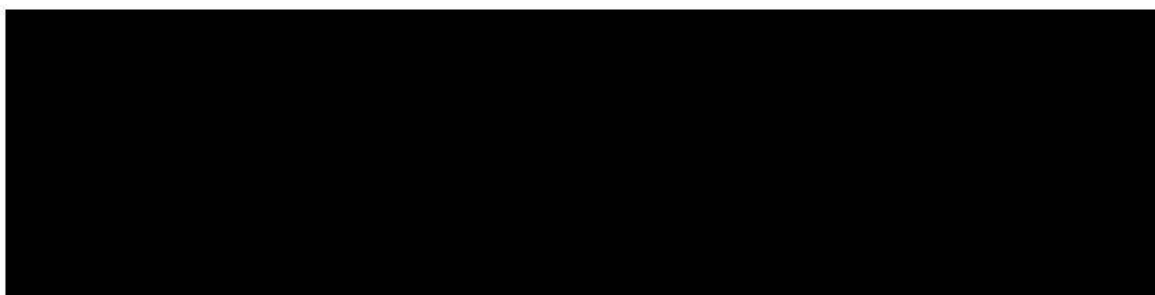


Section A 5.3.1(01)	Efficacy data	
Annex Point IIB V.5.11		
	1 REFERENCE	Official use only
1.1 Reference	██████████ (2009). Basic bactericidal activity on copper sulphate pentahydrate. eurofins Pharma Services, Biolab S.p.A, Italy. Report no. 2009/1026 Ami, 28 December 2009.	
1.2 Data protection	████	
1.2.1 Data owner	██████████	
1.2.2 Companies with letter of access	████	
1.2.3 Criteria for data protection	██ ██	
1.3 Guideline study	Yes. BS EN 1040 (2005) (phase 1).	
1.4 Deviations	None.	
	2 METHOD	
2.1 Test Substance	██	
2.1.1 Trade name/ proposed trade name	██████████	
2.1.2 Composition of Product tested	██████████	
2.1.3 Physical state and nature	██	
2.1.4 Monitoring of active substance concentration	████	
2.1.5 Method of analysis	██████████	
2.2 Reference substance	████	
2.2.1 Method of analysis for reference substance	██████████	
2.3 Testing procedure		
2.3.1 Test population / inoculum / test organism	██	
2.3.2 Test system	██	
2.3.3 Application of TS	██	
2.3.4 Test conditions	██	
2.3.5 Duration of the test / Exposure time	██████████	
2.3.6 Number of replicates	████	

Section A 5.3.1(01)	Efficacy data	
Annex Point IIB V.5.11		
performed		
2.3.7 Controls		
2.4 Examination		
2.4.1 Effect investigated		
2.4.2 Method for recording / scoring of the effect		
2.4.3 Intervals of examination		
2.4.4 Statistics		
2.4.5 Post monitoring of the test organism		
	3 RESULTS	
3.1 Efficacy		
3.1.1 Dose/Efficacy curve		
3.1.2 Observed effects in the post monitoring phase		
3.2 Effects against organisms or objects to be protected		
3.3 Other effects		
3.4 Efficacy of the reference substance		
3.5 Tabular and/or graphical presentation of the summarised results		



3.6	Efficacy limiting factors		
3.6.1	Occurrences of resistances		
3.6.2	Other limiting factors		
		4 RELEVANCE OF THE RESULTS COMPARED TO FIELD CONDITIONS	
4.1	Reasons for laboratory testing		
4.2	Relevance compared to field conditions		
4.2.1	Application method		
4.2.2	Test organism		
4.2.3	Observed effect		
4.3	Relevance for read-across		
		5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1	Materials and methods		
5.2	Reliability		
5.3	Assessment of efficacy, data analysis and interpretation		
5.4	Conclusion	On the basis of the results obtained (and presented in the table in 3.5) copper sulphate pentahydrate was bactericidal when tested against <i>Staphylococcus aureus</i> (ATCC 6358) and <i>Pseudomonas aeruginosa</i> (ATCC 15442) at concentrations of 14000 and 21000 ppm.	
5.5	Proposed efficacy specification		
		Evaluation by Competent Authorities	
		EVALUATION BY RAPPORTEUR MEMBER STATE	
Date			
Comments			

Summary and conclusion	
	COMMENTS FROM ... (<i>specify</i>)
Date	
Comments	
Summary and conclusion	

[illegible]

Table A 5.3.1-2: Test organism

[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED] [REDACTED]
[REDACTED]	[REDACTED] [REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED] [REDACTED] [REDACTED]
[REDACTED]	[REDACTED] [REDACTED] [REDACTED]
[REDACTED] [REDACTED]	[REDACTED] [REDACTED] [REDACTED]

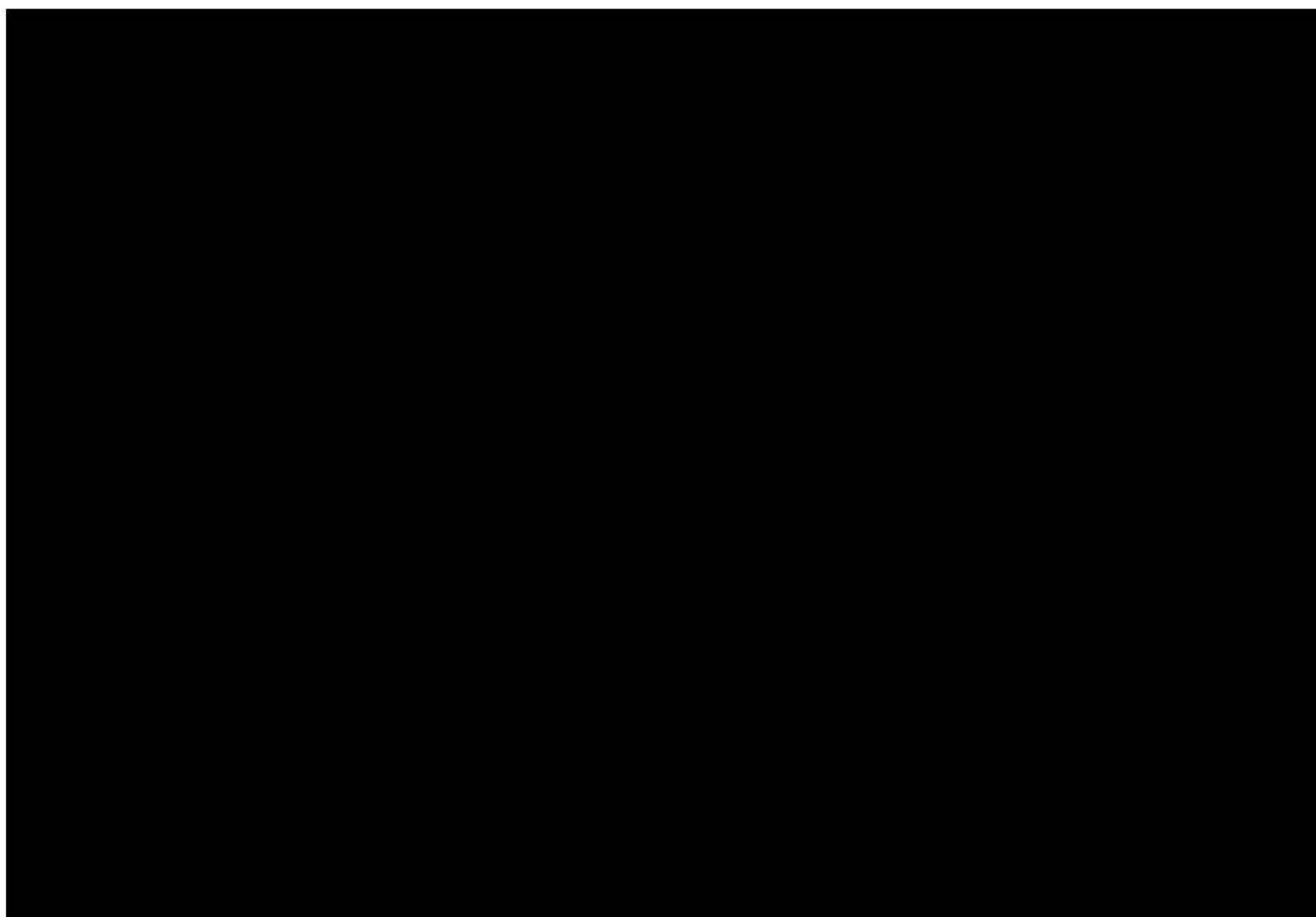
[REDACTED]	
[REDACTED]	[REDACTED] [REDACTED] [REDACTED] [REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]
[REDACTED]	[REDACTED]

[REDACTED]	
[REDACTED]	
[REDACTED]	
[REDACTED]	

Section A 5.3.1(02)	Efficacy data	
Annex Point IIB V.5.11		
	1 REFERENCE	Official use only
1.1 Reference	██████ (2011). Copper sulphate laundry test using a Stomacher model. 21 st October 2011.	
1.2 Data protection	██████	
1.2.1 Data owner	██████████	
1.2.2 Companies with letter of access	██████	
1.2.3 Criteria for data protection	██ ██	
1.3 Guideline study	No. Stomacher laundry model using a protocol approved by ANSES	
1.4 Deviations	None.	
	2 METHOD	
2.1 Test Substance	██████████	
2.1.1 Trade name/ proposed trade name	██████████	
2.1.2 Composition of Product tested	██ ██████████	
2.1.3 Physical state and nature	████████████████████	
2.1.4 Monitoring of active substance concentration	██████	
2.1.5 Method of analysis	██████████	
2.2 Reference substance	██ ██ ██	
2.2.1 Method of analysis for reference substance	██████████	
2.3 Testing procedure		
2.3.1 Test population / inoculum / test organism	████████████████████	
2.3.2 Test system	████████████████████	
2.3.3 Application of TS	████████████████████	
2.3.4 Test conditions	████████████████████	
2.3.5 Duration of the test / Exposure time	██	
2.3.6 Number of replicates	██████	

Section A 5.3.1(02)	Efficacy data	
Annex Point IIB V.5.11		
performed		
2.3.7 Controls		
2.4 Examination		
2.4.1 Effect investigated		
2.4.2 Method for recording / scoring of the effect		
2.4.3 Intervals of examination		
2.4.4 Statistics		
2.4.5 Post monitoring of the test organism		
	3 RESULTS	
3.1 Efficacy		

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3.6	Efficacy limiting factors		
3.6.1	Occurrences of resistances		
3.6.2	Other limiting factors		
	4	RELEVANCE OF THE RESULTS COMPARED TO FIELD CONDITIONS	
4.1	Reasons for laboratory testing		
4.2	Relevance compared to field conditions		
4.2.1	Application method		
4.2.2	Test organism		
4.2.3	Observed effect		
4.3	Relevance for read-across		
	5	APPLICANT'S SUMMARY AND CONCLUSION	
5.1	Materials and methods		

5.2	Reliability	I
5.3	Assessment of efficacy, data analysis and interpretation	
5.4	Conclusion	The present study demonstrates significant biocidal activity of CuSO ₄ at concentrations of 153 and 430 mg/L against MRSA, both alone and in combination with Ariel detergent.
5.5	Proposed efficacy specification	
		Evaluation by Competent Authorities
		EVALUATION BY RAPPORTEUR MEMBER STATE
Date		
Comments		
Summary and conclusion		
		COMMENTS FROM ... (specify)
Date		
Comments		
Summary and conclusion		

Tables for Method

Table A 5.3.1-1: (mixed) Population / Inoculum

Table A 5.3.1-2: Test organism and uniform fabric

Criteria	Details

Table A 5.3.1-3: Test system

[illegible]

Table A 5.3.1-4: Test conditions

[illegible]

SECTION IIIA 5	EFFECTIVENESS AGAINST TARGET ORGANISMS AND INTENDED USES	Official use only
IIIA 5.1 Function	[REDACTED]	
IIIA 5.2 Organism(s) to be controlled and products, organisms or objects to be protected	[REDACTED]	
IIIA 5.2.1 Organism(s) to be controlled	[REDACTED] [REDACTED]	
IIIA 5.2.2 Products, organisms or objects to be protected	[REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]	
IIIA 5.3 Effects on target organisms, and likely concentration at which the active substance will be used	[REDACTED]	
IIIA 5.3.1 Effects on target organisms	[REDACTED] [REDACTED] [REDACTED]	
IIIA 5.3.2 Likely concentrations at which the A.S. will be used	[REDACTED] [REDACTED] [REDACTED] [REDACTED]	
IIIA 5.4 Mode of action (including time delay)	[REDACTED]	
IIIA 5.4.1 Mode of action		
IIIA 5.4.1-01	[REDACTED]	
Reference	[REDACTED] [REDACTED] [REDACTED] [REDACTED]	
Data protection	[REDACTED]	
Data owner	[REDACTED]	
Companies with letter of access	[REDACTED]	
Criteria for data	[REDACTED]	

SECTION IIIA 5	EFFECTIVENESS AGAINST TARGET ORGANISMS AND INTENDED USES	Official use only
protection		
Guideline study		
GLP		
Deviations		
Materials and Methods		
Results		
Applicant's Summary and conclusion		
Reliability		
Deficiencies		
	Evaluation by Competent Authorities	
	Evaluation by Rapporteur Member State	
Date		
Materials and methods		
Conclusion		
Reliability		
Acceptability		
Remarks		
	Comments from ...	
Date		
Results and discussion		
Conclusion		
Reliability		

SECTION IIIA 5	EFFECTIVENESS AGAINST TARGET ORGANISMS AND INTENDED USES	Official use only
Acceptability		
Remarks		

IIIA 5.4.2 Time delay	[REDACTED]	Official use only
IIIA 5.5 Field of use envisaged	[REDACTED]	
IIIA 5.6 User: Industrial, professional, general public (non-professional)	[REDACTED]	
IIIA 5.7 Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies	[REDACTED]	Official use only
IIIA 5.7.2 Management strategies	[REDACTED]	Official use only
IIIA 5.8 Likely tonnage to be placed on the market per year	[REDACTED]	
	Evaluation by Competent Authorities	
	[REDACTED]	

	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	
Materials and methods	
Conclusion	
Reliability	
Acceptability	
Remarks	
	COMMENTS FROM...
Date	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	