

TEMPLATE

for third party submission of information on potential candidates for substitution

NON-CONFIDENTIAL

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INTRODUCTION

For more than 110 years, Laboratoires ANIOS has been committed to fighting germs, becoming a leader in high performance cleaning and disinfection. Located in Lille, north of France, Laboratoires ANIOS is now present in 85 countries, with an expertise dedicated to hospitals, clinics and medical professions.

Our products are designed to meet the full range of disinfection needs:

- Disinfecting floors and surfaces
- Disinfection sprays
- Disinfecting equipment
- Disinfectants for washing machines and tunnel washers
- Cleaning solutions, mild soap, hand sanitizers gels/liquids and equipment for hand washing
- Specific disinfectants for haemodialysis machines, laundry, bedpan washers etc.

Among other professional associations, our company is a member of AFISE, the French association for Soaps, Detergents and Maintenance Products.

1. ALTERNATIVE IDENTITY AND PROPERTIES

PHMB has various attributes which makes it a very flexible ingredient in the formulation of disinfectants for a wide range of applications. The physical performance attributes of PHMB (not leaving streak marks on surfaces, ease of water rinsing from surfaces, it's low corrosiveness to construction materials, it's low-foaming activity) and the ability of PHMB to maintain effectiveness in use applications (tolerance to hard water, effectiveness over a wide pH range, tolerance to organic load) means PHMB delivers unique performance benefits for a wide range of end use applications such as food, institutional, industrial, health institutions and domestic. Some of the key benefits are:

- Broad spectrum – bactericidal and virucidal
- No known development of resistance
- Fast speed of kill
- Tolerant of organic matter
- Tolerant of hard water
- Stable and effective over wide pH range
- No taste or smell
- Non-staining
- Non tainting to food
- Low corrosivity
- Very low foaming properties,
- Easy to detect (traces analysis)
- Possibly used in concentrates or ready to use products
- Synergistic properties when used in association with other active ingredients

PHMB is an effective biocide in use and has been proven over time in work environments to provide critical protection against key food borne pathogens such as listeria, E-coli and Salmonella.

Other available chemistries do not offer the same blend of characteristics and are not supported for equivalent PTs and therefore cannot be considered as alternative. Each chemistry has a unique blend of properties which together with its activity spectrum makes it suited to certain applications but not others.

Moreover, some other available chemistries may become, candidates for substitution in their own right.

Reducing the already limited choice of chemistries may make it very difficult for users to select a suitable chemistry for their application and places increased resistance development pressure on the remaining chemistries.

2. TECHNICAL FEASIBILITY

Other available chemistries do not offer the same blend of characteristics and are not supported for equivalent PTs and therefore cannot be considered as alternative. Each chemistry has a unique blend of properties which together with its activity spectrum makes it suited to certain applications but not others.

3. ECONOMIC FEASIBILITY

A continued reduction in the number of available chemistries:

- makes it hard for formulators to create products which meet the needs of users
- reduce the differentiation of products in the marketplace
- make it very difficult for users to select a suitable product/chemistry for their application

4. HAZARDS AND RISKS OF THE ALTERNATIVE

As some of the other active ingredients can be subject to the substitution criteria, a full analysis of the potential risks of an increase in microbiological contamination against the potential benefits of removing a biocidal active from the market should be considered more globally before any decision is taken.

5. AVAILABILITY

As some of the other active ingredients can be subject to the substitution criteria, availability can become difficult.

6. CONCLUSION ON SUITABILITY AND AVAILABILITY OF THE ALTERNATIVE

- A decision on an individual active substance should not be taken in isolation
- A full analysis of the potential risks of an increase in microbiological contamination against the potential benefits of removing one more chemical from the market should be commissioned by the ECHA before any decision is taken.
- PHMB has a number of unique performance attributes which are not found all together in the available active substances and thus cannot be readily substituted.

7. OTHER COMMENTS

REFERENCES

APPENDIXES