increased drag with 44% while a heavily fouled hull can have as much as an 69% increase (Schultz, 2011). Therefore, if hull resistance and subsequent drag is kept low it results in less fuel consumption and less greenhouse gas (GHG) emissions

When compared to medetomidine, the hard non-biocidal coatings score lower for economic feasibility (see Table 43). Since the coating will require maintenance to keep a clean hull, which adds cost, the maintenance needs are considered as significantly different and scored as 1. For all other factors the technology is considered is economically comparable.

Table 43 Economic feasibility assessment score for hard non-biocidal coatings Use type 1

Technology	**Price per litre**	**Cost of equipment**	**Application rates / maintenance**	**Risk management**	**Overall score**
Hard non-biocidal coatings	3	3	1	3	10

6.1.2.1.5 Availability

Hard non-biocidal coatings are commercially available in EU, however it is difficult to assess the volumes available. A clear limitation with the technology is access to the cleaning procedures needed to maintain as fouling-free hull. Cleaning of ship hulls is restricted in some EU Member States or considered an environmentally hazardous activity requiring permission beforehand, for example in Sweden, Poland, Germany and Denmark (Annika Krutwa, 2019). This means that cleaning is not an antifouling method that is available across the entire EEA and so there would be limitations in its application.

6.1.2.1.6 Conclusion on the suitability and availability of Hard non-biocidal coatings

Hard non-biocidal coatings cannot be considered to achieve protection against hard fouling and are therefore not a suitable alternative to medetomidine containing antifouling coatings.

The qualitative assessment of hazard of hard non-biocidal coatings concludes that there is a reduction in the overall risk for humans, animals or the environment in comparison to medetomidine, which is not surprising for this coating's technology without biocides.

In the technical feasibility assessment, hard non-biocidal coatings receive a lower score than medetomidine due to availability concerns, significant changes in maintenance requirements, significant reduced efficacy and risk for transport of invasive species. The economic assessment has a slightly lower score than medetomidine due to the cost increase foreseen for cleaning and availability assessments shows that there are concerns regarding access to cleaning procedures to keep a hull free from fouling. The overall conclusion is that hard non-biocidal coatings has a less favourable overall score regarding suitability than medetomidine for the specified use type 1.

Table 44 Overall assessment score for hard non-biocidal coatings

Substance name	**Hazard score**	**Exposure assessment**	**Technical Feasibility**	**Economic Feasibility**	**Overall score**
Hard non-biocidal coatings	12	n.a	8	10	30

Silicone-based coatings

6.1.2.1.7 Identity and properties

Example product	Hazard Class and Category Code(s)	Hazard statement Code(s)
Hempasil X3 + base	Skin irr 2 Chronic aquatic 3	H315 H412
Hempasil X3 + curing agent	Skin irr 2 Skin Sens. 1 Muta. 2 Repr. 1B STOT SE 2 STOT RE 2 Chronic aquatic 2	H315 H317 H341 H360 H371 H373 H411

Silicone based fouling control coatings are also often called Fouling Release Coatings (FRC). Biocide free FRC are based on a silicone matrix that either prevents fouling attachment or facilitates removal through the action of water while the ship sails. Fouling-resistant coatings can prevent the adhesion of marine organisms. They are generally made of hydrophilic polymers such as those based on poly(ethylene glycol) (PEG) and zwitterions. FRCs cannot inhibit the attachment of organisms, but the interfacial bond between organisms and the coating surface is weak due to their low surface free energy (SFE) so that the attached organisms can be readily removed by the water shear force coming from mechanical cleaning or the ship's navigation. Besides the low SFE, the low elastic modulus also plays an important role in FR performance. A surface with a low elastic modulus can detach hard foulants such as barnacles. (Peng Hu, 2020).

6.1.2.1.8 Reduction of overall risk

The assessment of the reduction in overall risk followed the methodology outlined in Section 2.

Human health – Risk slightly reduced based on self-classification of example product (Hempasil X3+ base and curing agent). The product is classified as mutagenic category 2 and reprotoxic category 1B, when using the Column model to compare, this results in a human health hazard score of 4, 2 for high danger of acute toxicity and 2 for high danger of chronic toxicity which can be considered comparable to the classification proposal for medetomidine (Hempel, 2023).

Animal health – Risk slightly reduced based on self-classification of example product. The product is classified as having chronic aquatic toxicity category 2 and 3, this results in a hazard score of 2 for high danger.

Environment – Risk not significantly reduced based on classification, the scoring is driven by the chronic aquatic toxicity classification (2) and the classification of silicone oils as very persistent (vP), same danger score as for the chronic aquatic toxicity. A factor not included in the hazard score is release of silicone oil from FRC, which has been raised as an environmental risk since the early days of the technology (Nendza, 2007). However, since the antifouling protection from FRCs is physical and not chemical the product type does not require any formal hazard or risk assessment before being placed on the European market. Comparison with biocidal technologies are therefore difficult (Waterman, 2005) but scientific studies show that they can have impacts on marine environments by adsorption to suspended particulate matter and may settle into sediment. If oil films build up on sediments, infiltration may inhibit pore water exchange. The silicone oils do not bioaccumulate in marine organisms and soluble fractions have low toxicity to aquatic and benthic organisms. At higher exposures, undissolved silicone oil films or droplets can cause physical-mechanic effects with trapping and suffocation of organisms (Nendza, 2007).

The example product do not have any physical-chemical hazard classification and therefore get a hazard score of 5.

Table 45 Hazard assessment based on safety data sheet for Hempasil X3+ base and curing agent (Hempel, 2023)

Technology	Human health	Environment inc animals	Phys-chem	Overall score
Silicone-based coatings	4	2	5	11

An exposure assessment has not been performed for silicone-based coatings since there is no biocidal content to base the exposure assessment on. The lack of exposure assessment score will be taken into consideration at comparison of alternatives.

The conclusion of the hazard assessment show that the silicone-based coatings score higher than medetomidine and so it could be considered that there is potential for a reduction in overall hazard compared to medetomidine.

Table 46 Risk score for silicone-based coatings Use type 1

Technology	**Hazard score**	**Exposure assessment score**	**Risk score**
Silicone-based coatings	11	n.a	11

6.1.2.1.9 Technical feasibility

The technical feasibility of FRC as an alternative technology has been assessed according to 4 key aspects: technical readiness, availability, the changes required for use and the efficacy. Resistance will not be discussed here as this is not relevant to non-biocidal coatings however other implications of this approach, such as the transfer of species, are discussed below.

Silicone-based coatings were developed more than 20 years ago and are commercially available in EU. Since the silicone-based coatings generally are biocide-fee no approvals are needed to place products on the market. The technology has taken some time to achieve readiness, initially the fouling protection was low, the coatings expensive and had adhesion problems and poor mechanical properties (Dam-Johanse, 2004)

The application process of FRCs can be challenging due to the need for masking to protect surrounding areas from contamination and the need for dedicated application equipment, adding time and cost to the operation. FRC are also sensitive to temperature and humidity during application. FRC have poor anti-abrasion properties and are easily damaged during poorly managed underwater cleans, via canal transits, entering / exiting ports and are unsuitable for ships trading in ice. Unlike biocidal antifouling coatings, the number of times FRC can be re-coated at drydock is limited, before full blasting of the hull is required (stakeholder communication).

FRCs require specific climatic conditions for application, such as temperatures above 5 degrees Celsius (Technical Data Sheet HEMPASIL X3+) and no precipitation during the application process. The required climatic conditions make applications e.g. in the Baltic sea area challenging.

Whilst FRC have shown excellent performance on some vessel types / trades they are generally more suitable for higher activity, faster ships due to the need of shear force to develop the release effect. Biofouling organisms are capable of attaching to the coatings, but most fouling types are removed at voyage speeds greater than 15 knots. Barnacles may detach at speeds around 10 knots but biofilm can remain intact even at speeds above 30 knots (Candries et al. 2001). The application of FRCs is therefore limited to high speed (>15 knots)/high activity vessels (Callow, 2009) such as fast ferries, container ships, gas carriers, vehicle carriers, tankers, reefers (refrigerated cargo ships), cruise liners and large roll-on, roll-off (RoRo) vessels (Townsin, 2009). Although recently developed products claim improved performance at lower speeds due to the use of hydrogels/silicone oils, they are currently not an option for all vessel trades.

However, producers of some commercially available FRCs claim that they can be used on all vessel types (PPG, 2023) (AkzoNobel, 2023) with speeds >10 knots. The efficacy of FRCs can last for 5 – 10 years if properly maintained (Anisimov, 2019) or even longer (Townsin, 2009).

Current silicone-based FRCs are susceptible to scraping or gouging damage caused by anchor chains or when moored alongside. As these coatings rely on the special properties of their surface to minimise adhesion of fouling organism, any damage would have a considerable impact on their efficacy (Lejars, 2012). Vessels using slow steaming to reduce fuel consumption or trade routes with risks of longer periods of idling are not suitable for this technology, since those factors increase the risk of failure of the coating system (Barnes & Guy, 2020) and the coatings are likely to be less effective and hull cleaning is required.

The reduced fouling protection offered by silicone-based coatings following idling makes vessels coated with the technology at risk of functioning as vectors for transport of invasive species (Aylin Ulman, 2019). IAS is considered to be one of the greatest threats to the world's coastal and marine ecosystems. The impacts of IAS, including through disruption to fisheries, biofouling of coastal industry and infrastructure and interference with human amenity, have been estimated at several hundred million dollars per year. The main vectors for unintentional transfer are ships' ballast water, biofouling of mobile marine structures and aquaculture (GloFouling, 2023).

When compared to medetomidine, the silicone-based coatings score lower for technical feasibility (see Table 47) due to significant changes, score 1, are required for application of silicone-based coatings to ensure that other vessels are not contaminated with the FRC. The reduced fouling protection during low speed or idling is the reason for the efficacy scored of 1 and the risk for transport of invasive species results in a score for Ecosystem effects of 1. Technical readiness in scored as 3 since there are products commercially available and the availability of alternatives is set to 2, since there are some concerns regarding availability of suitable products for the use type.

Table 47 Technical feasibility assessment score for silicone-based coatings Use type 1

Technology	**Technical readiness**	**Available alternatives**	**Changes required for use**	**Efficacy**	**Ecosystem effects**	**Overall score**
Silicone-based coatings	3	2	1	1	1	8

6.1.2.1.10 Economic feasibility

FRC technology is expensive due to the higher initial cost of paint and application (Lejars, 2012), the cost for FRCs are approximately 3 times higher than for a standard biocidal antifouling paint but feasibility limitations can be considered to be rather technical than economical (Xu Han, 2020).

When compared to medetomidine, the silicone-based coatings score lower for economic feasibility (see Table 48) due to a higher price per litre (score 2), increased costs of equipment for application (score 2) since protection of other vessels is crucial to not contaminate other surfaces with silicone-based coatings, which will destroy adhesion for non-silicone based coatings systems. There is reported increased maintenance needs (Barnes & Guy, 2020) to maintain a clean hull for the full service-life which results in a score of 1, since that is not needed for medetomidine containing coatings while risk management is considered comparable.

Table 48 Economic feasibility assessment for silicone-based coatings Use type 1

Technology	**Price per litre**	**Cost of equipment**	**Application rates / maintenance**	**Risk management**	**Overall score**
Silicone-based coatings	2	2	1	3	8

6.1.2.1.11 Availability

Silicone-based coatings are not suitable for all types of vessels and can therefore not be considered a suitable alternative for all medetomidine-containing coatings and the specified use type.

Cleaning of commercial vessels and subsequent collection of waste is not available everywhere or considered an environmentally hazardous activity requiring permission beforehand, for example in Sweden, Poland, Germany and Denmark (Annika Krutwa, 2019). This could be a limiting factor for silicone-based coatings.

6.1.2.1.12 Conclusion on the suitability and availability of Silicone based coatings

Silicone based coatings does not fulfil the requirements specified for use type 1 due to a lack of protection against hard fouling for the duration of the paints service-life and lack of fouling protection during periods of idling.

The qualitative assessment of hazard concludes that there is a reduction in the overall risk for humans, animals or the environment in comparison to medetomidine, which is not surprising for a technology without biocides.

In the technical feasibility assessment the coatings receive a lower score than medetomidine significant changes in application requirements, significant reduced efficacy and risk for transport of invasive species. The economic assessment has a lower score than medetomidine due to the cost for product, application and cleaning. The availability assessments shows that there are concerns regarding access to cleaning procedures to keep a hull free from fouling. The overall conclusion is that silicone-based coatings has a less favourable overall score regarding suitability than medetomidine for the specified use type 1.

Table 49 Overall assessment of silicone-based coatings as alternative

Substance name	**Hazard score**	**Exposure assessment**	**Technical Feasibility**	**Economic Feasibility**	**Overall score**
Silicone-based coatings	11	n.a	8	8	27

Cleaning (proactive)

6.1.2.1.13 Identity and properties

Proactive cleaning is carried out on microfouling, fouling at early stages of development, where hull grooming is performed at frequent intervals with gentle force without causing damage and minimal erosion to the coating. The procedure prevents or reduces the biofilm and disturbs the fouling at the juvenile and settlement stages, eliminating recruitment and transport of potential invasive marine species (Hunsucker, 2019).

The proactive cleaning is performed by autonomous or remotely controlled robots such as HullSkater (Kongsberg, 2023) (Jotun, 2023) or Shipshave (Shipshave, 2023).

6.1.2.1.14 Reduction of overall risk

A full hazard and exposure assessment cannot be performed on this method to avoid hard fouling on hulls since there is no hazard classification nor exposure to assess.

6.1.2.1.15 Technical feasibility

Proactive cleaning can be combined with biocidal coatings or with biocide free systems, however to be considered a non-chemical alternative in this assessment use non-biocidal coatings are considered only.

The concept is to clean in-service to proactively eliminate soft fouling like biofilm. This is in contrast to the currently used reactive cleaning when a vessel is only cleaned when fouling has been detected. For proactive cleaning, a regular cleaning schedule is planned to eliminate all types of fouling (Scianni, 2019). How effectively grooming can control biofouling on hulls depends on the fouling pressure, the frequency of treatment, the season, the type of grooming tool (e.g. rotating brush) used and the forces imparted by the tool (Tribou, Grooming using rotating brushes as a proactive method to control ship hull fouling', 2015) (Hearin, 2016). Gentle removal of microfouling should not damage antifouling coatings but more rigorous cleaning and removal of mature calcareous fouling can lead to coating damage (Scianni, 2019). Weekly groomed surfaces covered with copper ablative coatings showed only minimal loss of coating over a period of six years (Tribou, 2017). Similarly, a one-year study did not find significant wear or damage of AFC or FRC panels that were cleaned bi-monthly/monthly with waterjets during that period, applying adhesion-strength level cleaning forces (Oliveira, 2020).

If for any reason the proactive cleaning does not happen at the correct intervals and the hull fouls, an increase in fuel consumption due to increased hull resistance will occur and the risk for transfer of invasive species will increase.

Technology for proactive hull grooming is continuously evolving. Jotun, one of the main suppliers of marine coatings, has developed 'HullSkater', an underwater robotics system installed during dry-docking. The fitted system monitors vessel performance and fuel consumption data and predicts the time for an inspection mission which then determines whether a proactive grooming mission is required (Jotun, 2023). Shipshave ITCH is a semi-autonomous hull cleaning robot equipped with soft brushes that allows cleaning of the hull while the vessel is in service (Shipshave, 2023).

It is unclear whether proactive cleaning will be accepted as an antifouling technology in all EU Members States (Annika Krutwa, 2019). There are concerns regarding the potential release of invasive species and the generation of waste, work is ongoing to standardise proactive cleaning methods. With only two companies, Jotun and Shipshave, currently offering onboard solutions it will be challenging to offer such a technology to the full fleet.

When compared to medetomidine, the proactive cleaning score lower for technical feasibility due to several factors. Technical readiness is score as 3, since proactive cleaning solutions are commercially available, although with limited suppliers which results in a score of 1 regarding available alternatives. Significant changes are required for use compared to using a medetomidine containing coatings, both regarding equipment and maintenance to achieve a clean hull. The significantly reduced fouling protection gives an efficacy scored of 1 and the risk for transport of invasive species gives a ecosystem effect score of 1.

Table 50 Technical feasibility assessment score for proactive cleaning solutions, Use type 1

Technology	**Technical readiness**	**Available alternatives**	**Changes required for use**	**Efficacy**	**Ecosystem effects**	**Overall score**
Proactive cleaning	3	1	1	1	1	7

6.1.2.1.16 Economic feasibility

Proactive cleaning solutions are not used as an alternative on their own as they require hull coatings to increase their effectiveness. This technology also requires the use of a cleaning robot which comes with additional capital investment costs and operating costs over the period of use.

The actual procedure of cleaning the hull and the effects on running cost of a ship has been well documented and only increase the cost marginally (Schultz, 2011). However, when cost for the coating and proactive cleaning robot is taken into consideration the cost for using proactive cleaning in comparison to medetomidine containing coatings will be higher.

When compared to medetomidine, the proactive cleaning scores lower for economic feasibility (see Table 51) due to a significantly higher cost for equipment with the cleaning robot (score 1), the maintenance procedure is significantly more expensive (score 1) and the risk management is considered significantly higher due to uncertainty in the technology, score 1.

Table 51 Economic feasibility assessment score for proactive cleaning solutions, Use type 1

Technology	**Price per litre**	**Cost of equipment**	**Application rates / maintenance**	**Risk management**	**Overall score**
Proactive cleaning	n.a	1	1	1	3

6.1.2.1.17 Availability

Cleaning of commercial ship hulls is restricted in some EU Member States or considered as an environmentally hazardous activity requiring permission beforehand, for example in Sweden, Poland, Germany and Denmark (Annika Krutwa, 2019). The proactive cleaning solutions available (Jotun and Shipshave) cannot clean all surfaces of a ships hull, therefore it cannot be considered to achieve full antifouling protection.

6.1.2.1.18 Conclusion on the suitability and availability of Cleaning

The proactive cleaning solutions available (Jotun and Shipshave) cannot be considered to achieve antifouling protection against hard fouling and are not a suitable alternative to medetomidine containing antifouling coatings due to the lack of availability.

Since hazard and exposure cannot be assessed for proactive cleaning the lack of these scores will need to be considered when comparing all alternative technologies for Use type 1.

In the technical feasibility assessment proactive cleaning receive a lower score than medetomidine significant changes in availability, application requirements, significant reduced efficacy and risk for transport of invasive species. The economic assessment has a lower score than medetomidine due to the cost for equipment, maintenance and increased risk management. The availability assessments shows that there are concerns regarding access to cleaning procedures. The overall conclusion is that proactive cleaning has a less favourable overall score regarding suitability than medetomidine for the specified use type 1.

Table 52 Overall assessment of proactive cleaning as alternative

Substance name	**Hazard score**	**Exposure assessment**	**Technical Feasibility**	**Economic Feasibility**	**Overall score**
Proactive cleaning	n.a	n.a	7	3	10

6.1.3. Overall comparison of alternatives for intended use 1 (summary table)

Chemical alternative	Hazard score	Exposure assessment	Technical Feasibility	Economic Feasibility	Overall score
Medetomidine	8	14	15	12	49
Copper compounds	14	10	12	12	48
Tralopyril	9	10	13	12	43

Non-chemical alternative	Hazard assessment	Exposure assessment	Technical Feasibility	Economic Feasibility	Overall score
Hard non-biocidal coatings	12	n.a	8	10	30
Silicone-based coatings	11	n.a	8	8	27
Proactive cleaning	n.a	n.a	7	3	10

6.2. Intended use 2 – Leisure vessels

As outlined in Section 3.3 and 3.4, alternatives to medetomidine should be approved for use and available for application to leisure vessels (Use type 2).

The products should fulfil the following technical requirements:

- barnacle protection in system for leisure vessels with a minimum service-life of 1 year
- approved for use on leisure vessels in EEA and
- approved for non-professional application (DIY)

Antifouling protection for leisure vessels (use type 2) are very different from antifouling measures intended for commercial vessels (use type 1). Since the vessel size, service-life length and the use pattern is completely different, systems that are considered unfit for commercial vessels can give sufficient protection for leisure vessels. To be acceptable for Use type 2 products need to be approved for non-professional application/do-it-yourself, a procedure common in many European countries. The assessment of alternatives and outcome for use type 2 will therefore be different both regarding human and environmental risk, technical feasibility and availability to alternatives.

Chemical alternatives

Copper compounds

6.2.1.1.1 Substance ID and properties

Substance Name	CAS #	Hazard Class and Category Code(s)	Hazard statement Code(s)
Copper flakes	7440-50-8 231-159-6	no hazard classification available	-
Dicopper oxide	1317-39-1 215-270-7	Acute tox. 4 Acute tox. 4 Eye damage 1 Aquatic Acute 1 Aquatic chronic 1	H302 H332 H318 H400 H410
Copper thiocyanate	111-67-7 214-183-1	Aquatic Acute 1 Aquatic chronic l	H400 H410

None of the copper compounds are classified as PBT. Metallic compounds are not classified for persistence, due to their elemental status as they are unable to degrade (Jessica Briffa, 2020).

None of the compounds have been fully assessed for endocrine disruptive properties, this will be performed at renewal of the current approval which expires 31st of December 2025 (ECHA, 2016).

The mode of action in all three copper compounds is generated by the cupric ion, Cu^{2+}. When copper from metallic copper, copper thiocyanate or cuprous oxide leaches into marine water in the presence of oxygen, the predominant form of the copper is the active substance, the cupric ion, Cu^{2+}. The cupric ion acts to retard settlement of the microscopic larvae of fouling organisms within a microlayer of water at the paint surface via two mechanisms:

(1) the ion retards organism's vital processes by inactivating enzymes;
(2) the ion acts more directly by precipitating cytoplasmic proteins as metallic proteinates (ECHA, 2016).

Antifouling products containing 37.5 - 42.5 % w/w Cu_2O have been proved efficacious against biofouling in European sea waters up to 25 months and in tropical sea waters during 12 months, depending on film thickness and final product composition (ECHA, 2016). Copper thiocyanate demonstrated a sufficient activity for the approval of the active substance at 19.25 % w/w of active substance when considering use in European sea water (ECHA, 2016).

6.2.1.1.2 Reduction of overall risk

The assessment of the reduction in overall risk followed the methodology outlined in Section 2.

Human health hazards – Reduced risk based on EU hazard classification for human health. The copper-based substances have harmonised classifications for acute tox. 4 and eye damage 1. When using the Column model to compare, this results in a human health hazard score of 8. It should be noted that the copper-based substances have not yet been assessed for endocrine disruption and a full human health hazard comparison is therefore not possible at this stage due to a lack of data. The full assessment is expected to be completed during the renewal of the approvals for the active substances under the EU BPR, with current approvals valid until 31st of December 2025.

Animal health – Risk not significantly reduced. The cooper-based substances have harmonised classifications for having aquatic acute 1 and chronic 1 toxicity (very high danger) which results in a hazard score of 1. Factors not taken into consideration during hazard scoring are ongoing discussions around possible endocrine disrupting effects against non-target organisms, testing for endocrine disruptive properties towards amphibians under discussion (ECHA, 2022).

Environment – Risk not significantly reduced. The scoring for this category is driven by the harmonised acute and chronic aquatic toxicity classification. However, a factor not taken into consideration is that metallic compounds are not classified for persistence, even though they do not degrade in the environment (ECHA, 2023).

The copper compounds do not have any physical-chemical hazard classification and therefore get a hazard score of 5.

Table 53 Hazard score copper compounds

Substance name	Human health	Environment inc animals	Phys-chem	Overall score
Copper compounds	8	1	5	14

To assess the reduction in overall risk, a qualitative exposure assessment has been carried out according to the methodology in Section 2. The concentration of copper compounds in antifouling coatings of 40% w/w gives as score of 1, The human and environmental exposures are based on the risk quota (RQ) between exposure and safe exposure levels where for humans the RQ below 1 gives the highest score of 5 and for the environment the RQ of 2.27 gives a score of 4. The difference in exposure between medetomidine and the copper compounds are that a significantly higher amount of substance is used in the coating, 40% of copper compound compared to 0.1% of medetomidine. For human and environmental exposure, the scenarios used for assessment are standardised for assessment of antifouling coatings intended for leisure vessels and no major differences can be identified.

Table 54 Exposure assessment score for copper compounds Use type 2 based on information in BPR approval for dicopper oxide (ECHA, 2016).

Substance name	**Exposure (% in EU BPR approval dossier)**	**Human exposure (RQ non-professional combined exposure)**	**Environmental exposure (RQ for OECD marina, water+sediment)**	**Overall score**
Copper compounds	40 – score 1	0.51 – score 5	2.27 – score 4	10

The qualitative hazard and exposure assessments have been combined to produce a final risk reduction score, as per Section 2. The conclusion of this assessment suggests that the copper compounds score higher than medetomidine and so it could be considered that there is potential for a reduction in overall risk compared to medetomidine. As noted above, this assessment does not take into consideration endocrine effects on humans as there is a lack of data.

Table 55 Risk score for copper compounds use type 2

Substance name	**Hazard score**	**Exposure assessment score**	**Risk score**
Copper compounds	14	10	24

6.2.1.1.3 Technical feasibility

The technical feasibility of copper based antifouling coatings as an alternative can be assessed according to 5 key aspects: technical readiness, availability, the changes required for use, the efficacy, and any issues of resistance. These are covered in detail in this section and then scored accordingly for comparison with medetomidine.

To deter barnacle larvae settlement, and perform a similar function to medetomidine, a release of 4.5 microgram/cm^2/day is needed for the copper antifouling coating. If that is achieved by available products is not certain, averages below 4 microgram/cm^2/day has been reported (Aldis O. Valkirs, 2003).   However, fouling pressure depends on many factors like nutrients, light, water temperature, water depth etc and as the fouling pressure varies, the required concentration of active substance may also vary. The risk for copper containing coatings to foul under idle conditions depends on the length of their idling periods and the risk of fouling, longer idling and higher fouling pressure gives a larger risk of fouling (Hoffman, 2023). Yachts where the release rate does not match the needed concentrations are a vector for spreading invasive species (Clarke Murray, 2011).

Copper based antifouling products are widely used for leisure boats and dominates the biocidal antifouling market in Europe, approximately 15 coatings for leisure vessels are approved according to BPR, predominantly in Norway and Italy. Copper based compaounds and medetomidine generally function well in the same coating systems. Minimal adaptations in the technology, application or regarding risk mitigation measures would be necessary to replace the potential candidate for substitution for use in coatings intended for leisure vessels.

The mode of action for copper outlined above is different to medetomidine and concerns have been raised as to the development of tolerance towards it. It has been reported that barnacles have developed tolerance against copper, with the invasive barnacle *Amphibalanus amphitrite* having tolerance observed in Florida by the Center for Corrosion and Biofouling Control since 2012 and by Weiss (1947). To test the theory that this barnacle preferentially settles on copper coated surfaces to avoid settlement competition by other sessile species, a series of two experiments and a literature review of historical copper toxicity tests on larval barnacles was conducted. The barnacle *A amphitrite* was preferentially used in many previous toxicity studies because it is readily available, has high fecundity, and is more sensitive to some toxicants than other species, including the native barnacle *A eburneus*. Copper tolerance in the barnacle *A amphitrite* has been observed through recruitment studies and observations in several parts of Florida. Though this barnacle is known to be sensitive to copper in the literature, the anomaly of its recruitment to copper coated surfaces is yet to be determined. Settlement studies of *A amphitrite* revealed a preference for settlement on inert surfaces without competing recruits, which is indicative of the literature sensitivity results but not the observed recruitment of this organism. Experiments were conducted to assess the effects of copper on larval development in the barnacle *A amphitrite*. Results showed that molting was a more sensitive endpoint than survival and that whole larval development assay was more sensitive than assays using a particular larval stage (Brinson, 2017) (Jian-Wen Qiu, 2005). *A amphitrite* is native to the south west Pacific Ocean and the Indian Ocean but can today found in most tempered European waters including the Mediterranean and the southern North Sea up to the Netherlands (HaV, 2021).

It has also been reported that in some regions (UK, Chile, Red Sea) algae have developed tolerance against copper compounds. A review article provided evidence that green and red macroalgae display several defences against copper to prevent, or at least reduce, stress and damage, among which are cellular exclusion mechanisms, synthesis of metal-chelating compounds, and the activation of the antioxidant system. The most important defence mechanisms identified in green and red seaweed involve: metal-binding to cell wall and epibionts; syntheses of metallothioneins and phytochelatins that accumulate in the cytoplasm; and the increase in the activity of antioxidant enzymes such as superoxide dismutase, ascorbate peroxidase, glutathione peroxidase and catalase, and greater production of antioxidant metabolites as glutathione and ascorbate in organelles and the cytoplasm (Alejandra Moenne, 2016).

A possible connection between resistance development in micoorganisms and exposure to high concentrations of copper has also been reported, metal pollution in temperate forests promotes soil bacterial antibiotic resistance, illustrating a previously unknown reservoir of microbial antibiotic resistance (Rabow, 2022).

The use of copper is technically feasible with a higher risk of invasive species spreading by yachts and a significant higher risk of fouling and higher carbon carbon dioxide emissions. When compared to medetomidine, the copper compounds score worse for technical feasibility (see **Fel! Hittar inte referenskälla.**). For technical readiness and availability copper compounds are market leader for antifouling coatings and no limitations can be identified regarding these criteria, they therefore received the highest score of 3. No major adaptations or changes to the product are necessary to replace medetomidine for the specified use and requirements for equipment, risk management measures and training needs are comparable. The reason for the lower score compared to medetomidine are efficacy, where the concentration needed to achieve the same effect as medetomidine is much higher (score 1) and risk for ecosystem effects, which was scored as 2 since resistance its not proven in EU.

Table 56 Technical feasibility assessment score for copper compounds use type 2

Substance name	**Technical readiness**	**Availability**	**Changes required for use**	**Efficacy**	**Ecosystem effects**	**Overall score**
Copper compounds	3	3	3	1	2	12

6.2.1.1.4 Economic feasibility

No specific economic advantage or disadvantage from using copper in antifouling coatings can be identified. For some premium antifouling coatings with high concentrations of copper, the amount of copper is slightly more costly than the required amount of medetomidine, while in some other premium antifouling coatings, copper is slightly less costly. An average cost of copper oxide at €8 per kg (market price November 2023) was the basis for determination of economic feasibility.

When compared to medetomidine, the copper compounds score the same for economic feasibility due to similar price for product, same equipment needed for application, same type of application and requirements to manage risk.

Table 57 Economic feasibility score for copper compounds use type 2

Substance name	**Price per litre**	**Cost of equipment**	**Application rates / maintenance**	**Risk management**	**Overall score**
Copper compounds	3	3	3	3	12

6.2.1.1.5 Availability

The alternative substance is readily available for use in antifouling products, as it is the most commonly used active substance to prevent all types of biofouling. Currently approximately 15 products for leisure vessels are approved in EU, predominantly in Norway and Italy.

The only risk foreseen regarding availability of the substance is a revised concentration limit or non-approval decision at the renewal procedure according to the BPR.

6.2.1.1.6 Conclusion on the suitability and availability of copper

Copper containing antifouling paints may reduce the overall risk for humans due to the beneficial classification profile as non-toxic. However, risk for animals and the environment cannot be considered reduced in comparison to medetomidine.

Table 58 Overall score for copper compounds use type 2

Substance name	**Hazard score**	**Exposure assessment**	**Technical Feasibility**	**Economic Feasibility**	**Overall score**
Copper compounds	14	10	12	12	48

Tralopyril

6.2.1.1.7 Substance ID and properties

Substance Name	CAS #	Hazard Class and Category Code(s)	Hazard statement Code(s)
Tralopyril	122454-29-9	Acute Tox. 2 Acute Tox. 3 STOT RE 1 STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1	H300, H330 H311 H372 (oral) H373 (inhalation) H400 H410

Tralopyril is not classified as PBT, only as T in the current approval.

Tralopyril's antifouling mode of action is generated by a disruption of ATP (adenosin triphosphate) production and energy production within the cells. This causes an energy metabolism dysfunction in exposed organisms and eventually death. This is a different mode of action compared to the fouling deterrent mode of action by medetomidine and the enzyme inactivation caused by the cupric ion, Cu^{2+} (ECHA, 2014) (ECHA, 2015) (ECHA, 2016).

6.2.1.1.8 Reduction of overall risk

The assessment of the reduction in overall risk followed the methodology outlined in Section 2.

Human health – Risk not significantly reduced based on EU hazard classification. Tralopyril has no harmonized classification, however human hazard classifications included in BPR approval dossier include acute tox. 2 and specific target organ toxicity for both oral and inhalation routes. When using the Column model to compare, this results in a human health hazard score of 3, 1 for very high danger of acute toxicity and 2 for high danger of chronic toxicity. It should be noted that the tralopyril have not yet been assessed for endocrine disruption and a full human health hazard comparison is therefore not possible at this stage due to a lack of data. The full assessment is expected to be completed during the renewal of the approvals for the active substances under the EU BPR, with current approvals valid until 31st of March 2025.

Animal health – Risk not significantly reduced based on classification as having aquatic acute and chronic toxicity, same as medetomidine, giving a score of 1. A factor not included in this assessment is the scientific publications describing possible endocrine disruptive effects in fish (T-modality) where adverse effects on carbohydrate and lipid metabolism caused by mitochondrial dysfunction are indicated in Zebra fish (X Chen, 2021).

Environment – Risk not significantly reduced based on classification, the scoring is driven by the acute and chronic aquatic toxicity classification. An additional concern for the environmental hazard needs to be addressed here to make to comparison comprehensive, the degradation of tralopyril and the fulfilment of EU criteria as PFAS (per- and poly fluoroalkyl substance). The CF_3-group in the molecular structure of tralopyril, can result in formation of metabolites and/or degradation products that are extremely stable and potentially hazardous. Trifluoroacetic acid (TFA) is one of the possible major metabolites/degradation products, which is very persistent and very mobile in the environment (vPvM) (ECHA, 2023).

Tralopyril do not have any physical-chemical hazard classification and therefore get a hazard score of 5.

Taking the existing classifications and the ongoing discussion regarding PFAS tralopyril cannot be considered to have a more favourable hazard classification than medetomidine.

Table 59 Hazard score for tralopyril use type 2

Substance name	**Human health**	**Environment inc animals**	**Phys-chem**	**Overall score**
Tralopyril	3	1	5	9

To assess the reduction in overall risk, a qualitative exposure assessment has been carried out according to the methodology in Section 2. The concentration of tralopyril in antifouling coatings of 4% w/w gives as score of 5. The human and environmental exposures are based on the risk quota (RQ) between exposure and safe exposure levels where for humans the RQ below 5 gives a score of 4 and for the environment the RQ of 21.2 gives a score of 1. The major difference in exposure assessment between medetomidine and tralopyril is that the environmental exposure is much higher when considering water and sediment concentration inside an OECD harbour. The scenarios used for assessment of human and environmental are standardised for assessment of antifouling coatings and no major differences in use can be identified between tralopyril and medetomidine. However, the approval for tralopyril does not specifically mention if the substance can be used for non-professional application, something that should be kept in mind when comparing the technologies.

Table 60 Exposure assessment score tralopyril use type 2

Substance name	Exposure (% in EU BPR approval dossier)	Human exposure (RQ non-professional combined exposure)	Environmental exposure (RQ for OECD marina, water+sediment)	Overall score
Tralopyril	4 – score 5	1 – score 4	54.5 – score 1	10

The qualitative hazard and exposure assessments have been combined to produce a final risk reduction score, as per Section 2. The conclusion of this assessment suggests that tralopyril score lower than medetomidine and so it could be considered that there is unlikely to be a reduction in overall risk compared to medetomidine. As noted above, this assessment does not take into consideration endocrine effects on humans as there is a lack of data.

Table 61 Risk score for tralopyril use type 2

Substance name	Hazard score	Exposure assessment score	Risk score
Tralopyril	9	10	19

6.2.1.1.9 Technical feasibility

The technical feasibility of tralopyril antifouling coatings as an alternative has been assessed according to 5 key aspects: technical readiness, availability, the changes required for use, the efficacy, and any issues of resistance. These are covered in detail in this section and then scored accordingly for comparison with medetomidine.

Based on information gathered during stakeholder dialogue tralopyril has so far only found limited use in antifouling coatings, it is unclear if this is because of technical or economic reasons. For leisure vessels one product have been authorised for PT21 according to the BPR, Velox Super Nero in Italy, and it is unclear if further national authorisations have been sought for the EU market.

Tralopyril has a water solubility of 0.17 mg/l at 20° Celsius. This high solubility can cause a fast release of tralopyril out of the coating which limits the service-life and makes formulation more technically challenging. To control the release of tralopyril it is necessary to encapsulate the biocide (Kartal GE, 2022). In contrast to medetomidine, which is used in concentrations of only 0.1 %, tralopyril formulations have to be optimised for its use. Medetomidine can just be added to a coating system without changing the formulation principle and thus improve hard fouling protection easily (stakeholder communication).

Tralopyril has a broad spectrum of activity against hard-shelled and soft-bodied invertebrate fouling organisms including barnacles, hydroids, mussels, oysters, polychaete tube worms, ascidians, bryozoans, and sponges. It is normally used in concentrations of up to 5 % in weight. To achieve protection against soft fouling organisms tralopyril is combined with a co-biocide like copper pyrithione, zinc pyrithione or DCOIT.

No resistance issues has been reported for tralopyril, likely due to the mode of action which is uncoupling mitochondrial oxidative phosphorylation. Development of resistance against this mode of action can be considered unlikely and rare for a variety of reasons; a lack of target site for mutation, the need for combined mechanisms in order to enable detoxification or uptake decrease, and a steep concentration-dependence in uncoupling phosphorylation (ECHA, 2014).

When compared to medetomidine, the tralopyril scores slightly lower for technical feasibility. For technical readiness and availability tralopyril is proven commercially and no limitations can be identified regarding the availability of substance, tralopyril therefore received the highest score of 3. Adaptations or changes to the product are necessary to replace medetomidine for the specified use and is therefore scored as 2. Requirements for equipment, risk management measures and training needs are comparable and scored 3. The reason for the lower score compared to medetomidine is efficacy, where the concentration needed to achieve the same effect as medetomidine is much higher (score 1). Regarding risk for resistance development, tralopyril scored 3 since no indications of ecosystem effects such as resistance development has been published.

Table 62 Technical feasibility assessment for tralopyril use type 2

Substance name	**Technical readiness**	**Availability**	**Changes required for use**	**Efficacy**	**Ecosystem effects**	**Overall score**
Tralopyril	3	3	2	1	3	12

6.2.1.1.10 <u>Economic feasibility</u>

An analysis of the economic feasibility has been made using a hypothetical coating and compared the square meter price between medetomidine and tralopyril. No specific economic advantage or disadvantage with using tralopyril in antifouling paint can be identified based on cost per litre of coating. Cost of tralopyril assumed to €73 per kg (Report Biocides in Antifouling Paint, 2021). Unfortunately access to newer information regarding cost of tralopyril is not publicly available.

When compared to medetomidine, the tralopyril scores the same for economic feasibility due to similar price for product in end-product, same equipment needed for application, same type of application and requirements to manage risk

Table 63 Economic feasibility score for tralopyril use type 2

Substance name	**Price per litre**	**Cost of equipment**	**Application rates / maintenance**	**Risk management**	**Overall score**
Tralopyril	3	3	3	3	12

6.2.1.1.11 Availability

The alternative active substance is available for use in antifouling products. For leisure vessels one product was authorised for PT21 according to the BPR in 2022, Velox Super Nero in Italy (ECHA, 2023), and it is unclear if further national authorisations have been sought for the EU market.

Risk foreseen regarding availability of the substance in EU for use type 2 is that the current approval does not specifically describe an approved use for leisure vessels, a revised concentration limit due to changes human or environmental risk assessments or non-approval decision at the renewal procedure according to the BPR.

6.2.1.1.12 Conclusion on the suitability and availability of tralopyril

The qualitative assessment of hazard and exposure for tralopyril containing antifouling paints concludes that there is unlikely to be a reduction in the overall risk for humans, animals or the environment in comparison to medetomidine. Hazard classifications for humans, animals and the environment are comparable to the hazards posed by medetomidine, especially when considering the fulfilment of PFAS criteria.

In the technical feasibility assessment, tralopyril has a slightly lower score than medetomidine due to the higher concentration needed to achieve efficacy. A factor not included in the scoring is that medetomidine can be added into most coating formulations without adjustment, something that is not possible with tralopyril (stakeholder communication). The economic and availability assessments shows that there are no differences identified between tralopyril and medetomidine. The overall conclusion is that tralopyril has a less favourable overall score regarding suitability than medetomidine for the specified use type 2.

Table 64 Overall score for tralopytil use type 2

Substance name	**Hazard score**	**Exposure assessment**	**Technical Feasibility**	**Economic Feasibility**	**Overall score**
Tralopyril	9	10	12	12	43

6.2.2. Non-chemical alternatives

Hard non-biocidal coatings

6.2.2.1.1 Identity and properties

Example product	Hazard Class and Category Code(s)	Hazard statement Code(s)

Hard Bottom Paint, Biltema	Carc. 2 STOT SE 2 STOT SE 3 Aquatic chronic 2	H351 H336 H335 H411

Hard non-biocidal coatings are usually based on epoxy technology, creating a smooth hard surface which does not in itself prevent biofouling. The fouling protection is achieved if the coating is subjected to regular in-water cleaning, which can be done without damaging the integrity of the coating (Barnes, 2023).

6.2.2.1.2 Reduction of overall risk

Human health – Risk slightly reduced based on hazard self-classification of example product (Hard bottom paint, Biltema). The basis for this assessment is the product classification as carcinogenic category 2 and the specific target organ toxicity, which gives an acute score of 4 (small danger) and a chronic score of 2 (high danger) for human health hazards.

Animal health – Risk not significantly reduced based on the product classification as having aquatic chronic properties class 2 which gives a score of 1 – very high danger. This is the same hazard score as for medetomidine.

Environment – Risk not significantly reduced, the scoring is driven by the chronic aquatic toxicity classification. A factor not taken into consideration here is the additional risk for transport of invasive species with this type of coating and the risk posed for the ecosystem, which is further discussed under technical feasibility.

The coatings do not have any physical-chemical hazard classification and therefore get a hazard score of 5, negligible danger.

Table 65 Hazard score hard non-biocidal coatings use type 2

Technology	Human health	Environment inc animals	Phys-chem	Overall score
Hard non-biocidal coatings	6	1	5	12

An exposure assessment has not been performed for hard non-biocidal coatings since there is no biocidal content to base the exposure assessment on. The lack of exposure assessment score will be taken into consideration at comparison of alternatives.

Table 66 Risk score hard non-biocidal coatings for use type 2

Substance name	Hazard score	Exposure assessment score	Risk score
Hard non-biocidal coatings	12	n.a	12

6.2.2.1.3 Technical feasibility

The technical feasibility of hard non-biocidal coatings as an alternative technology has also been assessed according to 4 key aspects: technical readiness, availability, the changes required for use and the efficacy. Resistance will not be discussed here as this is not relevant to non-biocidal coatings however other implications of this approach, such as the transfer of species, are discussed below.

Hard non-biocidal coatings are available on the EU market and can are applied in similar fashion as generic biocidal antifouling coatings therefore few changes would be needed. However, one major difference is that the coating type do not prevent the occurrence of fouling of surfaces, they instead rely on regular cleaning of the attached fouling (Esmaeili, 2023) or continuous proactive cleaning. The degree of fouling and the forces required for a sufficient cleaning effect are of high importance, cleaning in the biofilm stage will be quite less abrasive than in the macrofouling stages. Cleaning of leisure vessels is not limited or controlled as it is for commercial vessel and can therefore be considered a readily available option for maintenance of this coating type.

The lack of fouling protection offered by hard non-biocidal coatings makes leisure vessels coated with the technology at risk of functioning as vectors for transport of invasive species (Aylin Ulman, 2019). IAS is considered to be one of the greatest threats to the world's coastal and marine ecosystems. The impacts of IAS, including through disruption to fisheries, biofouling of coastal industry and infrastructure and interference with human amenity, have been estimated at several hundred million dollars per year (GloFouling, 2023). Studies of leisure vessels as vectors for invasive species has demonstrated the potential for spreading invasive species, especially as 71% of sampled vessels host at least one (and up to 11) non-indigenous species. Boats with high richness of invasive species strongly correlate with home marinas with high invasive species richness. Over half of the vessels were carriers of invasive species which were not yet present in the marinas they were visiting. The presence of biofouling in niche areas of the hull (i.e. in the cavities and metallic parts) emerges as the best predictor for invasive species richness on boats, along with longer times since their last cleaning and antifouling applications. Interestingly, colonisation of invasive species occurred rapidly, even on boats that had recently had their hulls cleaned professionally (Aylin Ulman, 2019).

When compared to medetomidine, hard non-biocidal coatings score lower for technical feasibility. Technical readiness is scored the same as for medetomidine, 3, since there are commercially available products. Availability of alternatives in sufficient quantities is also scored to 3 since no limitation regarding availability can be identified. Significant changes, score 1, are required for use of hard non-biocidal coatings, not for application of the coatings, however a very different maintenance practice will be needed to avoid fouling. The alternatives available when using a hard non-biocidal coating is some form of cleaning of the hull. Due to the lack of fouling protection in the coating system the efficacy is scored as 1 and the risk for ecosystem effects such as transport of invasive species is therefore also set to 1.

Table 67 Technical feasibility assessment score for hard non-biocidal coatings use type 2

Technology	**Technical readiness**	**Availability**	**Changes required for use**	**Efficacy**	**Ecosystem effects**	**Overall score**

Hard non-biocidal coatings	3	3	1	1	1	9

6.2.2.1.4 Economic feasibility

The cost for hard non-biocidal coatings does not limit the technology as an alternative to medetomidine containing antifouling products. Cleaning of hard non-biocidal coatings on a leisure vessel is not assumed to generate additional cost, this could be done as a DIY process.

When compared to medetomidine, the hard non-biocidal coatings score slightly lower for economic feasibility. Since the coating will require maintenance to keep a clean hull the maintenance needs are considered as higher and scored as 2. For all other factors the technology is considered is economically comparable.

Table 68 Economic feasibility assessment score for hard non-biocidal coatings use type 2

Technology	**Price per litre**	**Cost of equipment**	**Application rates / maintenance**	**Risk management**	**Overall score**
Hard non-biocidal coatings	3	3	2	3	11

6.2.2.1.5 Availability

Hard non-biocidal coatings are available on the EU market, there are no known limitations regarding availability. The coating type is increasing in popularity in areas where boat washes are available (stakeholder communication) but the use is not widespread. However, boat wash solution are primarily suitable for boats without keels (powerboats). DIY cleaning is an available option but is difficult to execute to achieve a clean hull, especially if hard fouling has attached (GloFouling, 2022). There is currently no limitations regarding cleaning of leisure vessels in EU.

6.2.2.1.6 Other relevant information

The lack of fouling protection is a problem with products dependent on removing of fouling for protection. Studies of leisure vessels as vectors for invasive species has demonstrated the potential for fouled vessels spreading of invasive species between Mediterranean marinas.

6.2.2.1.7 Conclusion on the suitability and availability of Hard non-biocidal coatings

Hard non-biocidal coatings cannot be considered to achieve protection against hard fouling and does pose and increased risk for transport of invasive species.

The qualitative assessment of hazard of hard non-biocidal coatings concludes that there is a reduction in the overall risk for humans, animals or the environment in comparison to medetomidine, which is not surprising for this coating's technology without biocides.

In the technical feasibility assessment, hard non-biocidal coatings receive a lower score than medetomidine due significant changes in maintenance requirements, significant reduced efficacy and risk for transport of invasive species. The economic assessment has a slightly lower score than medetomidine due the changes foreseen in maintenance procedures. The overall conclusion is that hard non-biocidal coatings has a less favourable overall score regarding suitability than medetomidine for the specified use type 2.

Table 69 Overall assessment score for Hard non-biocidal coatings use type 2.

Substance name	**Hazard score**	**Exposure assessment**	**Technical Feasibility**	**Economic Feasibility**	**Overall score**
Hard non-biocidal coatings	10	n.a	9	11	30

Silicone-based coatings

6.2.2.1.8 Identity and properties

Example product	Hazard Class and Category Code(s)	Hazard statement Code(s)
SilicOne	Aquatic chronic 3 Flam Liq 3	H412 H226

Silicone based fouling control coatings are also often referred to as Fouling Release Coatings (FRC). Biocide free FRC are based on a silicone matrix that either prevents fouling attachment or facilitates removal through the action of water while the vessel sails.

6.2.2.1.9 Reduction of overall risk

Human health – Risk significantly reduced based on self-classification of example product (SilicOne), danger considered negligible and scored as 5 for both acute and chronic hazards.

Animal health – Risk significantly reduced based on self-classification as aquatic chronic 3, which gives a middle danger and is scored as 3.

Environment – Risk slightly reduced based on classification as aquatic chronic 3 and the classification of silicone oils as very persistent (vP), which gives a danger score of 2. A factor not included in the hazard score is release of silicone oil from FRC, which has been raised as an environmental risk since the early days of the technology (Nendza, 2007). However, since the antifouling protection from FRCs is physical and not chemical the product type does not require any formal hazard or risk assessment before being placed on the European market. Comparison with biocidal technologies are therefore difficult (Waterman, 2005) but scientific studies show that they can have impacts on marine environments by adsorption to suspended particulate matter and may settle into sediment. If oil films build up on sediments, infiltration may inhibit pore water exchange. The silicone oils do not bioaccumulate in marine organisms and soluble fractions have low toxicity to aquatic and benthic organisms. At higher exposures, undissolved silicone oil films or droplets can cause physical-mechanic effects with trapping and suffocation of organisms (Nendza, 2007).

The example product do have a physical-chemical hazard classification with middle danger and therefore get a hazard score of 3.

The hazards identified for the silicone-based coating for leisure vessels is significantly reduced compared to the product intended for commercial vessels. The main reason for this is the differences in formulation and the differences between products which can be used for professional and non-professional application. A product intended for non-professionals cannot require extensive personal protection equipment and certain ingredients are not allowed based on hazard class.

Table 70 Hazard assessment based on safety data sheet for SilicOne (Hempel) use type 2

Technology	**Human health**	**Environment inc animals**	**Phys-chem**	**Overall score**
Silicone-based coatings	10	2	3	15

An exposure assessment has not been performed for silicone-based coatings since there is no biocidal content to base the exposure assessment on. The lack of exposure assessment score will be taken into consideration at comparison of alternatives.

The conclusion of the hazard assessment show that the silicone-based coatings score higher than medetomidine and so it could be considered that there is potential for a reduction in overall hazard compared to medetomidine.

Table 71 Risk score for silicone-based coatings use type 2

Technology	**Hazard score**	**Exposure assessment score**	**Risk score**
Silicone-based coatings	15	n.a	15

6.2.2.1.10 Technical feasibility

The technical feasibility of FRC as an alternative technology has been assessed according to 4 key aspects: technical readiness, availability, the changes required for use and the efficacy. Resistance will not be discussed here as this is not relevant to non-biocidal coatings however other implications of this approach, such as the transfer of species, are discussed below.

Silicone-based coatings were developed more than 20 years ago and are commercially available in EU. Since the silicone-based coatings generally are biocide-fee no approvals are needed to place products on the market. The technology has taken some time to achieve readiness, initially the fouling protection was low, the coatings expensive and had adhesion problems and poor mechanical properties (Dam-Johanse, 2004).

Whilst FRC have shown excellent performance on some vessel types they are generally more suitable for higher activity, faster vessels due to the need of shear force to develop the release effect. Biofouling organisms are capable of attaching to the coatings, but most fouling types are removed at voyage speeds greater than 15 knots. Barnacles may detach at speeds around 10 knots but biofilm can remain intact even at speeds above 30 knots (Candries et al. 2001). The application of FRCs is therefore limited to high speed (>15 knots)/high activity vessels (Callow, 2009) Although recently developed products claim improved performance at lower speeds due to the use of hydrogels/silicone oils, they are currently not an option for all vessel trades such as sailboats. Silicone based coatings do therefore not fulfil the requirements specified for use type 2 due to lack of protection against hard fouling during a 1 year service-life. The alternative can be considered suitable for certain types of leisure vessels, which do not idle for long periods and achieve a speed which allows for hard fouling to release.

Current silicone-based FRCs are susceptible to damage caused by scraping. As these coatings rely on the special properties of their surface to minimise adhesion of fouling organism, any damage would have a considerable impact on their efficacy (Lejars, 2012).

The application process of FRCs can be challenging due to the need for masking to protect surrounding areas from contamination and the need for dedicated application equipment, adding time and cost to the application. FRC are also sensitive to temperature, requires air temperature above 5°C, and is sensitive for humidity during application. The required climatic conditions make applications e.g. in the Baltic sea area challenging.

The reduced fouling protection offered by silicone-based coatings following idling makes vessels coated with the technology at risk of functioning as vectors for transport of invasive species (Aylin Ulman, 2019). IAS is considered to be one of the greatest threats to the world’s coastal and marine ecosystems. The impacts of IAS, including through disruption to fisheries, biofouling of coastal industry and infrastructure and interference with human amenity, have been estimated at several hundred million dollars per year. The main vectors for unintentional transfer are ships' ballast water, biofouling of mobile marine structures and aquaculture (GloFouling, 2023). Studies of leisure vessels as vectors for invasive species has demonstrated the potential for spreading invasive species, especially as 71% of sampled vessels host at least one (and up to 11) non-indigenous species. Boats with high richness of invasive species strongly correlate with home marinas with high invasive species richness. Over half of the vessels were carriers of invasive species which were not yet present in the marinas they were visiting. The presence of biofouling in niche areas of the hull (i.e. in the cavities and metallic parts) emerges as the best predictor for invasive species richness on boats, along with longer times since their last cleaning and antifouling applications. Interestingly, colonisation of invasive species occurred rapidly, even on boats that had recently had their hulls cleaned professionally (Aylin Ulman, 2019).

When compared to medetomidine, the silicone-based coatings score lower for technical feasibility due to significant changes, score 1, are required for application of silicone-based coatings to ensure that other vessels are not contaminated with the FRC. The reduced fouling protection is the reason for the efficacy scored of 1 and the risk for ecosystem effects such as transport of invasive species is therefore also set to 1. Technical readiness in scored as 3 since there are products commercially available and the availability of alternatives is set to 2, since there are significant limitations for which vessel types silicone-based coatings are suitable for.

Table 72 Technical feasibility assessment score for silicone-based coatings use type 2

Technology	**Technical readiness**	**Availability**	**Changes required for use**	**Efficacy**	**Ecosystem effects**	**Overall score**

Silicone-based coatings	3	1	1	1	1	7

6.2.2.1.11 Economic feasibility

FRC technology is expensive due to the higher initial cost of paint and application (Lejars, 2012), the cost for FRCs are approximately 3 times higher than for a standard biocidal antifouling paint but feasibility limitations can be considered to be rather technical than economical (Xu Han, 2020).

When compared to medetomidine, the silicone-based coatings score lower for economic feasibility due to a higher price per litre (score 2), increased costs of equipment for application (score 2) since protection of other vessels is crucial to not contaminate other surfaces with silicone-based coatings, which will destroy adhesion for non-silicone based coatings systems. There is reported increased maintenance needs (Barnes & Guy, 2020) to maintain a clean hull which results in a score of 2, since that is not needed for medetomidine containing coatings while risk management is considered comparable. The economic feasibility is scored slightly different between use type 1 and 2 due to the higher importance to maintain a clean hull for commercial vessels compared to leisure vessels.

Table 73 Economic feasibility assessment for silicone-based coatings use type 2

Technology	**Price per litre**	**Cost of equipment**	**Application rates / maintenance**	**Risk management**	**Overall score**
Silicone-based coatings	2	2	2	3	9

6.2.2.1.12 Availability

Silicone-based coatings are not suitable for all leisure vessel types due to speed needed for foul-release. The system can therefore not be considered a full alternative to medetomidine containing coatings and the specified use type regarding protection against barnacles.

DIY cleaning is an available option for silicone-based coatings but cleaning can be difficult to execute to achieve a clean hull, especially if hard fouling has attached (GloFouling, 2022). There is currently no limitations regarding cleaning of leisure vessels in EU.

6.2.2.1.13 Other relevant information

The lack of fouling protection is a problem with products dependent on removing of fouling for protection. Studies of leisure vessels as vectors for invasive species has demonstrated the potential for fouled vessels spreading of invasive species between Mediterranean marinas (Aylin Ulman, 2019).

6.2.2.1.14 Conclusion on the suitability and availability of Silicone-based coatings

Silicone based coatings do not fulfil the requirements specified for use type 2 due to lack of protection against hard fouling during a 1 year service-life. The alternative can be considered suitable for certain types of leisure vessels, which do not idle for long periods and achieve a speed which allows for hard fouling to release.

The qualitative assessment of hazard concludes that there is a reduction in the overall risk for humans, animals or the environment in comparison to medetomidine, which is not surprising for a technology without biocides.

In the technical feasibility assessment the coatings receive a lower score than medetomidine due to significant changes in application requirements, significant reduced efficacy and risk for transport of invasive species. The economic assessment has a lower score than medetomidine due to the cost for product, application and cleaning. The availability assessments shows that there are concerns regarding access to cleaning procedures to keep a hull free from fouling. The overall conclusion is that silicone-based coatings has a less favourable overall score regarding suitability than medetomidine for the specified use type 2.

Table 74 Overall assessment of silicone-based coatings for use type 2

Substance name	**Hazard score**	**Exposure assessment**	**Technical Feasibility**	**Economic Feasibility**	**Overall score**
Silicone-based coatings	15	n.a	7	9	31

Ultrasonic systems

6.2.2.1.15 Identity and properties

Ultrasonic antifouling has been around in the leisure market for nearly 10 years. The technology includes the use of an electronic device mounted on the vessel hull which produces intermittent sound waves via transducers that are attached to the inside of the hull. Ultrasonic systems protect hulls against fouling by destroying microfouling at the cellular level, by rupturing the cell walls of the organisms the system aims to prevent fouling from attaching to the hull (Noelia Estévez-Calva, 2018).

Ultrasonic is not marketed as a replacement for antifouling coatings but rather as a complimentary system that will extend the paint's life and reduce the fouling that builds up (Meakins, 2023).

6.2.2.1.16 Reduction of overall risk

A full hazard and exposure assessment cannot be performed on this method to avoid hard fouling on hulls since there is no hazard classification nor exposure to assess.

6.2.2.1.17 Technical feasibility

Ultrasonic systems are ineffective on two relatively common materials for leisure vessels, wooden-hulled vessels, or vessels made from ferro-cement composite as these materials dampen the vibrations from the transducers. Composite hulls with a sandwich construction may also require modification to form monolithic plinths of solid material at each transducer location.

Ultrasonic systems are an effective antifouling solution in niche surfaces like propellers and stern drives. However ultrasonic systems cannot replace the need for an antifouling coating on the hull, it is considered as a complimentary system that will extend the paint’s life and reduce the fouling that builds up (Meakins, 2023).

When compared to medetomidine, the ultrasonic system score lower for technical feasibility due to significant changes, score 1, are required for use, which require both a coating and the system to generate the ultrasound. The reduced fouling protection is the reason for the efficacy scored of 1 and the risk for ecosystem effects such as transport of invasive species is therefore also set to 1. Technical readiness in scored as 3 since there are products commercially available and the availability of alternatives is set to 2, since there are limitations to the suitable vessel types.

Table 75 Technical feasibility assessment score for ultrasonic systems Use type 2

Technology	**Technical readiness**	**Availability**	**Changes required for use**	**Efficacy**	**Ecosystem effects**	**Overall score**
Ultrasonic systems	3	2	1	1	1	8

6.2.2.1.18 Economic feasibility

The ultrasonic equipment results in a significantly higher cost for equipment, score 1. The system needs to be combined with an antifouling coating, the cost of the antifouling coating is assumed to be comparable to a generic antifouling coating which is considered when scoring for application/maintenance costs, score 1. Risk management is considered to be comparable to coatings containing medetomidine, score 3.

Table 76 Economic feasibility assessment score for ultrasonic systems Use type 2

Technology	**Price per litre**	**Cost of equipment**	**Application rates / maintenance**	**Risk management**	**Overall score**
Ultrasonic systems	n.a	1	1	3	5

6.2.2.1.19 Availability

There are several brands on the European market that sell ultrasound systems for leisure vessels, for example Sonihull and UltraSonic Systems.

6.2.2.1.20 Other relevant information

Can cause noise pollution in the marine environment (Jennifer S. Trickey, 2022). Recent studies have revealed that a wide diversity of invertebrates are sensitive to sounds, especially via sensory organs whose original function is to allow maintaining equilibrium in the water column and to sense gravity (Marta Solé, 2023).

6.2.2.1.21 Conclusion on the suitability and availability of alternative

Ultrasonic systems do not fulfil the requirements specified for use type 2 due to lack of protection against hard fouling during a 1 year service-life, without support of an antifouling coating. The alternative can be considered as a complimentary system that will extend the paint's life and reduce the fouling that builds up (Meakins, 2023).

Since hazard and exposure cannot be assessed for proactive cleaning the lack of these scores will need to be considered when comparing all alternative technologies for Use type 2.

In the technical feasibility assessment the coatings receive a lower score than medetomidine due to significant changes in maintenance requirements, significant reduced efficacy and risk for transport of invasive species. The economic assessment has a lower score than medetomidine due to the cost for equipment, application and cleaning. The overall conclusion is that the ultrasonic systmes has a less favourable overall score regarding suitability than medetomidine for the specified use type 2.

Table 77 Overall assessment of ultrasonic systems for use type 2

Substance name	**Hazard score**	**Exposure assessment**	**Technical Feasibility**	**Economic Feasibility**	**Overall score**
Ultrasonic systems	n.a	n.a	8	5	13

Antifouling films / wraps

6.2.2.1.22 Identity and properties

Antifouling films/wraps are adhesive film applied to leisure vessel hulls, based on silicone technology. Instead of spraying and curing on the hull a FRC coating is applied and cured on an adhesive film which is then glued to the hull. The fouling prevention mechanism is identical to FRC systems. It can be compared to a fouling release coating meaning that fouling itself is not prevented, only the adhesion to the surface.

6.2.2.1.23 Reduction of overall risk

A full hazard and exposure assessment cannot be performed on this method to avoid hard fouling on hulls since there is no hazard classification nor exposure to assess

6.2.2.1.24 Technical feasibility

Protective or decorative film technology is widely used in many fields, with applications in aircraft or high-speed trains, for example. The performance of silicone antifouling coatings is known, they have shown excellent performance on some vessel types, however they are generally more suitable for higher activity, fast vessels. Although recently developed products claim improved performance at lower speeds, they are currently not an option for all leisure vessel, especially sailing boats. As for FRC, the antifouling films/wraps are generally more suitable for higher activity, faster vessels due to the need of shear force to develop the release effect. Biofouling organisms are capable of attaching to the coatings, but most fouling types are removed at voyage speeds greater than 15 knots. Barnacles may detach at speeds around 10 knots but biofilm can remain intact even at speeds above 30 knots (Candries et al. 2001). The application of the technology (same as for FRC) is therefore limited to high speed (>15 knots)/high activity vessels (Callow, 2009) Although recently developed products claim improved performance at lower speeds due to the use of hydrogels/silicone oils, they are currently not an option for all vessel trades such as sailboats. Antifouling film/wraps do therefore not fulfil the requirements specified for use type 2 due to lack of protection against hard fouling during a 1 year service-life. The alternative can be considered suitable for certain types of leisure vessels, which do not idle for long periods and achieve a speed which allows for hard fouling to release.

Installation of antifouling films/ wraps is difficult and should be done by professionals. The film must be perfectly laid edge to edge since gaps will allow for fouling.

A benefit of the film technology is that in the event of an impact on the film, the silicone film can be easily repaired by removing and replacing the damaged section. The film is cleanable, however there is some concern that microplastics might be released during cleaning.

The reduced fouling protection offered by Antifouling film/wraps following idling makes vessels coated with the technology at risk of functioning as vectors for transport of invasive species (Aylin Ulman, 2019). IAS is considered to be one of the greatest threats to the world's coastal and marine ecosystems. The impacts of IAS, including through disruption to fisheries, biofouling of coastal industry and infrastructure and interference with human amenity, have been estimated at several hundred million dollars per year. The main vectors for unintentional transfer are ships' ballast water, biofouling of mobile marine structures and aquaculture (GloFouling, 2023). Studies of leisure vessels as vectors for invasive species has demonstrated the potential for spreading invasive species, especially as 71% of sampled vessels host at least one (and up to 11) non-indigenous species. Boats with high richness of invasive species strongly correlate with home marinas with high invasive species richness. Over half of the vessels were carriers of invasive species which were not yet present in the marinas they were visiting. The presence of biofouling in niche areas of the hull (i.e. in the cavities and metallic parts) emerges as the best predictor for invasive species richness on boats, along with longer times since their last cleaning and antifouling applications. Interestingly, colonisation of invasive species occurred rapidly, even on boats that had recently had their hulls cleaned professionally (Aylin Ulman, 2019).

When compared to medetomidine, the antifouling film/wraps score lower for technical feasibility due to significant changes, score 1, are required for application of the technology, which is not suitable for non-professional application. The reduced fouling protection is the reason for the efficacy scored of 1 and the risk for ecosystem effects such as transport of invasive species is therefore also set to 1. Technical readiness in scored as 3 since there are products commercially available and the availability of alternatives is set to 2, since there are significant limitations for which vessel types these films are suitable for.

Table 78 Technical feasibility assessment score for antifouling films/ wraps use type 2

Technology	**Technical readiness**	**Availability**	**Changes required for use**	**Efficacy**	**Ecosystem effects**	**Overall score**
Antifouling film / wraps	3	2	1	1	1	8

6.2.2.1.25 Economic feasibility

The cost of antifouling film / wraps including application is estimated to be €3000 for a 40 feet boat (service-life 5 years). In comparison to a biocidal antifouling coating for the same vessel size would cost approximately €300 and application cost would double that to €600 in total. Based on service-life the cost would be comparable between the technologies over a 5 year period. However, the technology of antifouling films/wraps is still relatively new and cost for the material and application is difficult to assess in more detail.

When compared to medetomidine, the antifouling film / wraps score lower for economic feasibility due to increased costs for equipment and application, no DIY, (score 1). There is reported increased maintenance needs (Barnes & Guy, 2020) to maintain a clean hull which results in a score of 2, since that is not needed for medetomidine containing coatings while risk management is considered comparable. Risk management is considered to be comparable to coatings containing medetomidine, score 3.

Table 79 Economic feasibility assessment score for antifouling films/ wraps use type 2

Technology	**Price per litre or m²**	**Cost of equipment**	**Application rates / maintenance**	**Risk management**	**Overall score**
Antifouling film / wraps	3	1	2	3	9

6.2.2.1.26 Availability

Antifouling film / wraps technology do not seem to have a wide market presence in Europe and the availability of the technologies between the different Member States is difficult to assess. As such it is not possible to determine if there would be sufficient volumes on the market or sufficient professionals to apply this technology to all suitable vessel types.

6.2.2.1.27 Conclusion on the suitability and availability of alternative

Antifouling films/wraps do not fulfil the requirements specified for use type 2 due to lack of protection against hard fouling during a 1 year service-life. The alternative can be considered suitable for certain types of leisure vessels, which do not idle for long periods and achieve a speed which allows for hard fouling to release.

Since hazard and exposure cannot be assessed for proactive cleaning the lack of these scores will need to be considered when comparing all alternative technologies for Use type 2.

In the technical feasibility assessment the coatings receive a lower score than medetomidine due to significant changes in application requirements, significant reduced efficacy and risk for transport of invasive species. The economic assessment has a lower score than medetomidine due to the cost for product, application and cleaning. The availability assessments shows that there are concerns regarding access to the technology. The overall conclusion is that the antifouling films/wraps has a less favourable overall score regarding suitability than medetomidine for the specified use type 2.

Table 80 Overall assessment of antifouling film / wraps for use type 2

Substance name	**Hazard score**	**Exposure assessment**	**Technical Feasibility**	**Economic Feasibility**	**Overall score**
Antifouling film / wraps	n.a	n.a	8	9	17

In-water cleaning (proactive and reactive)

6.2.2.1.28 Identity and properties

In water cleaning has been developed as an alternative to lifting the vessel out of the water in order to mitigate the associated costs and time. There are typically two types of in-water cleaning:

- Proactive cleaning is carried out on microfouling, fouling at early stages of development, where hull grooming is performed at frequent intervals with gentle force without causing damage or erosion to the coating.
- Reactive cleaning is performed on macrofouling (fouling at later stages of development), which has heavier attachment to the hull and coating. Reactive cleaning has a higher risk of damaging the coating and can further cause release of aquatic invasive species to the local marine environment.

6.2.2.1.29 Reduction of overall risk

A full hazard and exposure assessment cannot be performed on this method to avoid hard fouling on hulls.

6.2.2.1.30 Technical feasibility

Depending on the level and type of biofouling, both types of cleaning can be conducted through divers or remotely operated vehicles (ROVs). However, if not performed correctly or in adequate circumstances, in-water cleaning can result in several unintended consequences, including:

(a) increased discharge of coating biocides to ambient waters.

(b) increased biosecurity risk through the active release of live biofouling species to local habitats; and

(c) diminished coating condition that reduces anti-fouling performance in subsequent months and years

In-water cleaning can be suitable for removing light fouling (e.g. the slime layer) with gentle techniques that minimise the degradation of the antifouling coating system. Cleaning of biocidal antifouling coatings is normally not needed and should be avoided to not increase release of biocides into the environment. A light sponge or brush should remove the biofilm. As the fouling increases, the level of abrasion required will increase, together with the release of paint chips and/ or fouling organisms into the local water and reducing the effectiveness of the remaining antifouling coating. Vessels with biocide-free antifouling coating systems are likely to require regular in-water cleaning,. It is important to use cleaning techniques that do not damage the anti-fouling coating and impair its function.

In addition, it should be noted that in-water cleaning often does not guarantee the total removal of viable fouling organisms. When carried out in marinas without capture of biofouling waste, in-water cleaning may even induce or trigger a spawning event for some organisms, presenting additional risks to biosecurity (GloFouling, 2022). The lack of fouling protection offered by hard non-biocidal coatings makes leisure vessels coated with the technology at risk of functioning as vectors for transport of invasive species (Aylin Ulman, 2019). Studies of leisure vessels as vectors for invasive species has demonstrated the potential for spreading invasive species, especially as 71% of sampled vessels host at least one (and up to 11) non-indigenous species. Boats with high richness of invasive species strongly correlate with home marinas with high invasive species richness. Over half of the vessels were carriers of invasive species which were not yet present in the marinas they were visiting. The presence of biofouling in niche areas of the hull (i.e. in the cavities and metallic parts) emerges as the best predictor for invasive species richness on boats, along with longer times since their last cleaning and antifouling applications. Interestingly, colonisation of invasive species occurred rapidly, even on boats that had recently had their hulls cleaned professionally (Aylin Ulman, 2019).

If for any reason the in-water cleaning does not happen at the correct intervals and fouling is left untreated, the risk for the transfer of species will increase. This limited availability and the lack of suitably effective fouling protection results in cleaning scoring lower than medetomidine for technical feasibility.

Table 81 Technical feasibility assessment score for in-water cleaning use type 2

Technology	**Technical readiness**	**Availability**	**Changes required for use**	**Efficacy**	**Ecosystem effects**	**Overall score**
In-water cleaning	3	2	1	1	1	8

6.2.2.1.31 Economic feasibility

Cleaning of a leisure vessel is not assumed to generate substantial cost, this could be done as a DIY process by utilising different cleaning equipment available or by local boat cleaners.

When compared to medetomidine, the in-water cleaning score slightly lower for economic feasibility. The cost for equipment is assumed to be comparable for DIY application of an antifouling coating and scored as 3. Cost for maintenance to keep a clean hull is considered as higher, if not done as DIY, and scored as 2. Risk management is considered as comparable and scored as 3.

Table 82 Economic feasibility assessment score for in-water cleaning use type 2

Technology	**Price per litre**	**Cost of equipment**	**Application rates / maintenance**	**Risk management**	**Overall score**
In-water cleaning	n.a	3	2	3	8

6.2.2.1.32 Availability

Commercially available systems for proactive in-water cleaning are more readily available for larger vessels than regular leisure vessels in EEA. Commercially available cleaning solution are primarily suitable for boats without keels (powerboats). DIY cleaning is an available option but is difficult to execute to achieve a clean hull, especially if hard fouling has attached (GloFouling, 2022).

6.2.2.1.33 Conclusion on the suitability and availability of alternative

Cleaning of leisure hulls cannot be considered to achieve antifouling protection against hard fouling during 1 year and is therefore not a fully suitable alternative to medetomidine containing antifouling coatings.

Since hazard and exposure cannot be assessed for proactive cleaning the lack of these scores will need to be considered when comparing all alternative technologies for Use type 2.

In the technical feasibility assessment cleaning receive a lower score than medetomidine significant changes in maintenance requirements, significant reduced efficacy and risk for transport of invasive species. The economic assessment has a lower score than medetomidine due to the cost for maintenance. The availability assessments shows that there are concerns regarding access to cleaning procedures, if DIY is not a viable option. The overall conclusion is that proactive cleaning has a less favourable overall score regarding suitability than medetomidine for the specified use type 2.

Table 83 Overall assessment of in-water cleaning for use type 2

Substance name	**Hazard score**	**Exposure assessment**	**Technical Feasibility**	**Economic Feasibility**	**Overall score**
In-water cleaning	n.a	n.a	8	8	16

6.2.3. Overall comparison of alternatives for intended use 2 (summary table)

Chemical alternative	Hazard assessment	Exposure assessment	Technical Feasibility	Economic Feasibility	Overall score
Medetomidine	8	13	15	12	48
Copper compounds	14	10	12	12	48
Tralopyril	9	10	12	12	43

Non-chemical alternative	Hazard assessment	Exposure assessment	Technical Feasibility	Economic Feasibility	Overall score
Hard non-biocidal coatings	10	n.a	9	11	30
Silicone-based coatings	15	n.a	7	9	31
Ultrasonic systems	n.a	n.a	8	5	13
Antifouling film/ wrap	n.a	n.a	8	9	17
In-water cleaning	n.a	n.a	8	8	16

7. EFFORTS TAKEN BY THE APPLICANT TO DEVELOP NEW ALTERNATIVES

Due to medetomidines efficacy against barnacle fouling there is a continued belief that medetomidine can deliver outstanding barnacle protection to antifouling coatings, partly in combination with other substances and especially in a market that focus on reduced emissions to air from commercial shipping and reduced biocidal loadings especially designed for the leisure yachting industry.

I-Tech is currently focusing its R&D capabilities on how to reduce emissions of medetomidine into the environment by controlling the release with different binder systems by still keeping the current efficacy. I-Tech is also looking into ways of reducing human exposure when handling medetomidine in production of antifouling coatings.

Medetomidine has been widely adopted by paint customers in their coating systems. The current formulation principles consist of pre-adsorbing medetomidine on the surface of different pigments (e.g. Zinc Oxide) and then proceed with the paint production. The adsorption of Medetomidine on pigments then enables the controlled release of medetomidine. Depending on the conditions of the paint production and the coatings formula the release of medetomidine might not be totally linear over the defined lifetime of the coating system. In an ideal system the biocide release maintains constant. To reduce risk of system failure formulators increase the concentrations to have a safety margin to stay within the needed concentrations.

Currently there are different projects ongoing at I-Tech to improve the adsorption and desorption on different particles and better understand parameters influencing the release of Medetomidine. Other projects include different ways to encapsulate medetomidine in different matrices and control the release over the lifetime. All these project have in common to control better the release of medetomidine from the coating systems and thus enable a consistent release to the surface. The aim is to keep or increase the performance with reduced concentrations of medetomidine in the paint and over the lifetime of the coating system a reduced release into the environment.

8. OVERALL CONCLUSION

I-Tech AB together with many stakeholders within the chemical- and maritime industry has conducted a thorough study to gather and assess the currently available suitable alternatives for medetomidine as an active substance used in antifouling coatings both for commercial shipping and the leisure yacht industry. Alternatives have been assessed through the use of multiple data sources such as: scientific research, intensive stakeholder communication and extensive knowledge internally regarding the antifouling market in the EU. A long list of identified alternatives was collated and then refined according to the minimum criteria for antifouling function, efficacy, economic impacts and market presence. The remaining 13 chemical- and non-chemical alternatives were reviewed in detail and compared to medetomidine regarding risk, technical feasibility, economic feasibility and availability. The antifouling coating market is transparent and thus the alternatives are clearly defined and well-known.

This AOA can conclude that no alternative currently available on the market is directly comparable to medetomidine. Even alternatives with similar properties do not match the properties of medetomidine. The biocide market in the EU is an oligopoly in which few active substances are approved for this application. Most biocides under PT 21 act against soft fouling but only three active substances (copper and tralopyril) including medetomidine are effective against the growth of hard fouling (mainly barnacles).

According to guidance related to the assessment of the chemical diversity for substitution (Commission, 2015), chemical diversity of the available active substances should be addressed and considered when assessing possible substitution of a chemical. Chemical diversity should be adequate for all different user categories to minimise the occurrence of resistance. **An inadequate chemical diversity for one user category could lead to resistance occurrence, which might spread afterwards across the target organism population.** As a general rule, at least three different and independent "active substances/mode of action" combinations should be available for a given use. Medetomidine, the copper compounds and tralopyril all have different mode of actions to hinder barnacle fouling. Loss of one of the substances would significantly reduce the chemical diversity for both use type 1 and 2 when it comes to hard fouling protection.

Comparison of the assessed chemical alternatives for hard fouling protection on commercial vessels (use type 1) show that medetomidine and the copper compounds have the same score while tralopyril is scored slightly lower due to a larger risk for humans and the environment. Technical and economical feasibility is more or less comparable for all biocidal substances.

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 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.

The non-chemical alternatives all have lower assessment scores, especially when focusing on the technical feasibility and fouling protection, the main purpose of these products. 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 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 use type 1 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 and the consequences for commercial vessels.**

The requirements for use type 2, leisure vessels, is considerably different, both regarding how the vessels are used but also regarding what amount of fouling that can be acceptable on a hull without limitations to functionality such as manoeuvrability. The biocidal antifouling alternatives all score between 44 and 48 points while the non-chemical alternatives score lower, due to lack of hazard and/or exposure assessment. Assuming that all non-chemical options have the least hazard and/or exposure for humans and the environment they would all score between 45 and 52. **However, an important factor here is the increased risk for leisure vessels with non-chemical alternatives to act as vectors for transport of invasive species between and within local ecosystems**.

Based on the research conducted, over 15 years knowledge of the EU biocidal market and stakeholder contributions this AOA concludes that for Use 1 the loss of medetomidine from the market could have negative impacts on:

- the diversity of the market
- resistance of the target organisms
- and knock on impacts of increased GHG emissions and the transfer of invasive species.

For use 2 the decision is less clear cut as alternative methods could be feasible with additional costs and increased ecosystem risks.

The health concerns associated with medetomidine are not irrelevant to the two chemical alternatives which have the closest efficacy to medetomidine and thus substitution is not guaranteed to offer a benefit to human health or the environment.

The benefits of medetomidine, like indirectly influencing the GHG emissions into air via less fuel consumptions of commercial vessels and yachts, disrupting settlement of invasive species and macro economically having an alternative towards the two comparable technologies is obvious for I-Tech AB, peers, customers and other stakeholder in the chemical- and maritime industry.

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ANNEX I – JUSTIFICATIONS FOR CONFIDENTIALITY CLAIMS[1]

Redacted item reference	Page number	Justification for confidentiality
Additional annex 3 - Stakeholder review		
Additional annex 4 – Customer 1		
Additional annex 5 – Customer 2		

[1] This annex will not be made publicly available on ECHA's website as part of the BPR Art.10(3) third party consultation.

ANNEX II – STAKEHOLDERS CONSULTATION INVOLVEMENT

Company	Address	Meetings type	WWW/E-Mail	Category
Chugoku Marine Paints, Ltd.	Tokyo, Club Building, 2-6, Kasumigaseki 3-chome, Chiyoda-ku, Tokyo, 100-0013, Japan	In-person& digital	www.cmp-chugoku.com	Direct customer
Hempel AS	Lundtoftegårdsvej 91 DK-2800 Kgs. Lyngby Denmark	In-person& digital	www.hempel.com hempel@hempel.com	Direct customer
Jotun AS	P.O.Box 2021 3202 Sandefjord Norway info@jotun.com	In-person& digital	www.jotun.com info@jotun.com	Direct customer
PPG Industries	P.O. Box 30170 College Station, TX 77842-3170 USA	In-person& digital	www.ppg.com reftechserv@ppg.com	Direct customer
American Chemet Corporation	740 Waukegan Rd Ste 202, Deerfield, IL 60015 USA	Digital resouces	www.chemet.com SALES@CHEMET.COM	Peer
Arxada AG	Peter Merian-Strasse 80 4052 Basel, Switzerland	Not directly included	www.arxada.com	Peer
Cosaco GmbH	Singapurstrasse 1 20457 Hamburg | Germany	Digital resouces	www.cosaco.com	Peer
Janssen PMP	Turnhoutseweg 30 2340 Beerse Belgium	Digital resouces	www.janssenpmp.com info@janssenpmp.com	Peer
LANXESS Deutschland GmbH	Kennedyplatz 1 50569 Cologne, Germany	Not directly included	www.lanxess.com lanxess-info@lanxess.com	Peer

NITTO CHEMICAL INDUSRY CO., LTD	Head office: 24-24, Harima-cho 1chome, Abeno-ku, Osaka, 545-0022, Japan	In-person	www.nitto-kasei.co.jp	Peer
Nordox AS	Østensjøveien 13 N-0661 Oslo, Norway	Digital resources	www.nordox.no	Peer
Hapag Lloyd AG	Ballindamm 25, 20095 Hamburg, Germany	In-person	www.hapag-lloyd.com	Indirect customer
Stena AB	Masthuggskajen SE-405 19 Göteborg, Sweden	In-person	www.stena.com info@stena.com	Indirect customer
Stolt-Nielsen Tankers	4th Floor, Aldwych House 71–91 Aldwych London, WC2B 4HN United Kingdom	In-person	www.stolt-nielsen.com	Indirect customer
CEPE	Bd du Triomphe 172, 1160 Auderghem, Belgium	Digital resources	www.cepe.org secretariat@cepe.org	Association
Word Coating Council	901 New York Ave NW, Suite 300 Washington, DC 20001	Digital resources	www.worldcoatingscouncil.org kberry@paint.org	Association
Intercargo	4th Floor 123 Minories London EC3N 1NT, U.K.	Digital	www.intercargo.org info@intercargo.org	Association
Intertanko		Digital resources	www.intertanko.com	Association
Verband Deutscher Reeder	Burchardstraße 24 20095 Hamburg, Germany	In-person	www.reederverband.de	Association

			vdrr@reederverband.de	
SNAME	Poseodonos Avenue Paleo Faliro, 175 62 Attica, Greece	In-person	sname@sname.org	Association
The Royal Institute of Naval Architects	8-9 Northumberland Street, London WC2N 5DA	In-person	www.rina.org.uk hq@rina.org.uk	Association
Mærsk Mc-Kinney Møller Center for Zero Carbon Shipping	Bredgade 6, 2. floor 1260 Copenhagen K Denmark	In-person	www.zerocarbonshipping.com info@zerocarbonshipping.com	Foundation
Safinah Group	4 The Staithes The Watermark Gateshead NE11 9SN	In-person	www.safinah-group.com enquiries@safinah-group.com	Independent consultant
Limnomar	Duvenwischen 4 22359 Hamburg, Germany	Digital	www.Limnomar.de mail@limnomar.de	Independent consultant
Dr. Brill & Partner	Stiegstück 34, 22339 Hamburg, Germany	Digital	www.brillinstitutes.com info@brillhygiene.com	Independent Laboratory
Bellona	Rådhusgata 28, 0151 Oslo, Norway	In-person	www.bellona.org info@bellona.no	NGO
Wärtsila, FI	Hiililaiturinkuja 2, FI-001180 Hesinki, Finland	Digital resources	www.sustainabilty@wartsila.com firstname.lastname@wartsila.com	None-Chemical
Fleet Cleaner, NL	Julianalaan 67A, 2628 BC Deft The Netherlands	In-person	www.fleetcleaner.com	None-Chemical

			info@fleetcleaner.com	
Hull Wiper, UAE	P.O. Box 170 Dubai United Arab Emirates	In-person	www.hullwiper.co Enquiries@hullwiper.com	None-Chemical
Hasytec, GER	Liebigstraße 17, 24145 Kiel, Germany	In-person	www.hasytec.com info@hasytec.com	None-Chemical
Outokumpu, FI	Terästie, 95490, Torino, Finland	Digital resources	www.outokumpu.com webmarketing@outkumpu.com	None-Chemical
Ocean Innovations, USA	7415 Cabrillo Avenue, La jolla,CA 92037, USA	Digital resources	brock@o-vations.com	None-Chemical

ANNEX III STAKEHOLDER REVIEW

ANNEX IV CUSTOMER 1 INFORMATION

ANNEX V CUSTOMER 2 INFORMATION