

**Subsection
(Annex Point)**
Official
use only

5.1 Function (IIA5.1)	Code MG01: Disinfectants, general biocidal products. Product types: PT2: Private and public area disinfectant PT3: Disinfectant for veterinary hygiene PT4: Disinfectant for food and feed areas Code MG02: Preservatives PT6: In-can preservative	
5.2 Organism(s) to be controlled and products, organisms or objects to be protected (IIA5.2)		
5.2.1 Organism(s) to be controlled (IIA5.2)	Bacteria	x
5.2.2 Products, organisms or objects to be protected (IIA5.2)	PT2: Disinfection of surfaces in bathrooms PT3: Udder hygiene PT4: Disinfection in brewery industry PT6: Preservation of fabric conditioner, and manual dishwashing liquid	
5.3 Effects on target organisms, and likely concentration at which the active substance will be used (IIA5.3)		
5.3.1 Effects on target organisms (IIA5.3)	General publication on effect on target organisms and mode of action included in Document IV as A5/01: Alakomi, H.-L., Skyttä, E., Saarela, M., Mattila-Sandholm, T., Latva-Kala, K., Helander, I.M. (2000). Lactic acid permeabilizes Gram-negative bacteria by disrupting the outer membrane. Applied and Environmental Microbiology, Vol. 66, No.5, p.2001-2005. Combined effect: - Lowering pH by penetrating the cytoplasmic membrane of bacteria, resulting in reduced intracellular pH and disruption of the transmembrane proton motive force - Function as permeabilizer of the gram-negative bacterial outer membrane.	x

5.3.2	Likely concentrations at which the A.S. will be used (IIA5.3)		
	PT2	2%	x
	PT3	8%	
	PT4	4%	
	PT6	0.05-1 %	
5.4	Mode of action (including time delay) (IIA5.4)		
5.4.1	Mode of action	<p>General publication on effect on target organisms and mode of action included in Document IV as A5/01:</p> <p>Alakomi, H.-L., Skyttä, E., Saarela, M., Mattila-Sandholm, T., Latva-Kala, K., Helander, I.M. (2000). Lactic acid permeabilizes Gram-negative bacteria by disrupting the outer membrane. Applied and Environmental Microbiology, Vol. 66, No.5, p.2001-2005.</p> <p>Combined effect:</p> <ul style="list-style-type: none"> - Lowering pH by penetrating the cytoplasmic membrane of bacteria, resulting in reduced intracellular pH and disruption of the transmembrane proton motive force - Function as permeabilizer of the gram-negative bacterial outer membrane. 	x
5.4.2	Time delay	Not relevant.	
5.5	Field of use envisaged (IIA5.5)		
	MG01: Disinfectants, general biocidal products	<p>PT2: Disinfection of surfaces in bathrooms</p> <p>PT3: Udder hygiene</p> <p>PT4: Disinfection of surfaces in slaughter houses and milking industry.</p>	
	MG02: Preservatives	PT6: In-can preservative in fabric conditioner, and manual dishwashing liquid.	
	MG03: Pest control	Not applicable	
	MG04: Other biocidal products	Not applicable	
	Further specification	Not applicable	
5.6	User (IIA5.6)		
	Industrial	PT4: Disinfection in brewery industry	
	Professional	PT3: Udder hygiene	

Section A5**Effectiveness against target organisms and intended uses**

	General public	PT2: Disinfection of surfaces in bathrooms PT6: In-can preservatives
5.7	Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies (IIA5.7)	
5.7.1	Development of resistance	No development of resistance expected.
5.7.2	Management strategies	No development of resistance expected.
5.8	Likely tonnage to be placed on the market per year (IIA5.8)	2-5 ton



Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPOREUR MEMBER STATE
Date	2017/01/17
Conclusion	
Remarks	<p><i>The comments by the RMS refer to PT2 even though the document by the applicant contains information for PT2, 3 and 4. The specific comments regarding PT 3 and 4 can be found in the corresponding CARs. PT 6 is not evaluated in this CAR.</i></p> <p>5.2.1: According to the studies provided within part B of the dossier, fungi are also target organisms; tests against <i>Aspergillus niger</i> using Oscar containing 2 % lactic acid showed a fungistatic activity.</p> <p>5.3.1: In this chapter, a short summary of the efficacy data is helpful:</p> <ul style="list-style-type: none"> • The lactic acid containing product Oscar shows a basic fungistatic activity against <i>Aspergillus niger</i> in the presence of 5% fetal bovine serum organic soil after 7 days. • Oscar is showed basic efficacy against <i>Staphylococcus aureus</i>, <i>Klebsiella pneumoniae</i> and <i>Escherichia coli</i> for inanimate non-food contact surfaces in the presence of 5% fetal bovine serum organic soil load after a 1 min contact period. • Under the same conditions Oscar was not an effective sanitizer against Vancomycin resistant <i>Enterococcus faecalis</i> for inanimate non-food contact hard surfaces. <p>The studies performed are sufficient at the Annex I inclusion stage.</p> <p>5.3.2: for PT2 tests using Oscar containing 2% of the active substance were performed</p> <p>5.4.1: The undissociated form of lactic acid is able to penetrate the cytoplasmatic membrane of bacteria, resulting in a reduction of the intracellular pH and disruption of the transmembrane proton motive force</p>
	COMMENTS FROM ...
Date	<i>Give date of comments submitted</i>
Results and discussion	<i>Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Reliability	<i>Discuss if deviating from view of rapporteur member state</i>
Acceptability	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	