	resistances	
3.6.2	Other limiting factors	None observed
		4 RELEVANCE OF THE RESULTS COMPARED TO FIELD CONDITIONS
4.1	**Reasons for laboratory testing**	The temperature (20°C), use concentrations, contact time [redacted]) and pH (6-7) were chosen as typical and representative of field conditions
4.2	**Intended actual scale of biocide application**	The testing was carried out using intended use dilutions into test conditions recognised as acceptable for the field of use (see 4.1 above).
4.3	**Relevance compared to field conditions**	
4.3.1	Application method	In the field, the biocidal product would be applied in a liquid medium, the target organisms would be resuspended and kill would take place in such a medium.
4.3.2	Test organism	The test organisms were relevant to the field of use, [redacted] spores are recognised as relevant to the field of use.
4.3.3	Observed effect	The observed effect has been achieved under conditions similar to those expected in the field and therefore it is reasonable to assume that the effect is similar to that which would be observed in the field.
4.4	**Relevance for read-across**	Yes, activity is relevant to both PT 2 and PT 4 applications
		5 APPLICANT'S SUMMARY AND CONCLUSION
5.1	**Materials and methods**	The test method was developed especially to determine the performance of glutaraldehyde against fungal spores. x The concentrations tested were similar to actual biocidal products used in the field.
5.2	**Reliability**	[redacted]
5.3	**Assessment of efficacy, data analysis and interpretation**	The results showed that the substance was active against [redacted] spores relevant to the field under conditions expected.
5.4	**Conclusion**	Glutaraldehyde is effective against [redacted]
5.5	**Proposed efficacy**	Glutaraldehyde is effective against [redacted]

Section B5.10 **Efficacy Data**
Annex Point IIB5.10
TNsG: Pt. I-B5.10, Pt. III-Ch. 6

specification [redacted]

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Key study	EN1275 & EN1650 Efficacy Testing of [redacted]% Glutaraldehyde), [redacted], BPD ID A5.3.1_21, 21st June 2007, Unpublished, Not GLP
Date	November 20, 2012
Comments	
Materials and methods	The fungicidal activity of the biocide ([redacted]) containing [redacted]% of glutaraldehyde as the active substance was tested by a suspension test. The method applied was based on EN 1275 and EN 1650 standards with a few deviations.
Point 2.3.1	Otherwise than advised by the guideline studies fungicidal activity was only tested against a single mould strain, [redacted]. Activity against yeasts was not tested. The origin of the target mould was identified but not in compliance with the recommendations of the guideline study. The preparation of the working culture of the target mould was adequately described in the original study report. The basic fungicidal activity was first tested under clean conditions in accordance with EN1275. In the next phase, testing for efficacy was conducted in accordance with EN 1650 both under clean and dirty conditions. In both studies the guideline was followed with one exception: instead of three concentration levels, testing was conducted [redacted]. Effectiviness was assessed after three different contact times [redacted]. The inactivation procedure used in recovering the surviving fungi, though not reported in detail, was according to the original study report adequately validated. According to the study summary, the test was not conducted under GLP. However, on the basis of the original study report generally accepted scientific principles were followed in the testing procedure. The deviations from the guideline studies did not essentially threaten the reliability of t he results.
Point 5.1	In the applicant's summary, under materials and methods the target organisms, concentrations tested and the method applied should be briefly described.
Results and their relevance	
Point 3.5	The results obtained and presented in Table under point 3.5 reveal that the number of surviving mould spores in control samples were quantitatively enumerated only after a contact time of [redacted]. The passing criteria are based on the difference in the survivors at the end of the contact time in the control sample and in the test sample. Thus, on the basis of results obtained in the current studies, reliable evidence of the required difference (> 4 logs) can not be shown. However, as the spores hardly germinate in the control suspension within [redacted], reduction rates of survivors can be calculated on the basis of the initial cfu/ml in the control sample [redacted].
Reliability	[redacted]

Evaluation by Competent Authorities	
Conclusion	Glutaraldehyde is effective against [redacted]
Acceptability	Acceptable
Remarks	Throughout the report, the percentage values of concentrations given should specify whether they relate to weight or volume percentages.

Tables for Method

I.1 (mixed) Population / Inoculum (*if necessary; include separate table for different samples*)

Criteria	Details
Nature	Fungal spores
Origin	[redacted]
Initial biomass	Not known
Reference of methods	BS EN 1275 quantitative suspension test BS EN 1650 quantitative suspension test
Collection / storage of samples	Not known
Preparation of inoculum for exposure	Not known
Pretreatment	Not known
Initial density of test population in the test system	Approximately 1.5-5.0 x 10^6 cfu/ml

I.2 Test organism (*if applicable*)

Criteria	Details
Species	[redacted]
Strain	[redacted]
Source	[redacted]
Laboratory culture	YES
Stage of life cycle and stage of stadia	Freshly germinated spores,
Mixed age population	No
Other specification	None
Number of organisms tested	As in initial density (1.2) above
Method of cultivation	Prepared from a 5 day 2nd passage culture.
Pretreatment of test organisms before exposure	See "cultivation" above
Initial density/number of test organisms in the test system	As in initial density (1.2) above

1.3 Test system

Criteria	Details
Culturing apparatus / test chamber	Test organisms/test substance suspended in fluid media at the temperature specified in the method. Recovery incubation was at 37C for at least 7 days(no additional humidity) in dry air incubators
Number of vessels / concentration	Not reported
Test culture media and/or carrier material	Culture Medium: Sabouraud Dextrose Agar
Nutrient supply	Not applicable, batch culture employed
Measuring equipment	Manual plate reading

1.4 Application of test substance

Criteria	Details
Application procedure	Test substance applied as an aqueous solution
Delivery method	Not reported
Dosage rate	Non variable discreet tests [redacted] active substance Glutaraldehyde)
Carrier	Aqueous
Concentration of liquid carrier	Not known
Liquid carrier control	Not reported
Other procedures	None reported

1.5 Test conditions

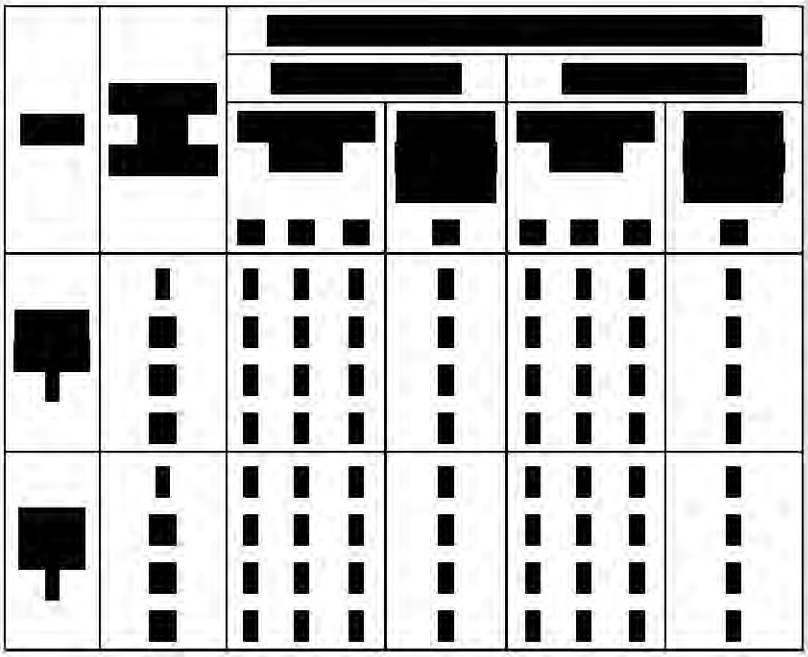
Criteria	Details
Substrate	BS EN 1275 - Sterile Distilled Water BS EN 1650 – Water of Standard Hardness
Incubation temperature	25°C (±1°C)
Moisture	Not reported
Aeration	Not reported
Method of exposure	individual subsamples
Aging of samples	None
Other conditions	BS EN 1275 Clean conditions - no added soilent BS EN 1650 – clean - 0.3g/l Bovine Albumin BS EN 1650 – dirty – 3.0g/l Bovine Albumin

Section A5.3.1_22+23 (combined) **Efficacy Data**
Laboratory study, Virucidal efficacy

			Official use only
		1 REFERENCE	
1.1	**Reference**	a) [redacted] (2012). Test report: EN 14476: 2005 Chemical disinfectants and antiseptics – Virucidal quantitative suspension test for chemical disinfectants and antiseptics used in human medicine - Test method and requirements under clean conditions (phase 2/step 1). [redacted] Unpublished. Revised report dated on April 26, 2012.	x
		b) [redacted] (2012). Test report: EN 14476: 2005 Chemical disinfectants and antiseptics – Virucidal quantitative suspension test for chemical disinfectants and antiseptics used in human medicine - Test method and requirements under dirty conditions (phase 2/step 1). [redacted] Unpublished. Revised report dated on April 26, 2012.	
		[redacted] (2012) Study erratum EN 14476:2006 [redacted]. Erratum dated on April 30, 2012	
1.2	**Data protection**	Yes	
1.2.1	Data owner	BASF SE	
1.2.2	Companies with letter of access	None	
1.2.3	Criteria for data protection	Data on new [a.s. / b.p.] for [first entry to Annex I/IA / authorisation]	
1.3	**Guideline study**	EN14476:2005	
1.4	**Deviations**	[redacted] tested as suggested in EN14476:2005: [redacted] Deviations in the disinfectant suppression control were noted. However, the study director was satisfied that these deviations did not invalidate the test results.	
		2 METHOD	
2.1	**Test Substance (Biocidal Product)**	[redacted] % Glutaraldehyde	
2.1.1	Trade name/ proposed trade name	[redacted]	
2.1.2	Composition of Product tested	[redacted]	x
2.1.3	Physical state and nature	liquid	
2.1.4	Monitoring of active substance concentration	No	
2.1.5	Method of analysis	N/A	
2.2	**Reference substance**	Formaldehyde (0.7 %)	
2.2.1	Method of analysis for reference	N/A	

	substance	
2.3	**Testing procedure**	Modified European standard EN 14476:2005: Chemical disinfectants and antiseptics – Virucidal quantitative suspension test for chemical disinfectants and antiseptics used in human medicine – Test method and requirements (phase 2 / step 1) under clean and dirty conditions, respectively
2.3.1	Test population / inoculum / test organism	The stock virus suspensions are multiplied in HeLa cells which produce high titres of infectious viruses and allow for a determination of a 4 lg reduction of the virus titre. Organisms tested: [redacted]
2.3.2	Test system	Virucidal quantitative suspension test, clean conditions (0.3 g/l bovine serum albumin) and dirty conditions (3 g/l bovine serum albumin + 3 ml/l sheep erythrocytes), respectively
2.3.3	Application of TS	Virus is exposed [redacted] respectively, which is then neutralized; virus is serially diluted and titred in tissue culture plates to determine the tissue culture infectious dose$_{50}$ ($TCID_{50}$) of surviving virus.
2.3.4	Test conditions	20 ± 1°C
2.3.5	Duration of the test / Exposure time	The virus is exposed to the test substance [redacted]
2.3.6	Number of replicates performed	1 replicate
2.3.7	Controls	Cytotoxicity control: The neutralized disinfectant is measured for its effects on the host cells used to propagate the virus. Interference control: The end point titration of the virus is exposed to three different sub-lethal concentrations of neutralized disinfectant to measure the effect of sub-lethal concentrations of disinfectant on virus infectivity in relation to the titre achieved on untreated cells. Disinfectant suppression control: Virus is added to the highest concentration of disinfectant and then the mixture is removed and neutralized. The neutralized virus titre is then determined to assess the efficiency of the neutralization procedure. Virus recovery control: Virus titre is determined for virus in contact with sterile hard water at t=0 and at t=60 min. The virus titre after 60 minutes is then compared to

		the recovery of disinfectant-treated virus to measure the log reduction in virus titre. Reference virus inactivation control: Virus is in contact with 0.7 % W/V formaldehyde and the recovery of virus determined by $TCID_{50}$ after [redacted], in order to assess that the test virus has retained reproducible biocide resistance. In addition, the formaldehyde cytotoxicity of neutralized formaldehyde is determined, to measure assay sensitivity.
2.4	**Examination**	
2.4.1	Effect investigated	Inactivation of viruses.
2.4.2	Method for recording / scoring of the effect	Monitoring the viral cytopathic effect (CPE), i.e. morphological alteration of cells and/or their destruction as a consequence of virus multiplication. Criteria for passing the test: at least a decimal log (lg) reduction of 4 in virus titer of the test strains.
2.4.3	Intervals of examination	3 to 4 days upon inoculating the cell culture with the [redacted] treated or untreated virus suspension, its putative infection is scored by the cytopathic effect (CPE) under a microscope.
2.4.4	Statistics	Simple pass / fail as per the criteria stated in the test method
2.4.5	Post monitoring of the test organism	N/A
		3 RESULTS
3.1	**Efficacy**	
3.1.1	Dose/Efficacy curve	[redacted]
3.1.2	Begin and duration of effects	[redacted]
3.1.3	Observed effects in the post monitoring phase	N/A
3.2	**Effects against organisms or objects to be**	No observed adverse effects.

	protected	
3.3	**Other effects**	None observed.
3.4	**Efficacy of the reference substance**	The +ve control (formaldehyde) passed the virucidal efficacy test after 60 minutes of exposure [redacted] respectively.
3.5	**Tabular and/or graphical presentation of the summarised results**	
3.6	**Efficacy limiting factors**	The presence of 3 g/l BSA + 3 ml/l erythrocytes (dirty conditions) slightly increased the required exposure time of [redacted] towards [redacted] for virucidal efficacy. [redacted]
3.6.1	Occurrences of resistances	None
3.6.2	Other limiting factors	None

4 RELEVANCE OF THE RESULTS COMPARED TO FIELD CONDITIONS

4.1	**Reasons for laboratory testing**	Use of [redacted] in disinfection systems under BPD against viral contamination.
4.2	**Intended actual scale of biocide application**	[redacted]
4.3	**Relevance**	This EN14476 test was designed to demonstrate antiviral efficacy of

	compared to field conditions	chemical disinfectants. It was designed to mimic as close as possible the field conditions. In general, [redacted] is used as part of a formulated product including e.g. surfactants, which is likely to improve its performance.
4.3.1	Application method	Products containing [redacted] will be applied by spraying, wiping or fogging.
4.3.2	Test organism	[redacted]
4.3.3	Observed effect	Adequate reduction of [redacted]
4.4	**Relevance for read-across**	[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	[redacted] was tested for virucidal efficacy as described in EN 14476:2005 which states that instrument and surface disinfectants should within 60 minutes show a 10^4 reduction in [redacted] Upon exposure of the virus [redacted] and its neutralization, virus suspensions were serially diluted and titred in tissue culture plates containing monolayers of host cells (HeLa cells). These were incubated and assayed for a cytopathic effect (cpe) within the monolayer as a readout for virus infectivity.
5.2	**Reliability**	[redacted]
5.3	**Assessment of efficacy, data analysis and interpretation**	Although not conducted to GLP, the test results fit in with other similar studies and experience in use. All of the required controls were satisfactory except for the disinfectant suppression control. However, the study director was satisfied that these deviations did not invalidate the test results.
5.4	**Conclusion**	[redacted]
5.5	**Proposed efficacy specification**	[redacted]

Evaluation by Competent Authorities	
EVALUATION BY RAPPORTEUR MEMBER STATE	
Reference	a) [redacted] (2012). Test report: EN 14476: 2005 Chemical disinfectants and antiseptics – Virucidal quantitative suspension test for chemical disinfectants and antiseptics used in human medicine - Test method and requirements under clean conditions (phase 2/step 1). [redacted] Unpublished. Reporting date of the revised report: April 26, 2012. b) [redacted] (2012). Test report: EN 14476: 2005 Chemical disinfectants and antiseptics – Virucidal quantitative suspension test for chemical disinfectants and antiseptics used in human medicine - Test method and requirements under dirty conditions (phase 2/step 1). [redacted] Unpublished. Reporting date of the revised report: April 26, 2012.
Date	July 18, 2012
Comments	
Materials and methods	The former versions of the reference study reports dated on October 31, 2010 (a) and December 30, 2010 (b) were first time evaluated on July 13, 2011. The current versions have been updated according to the erratum notice dated on April 30, 2012. The studies were conducted in compliance with the standard protocol EN 14476 (2005) only with a few minor deviations not affecting its reliability. The version of the reference standard method applied in the study was not the latest one (superseded in October 2006 by EN 14476:2005+A1). However, the amendment made to the methodology is not affecting the reliability of the results of this study. 2.1.2 Composition of product tested [redacted] 2.3.1Test population, inoculum/test organism The text in the first chapter is not relevant under 2.3.1 and is suggested to be removed. Table 1.2 Test organism Providing three tables coded with the same number (1.2) is slightly confusing. The information in Table 1.2.1 about [redacted] and the information in Table 1.2.2 about [redacted] could be combined to a single table. Table 1.2.3 about HeLa cells could either be combined with Table 1.2 or with Table 1.3, Test system.

	2.3.2 Test system At dirty conditions: deviating from the reference method instead of a mixture of bovine serum albumin (3g/l) and sheep erythrocytes (3 ml/l), a mixture of foetal bovine serum (0.6 g/l), bovine serum albumin [3 g/l÷0.3% (w/v)] and sheep erythrocytes [0.3% v/v)] were used as the interfering substances. At clean conditions: Deviating from the reference method instead of bovine serum albumin alone (0.3g/l) a mixture of foetal bovine serum (0.6 g/l) and bovine serum albumin [0.3 g/l÷0.03% (w/v)] were used as the interfering substances. For clarification, the text is suggested to be modified as follows, Viruses were exposed to disinfectant in 24-well plates using a set-up with one test per concentration of disinfectant. Four different contact times were assessed. The interfering agents used were for the under clean conditions 0.6 g/l foetal bovine serum and 0.3 g/l bovine serum albumin, and for the dirty conditions 0.6 g/l foetal bovine serum, 3.0 g/l bovine serum albumin and 3ml/l sheep erythrocytes, respectively.
	2.3.3 Application of TS Part of the text at the end of the chapter is not relevant under 2.3.3 (more applicable under 2.4.2) and should be removed (past tense preferred!) [redacted] respectively Table 1.4 Application of test substance Similarly, in Table 1.4 under Details describing the application procedure, the end part of the text (starting " then neutralized at 4°C…) is not relevant and should be removed. 2.4.2 Method for recording/scoring of the effect As primary results were not presented from monitoring of the cytopathic effects, on the basis of the original study report, the text should read as follows: *After exposing the viruses to disinfectant at the desired dose level for a fixed contact time, the disinfectant was neutralized, and suspension serially diluted. The tissue culture infectious dose $TCID_{50}$ of surviving viruses was determined in a 96 well tissue culture plate containing monolayer of HeLa cells, and calculated by the method of Spaerman-Kärber. For passing the test, the reduction of $TCID_{50}$ should be at least 4 logs.* 2.4.3 Intervals of examination On the basis of the original study report, the text should read as follows: *The samples for examination of infectious dose $TCID_{50}$ were taken after 5, 15, 30 and 60 minutes exposure time with the disinfectant.*
Results	In the study report (clean conditions) some shortages and misleading information were recorded. 1) Maximum detectable virus inactivation (7.17-2.5) was not reported as required by EN14476:2005. 2) Disinfectant suppression control value was elevated (difference to the test suspension is 2.5 log units, limit 0.5 logs) showing that neutralization of disinfectant was not complete. (Gel chromatography was applied to minimize the residual activity.) In the test report the conclusion on the neutralization validation is to some extent misleading and not in harmony with the results shown. 3.5 Tabular and/or graphical presentation of the summarised results Primary results were not presented from monitoring of the cytopathic effects (see EN 14476:2005, Annex D, Table D.2).

Applicant's summary and conclusion	5.1 Materials and methods As in the original study report, any primary results were not presented from monitoring of the cytopathic effects, the last sentence in the chapter is suggested to be modified as follows: *These were incubated and assayed for reduction of $TCID_{50}$.* 5.2 Reliability 2 5.4 Conclusion Both under clean and dirty conditions [redacted]
Acceptability	Acceptable
Remarks	Concentrations, if expressed as %, should be given in terms of mass per volume (m/v) or volume per volume (v/v). Instead of using ppm as the concentration unit, SI units should be preferred.

	COMMENTS FROM ... *(specify)*
Date	*Give date of comments submitted*
Comments	*Discuss if deviating from view of rapporteur member state*
Summary and conclusion	*Discuss if deviating from view of rapporteur member state*

Tables for Method

1.1 (mixed) Population / Inoculum

Criteria	Details
Nature	Frozen cultures
Origin	[redacted]
Initial biomass	N/A
Reference of methods	European norm method EN 12353 Storage of Test Strains
Collection / storage of samples	Received in post on request.
Preparation of inoculum for exposure	From a frozen culture, the organism is inoculated onto a monolayer of host cells at 24-48 hrs post seeding and incubated at 37°C + 5% CO_2 for 24 hours or until a cytopathic effect (cpe) is observed within the monolayer. The culture flask is subjected to three cycles of freeze/thaw, then the contents are transferred to a sterile centrifuge tube and centrifuged at 1500 rpm for 7 – 10 minutes. The supernatant is passaged to a fresh tissue culture flask containing a monolayer of host cells and incubated overnight. The culture flask is subjected to three cycles of freeze/thaw, then the contents are transferred to a sterile centrifuge tube and centrifuged at 1500rpm for 7 – 10 minutes as before. The supernatant is used as stock virus and is aliquoted into 1.0ml volumes, and stored at -80°C. European norm method EN 12353 Storage of Test Strains.
Pretreatment	From stock virus, a single vial is inoculated onto a monolayer of host cells at 24-48 hrs post seeding and incubated at 37°C + 5% CO2 for 24 hours. After three freeze/thaw cycles followed by centrifugation as before, the supernatant is aliquoted into 1.0ml volumes, and titred for viral load by Karbers method. If the titre is not sufficiently high to produce a >4 log reduction, the process of inoculating into fresh tissue culture flasks is repeated.
Initial density of test population in the test system	4.68 -6.67 x 10^7 $TCID_{50}$/ml ([redacted] 4.68 -6.67 x 10^7 $TCID_{50}$/ml ([redacted]

1.2 Test organism

Criteria	Details
Species	[redacted]
Strain	[redacted]
Source	[redacted]
Laboratory culture	Yes
Stage of life cycle and stage of stadia	NA
Mixed age population	Passage #3

Other specification	NA
Number of organisms tested	4.68 -6.67 x 10^6 $TCID_{50}$, in 100µl volume
Method of cultivation	Stock culture cultivated in HELA cells over 3-4 passages
Pretreatment of test organisms before exposure	The culture is removed from -80°C storage and thawed on ice.
Initial density/number of test organisms in the test system	4.68 -6.67 x 10^6 $TCID_{50}$, in 100µl volume

1.2 Test organism

Criteria	**Details**
Species	[redacted]
Strain	[redacted]
Source	[redacted]
Laboratory culture	Yes
Stage of life cycle and stage of stadia	NA
Mixed age population	Passage #3
Other specification	NA
Number of organisms tested	4.68 -6.67 x 10^6 $TCID_{50}$, in 100µl volume
Method of cultivation	Stock culture cultivated in HELA cells over 3-4 passages
Pretreatment of test organisms before exposure	The culture is removed from -80°C storage and thawed on ice.
Initial density/number of test organisms in the test system	4.68 -6.67 x 10^6 $TCID_{50}$, in 100µl volume

1.2 Test organism

Criteria	Details
Species	[redacted]
Strain	[redacted]
Source	[redacted]
Laboratory culture	Yes
Stage of life cycle and stage of stadia	N/A
Mixed age population	Passage #36- 40
Other specification	N/A
Number of organisms tested	1 x 10^4 HELA cells were seeded per test well and inoculated with test mixture 4-48 hrs post seeding.
Method of cultivation	Cell culture
Pretreatment of test organisms before exposure	Host cells were harvested from continuous culture by trypsinising in 0.25% Trypin-Versene (LONZA, lot no 782926). Cells were resuspended, counted and seeded in DMEM (LONZA, Lot no 0MB107), with 1.0% L-glutamine (LONZA, Lot no 9MB146) and 5% Foetal Bovine Serum (LONZA, Lot no 95B023)
Initial density/number of test organisms in the test system	1 x 10^4 HELA cells were seeded per test well and inoculated with test mixture 4-48 hrs post seeding.

1.3 Test system

Criteria	Details
Culturing apparatus / test chamber	24 well plates for exposure of virus [redacted] 96 well plates for determination of tissue culture infectious dose$_{50}$ (TCID$_{50}$). Relevant incubators.
Number of vessels / concentration	Test vessels were 2.0ml sterile wells in a 24 well plate, 1 well per test product concentration
Test culture media and/or carrier material	DMEM ([redacted]), with 1.0% L-glutamine ([redacted]) and 5% Foetal Bovine Serum ([redacted])
Nutrient supply	Cell culture media/host HELA cells
Measuring equipment	Inverted microscope for reading cell cultures microscopically, TCID$_{50}$ is calculated according to Spearman Karber method

1.4 Application of test substance

Criteria	Details
Application procedure	1 part interfering substance + 1 part virus suspension + 8 parts biocide were mixed and incubated at 20°C±1°C for the indicated time points, then neutralized at 4 °C, serially diluted and virus titred in 96 well tissue culture plates to determine the $TCID_{50}$ of surviving virus. Both, adenovirus-5 and poliovirus-1 were assayed in parallel in each test.
Delivery method	Pipetting & mixing
Dosage rate	[redacted]
Carrier	Sterile synthetic hard water
Concentration of liquid carrier	< 300mg $CaCO_3$/L
Liquid carrier control	N/A
Other procedures	N/A

1.5 Test conditions

Criteria	Details
Substrate	[redacted]
Incubation temperature	The test preparations were stored at 20 ± 1°C during the test period.
Moisture	Not measured
Aeration	Not measured
Method of exposure	Inoculum added with mixing by pipetting
Ageing of samples	Fresh samples, not aged.
Other conditions	N/A

Evaluation by Competent Authorities	
EVALUATION BY RAPPORTEUR MEMBER STATE	
RMS note November 20, 2012: This study was provided by the applicant and was evaluated below by the RMS. The applicant did not provide a study summary, but the already performed evaluation work is presented below for use as supplementary information.	
Reference	[redacted] (2010) EN 13697: version unknown. Chemical disinfectants and antiseptics – Quantitative non-porous surface test for the evaluation of bactericidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas – Test method and requirements without mechanical action (phase 2/step 2). [redacted] on clean, non-porous surface. Report dated on December 29, 2010 ([redacted])
Date	July 07, 2011
Comments	
Materials and methods	According to the study report received the assessment of bactericidal efficacy has been conducted in compliance with the guideline study without any deviations being reported. The efficacy [redacted] was tested against vegetative bacteria at three concentration levels [redacted] at room temperature (20±1°C) and under clean conditions, i.e. in the presence of 0.3 g bovine serum albumin as an interfering agent. In accordance with the guideline study, four strains of vegetative bacteria (two Gram positive cocci and two Gram negative rods) were used as the target organisms and three different contact times ([redacted]) with the surface material not specified were applied. Method applied for neutralizing the active substance after the contact time was adequately reported. Deviating from the guideline study the report did not provide any specification for the surface material used. It is assumed that the material used in the efficacy assessment has met the requirements specified in EN 13697. Verification of the methodology applied has basically been conducted in accordance with the guideline study. In comparison to the criteria given in EN 13697 some minor deviations were recorded. In calculations of viable counts on the test surfaces enumeration was mainly based on lower counts (usually ≤50 cfu per plate) than recommended (50-300 cfu/plate). Furthermore, the counts in decimal dilutions of bacterial suspensions exhibited some irregularities which may slightly affect the reliability of efficacy values obtained. Some minor mistakes were also recorded in NT and NC values provided for [redacted]. None of these deviations, however, seriously endanger the reliability of the results obtained.
Results	For demonstrating bactericidal activity on non-porous surface, a chemical disinfectant should show capability to reduce the viable counts of target organisms on the test surface by four logarithmic units within a fixed contact time. In this study the results obtained demonstrate that under clean conditions [redacted]
Conclusion	For general purposes under clean conditions, [redacted]

Reliability	[redacted]
Acceptability	Acceptable
Remarks	
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*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*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Evaluation by Competent Authorities	
EVALUATION BY RAPPORTEUR MEMBER STATE	
RMS note November 20, 2012: This study was provided by the applicant and was evaluated below by the RMS. The applicant did not provide a study summary, but the already performed evaluation work is presented below for use as supplementary information.	
Reference	[redacted]. (2011) EN 13697: version unknown. Chemical disinfectants and antiseptics – Quantitative non-porous surface test for the evaluation of bactericidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas – Test method and requirements without mechanical action (phase 2/step 2). [redacted] on dirty, non-porous surface. Report dated on March 31, 2011 ([redacted])
Date	July 11, 2011
Comments	
Materials and methods	According to the study report received the assessment of bactericidal efficacy has been conducted in compliance with the guideline study without any deviations being reported. The efficacy of [redacted] was tested against vegetative bacteria at three concentration levels [[redacted]] at room temperature (20 ± 1°C) and under dirty conditions, i.e. in the presence of 3.0 g bovine serum albumin as an interfering agent. In accordance with the guideline study, four strains of vegetative bacteria (two Gram positive cocci and two Gram negative rods) were used as the target organisms and three different contact times ([redacted]) with the surface material not specified were applied. Method applied for neutralizing the active substance after the contact time was adequately reported. Deviating from the guideline study the report did not provide any specification for the surface material used. It is assumed that the material used in the efficacy assessment has met the requirements specified in EN 13697. Verification of the methodology applied has basically been conducted in accordance with the guideline study. In comparison to the criteria given in EN 13697 some minor deviations were recorded. In the efficacy tests against [redacted] some criteria used in verification of methodology ($N\text{-}N_c \leq 2.0$; $NC\text{-}NT \leq \pm 0.3$) were not met. In the calculations of viable counts on the test surfaces enumeration was mainly based on lower counts (usually ≤50 cfu per plate) than recommended (50-300 cfu/plate). Furthermore, the counts in decimal dilutions of bacterial suspensions exhibited some irregularities which may slightly affect the reliability of efficacy values obtained. These deviations, however, do not endanger the reliability of the results obtained.
Results	For demonstrating bactericidal activity on non-porous surface, a chemical disinfectant should show capability to reduce the viable counts of target organisms on the test surface by four logarithmic units within a fixed contact time. In this study the results obtained demonstrate that under dirty conditions [redacted]
Conclusion	For general purposes under clean conditions, [redacted]

Reliability	[redacted]
Acceptability	Acceptable
Remarks	
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*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*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section B5.10
Annex Point IIB5.10
TNsG: Pt. I-B5.10, Pt. III-Ch. 6

Efficacy Data
PT 11

1 REFERENCE

1.1	**Reference**	Title: [redacted] - In Use Efficacy Study For Recirculating Cooling Tower Systems [redacted] Author: [redacted] [redacted] [redacted] Report date: 16 October 2002
1.2	**Data protection**	Yes
1.2.1	Data owner	BASF[redacted] [redacted] [redacted] [redacted] [redacted]
1.2.2	Companies with letter of access	[redacted]
1.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing [a.s. / b.p.] for the purpose of its [entry into Annex I/IA / authorisation]
1.3	**Guideline study**	Field Trial Conditions
1.4	**Deviations**	No

2 METHOD

2.1	**Test Substance (Biocidal Product)**	Glutaraldehyde	
2.1.1	Trade name/ proposed trade name	[redacted]	
2.1.2	Composition of Product tested	[redacted]% active substance	
2.1.3	Physical state and nature	Clear liquid.	
2.1.4	Monitoring of active substance concentration	No	
2.1.5	Method of analysis	Certificate of Analysis for batch number [redacted]	
2.2	**Reference substance**	No	
2.2.1	Method of analysis for reference substance	None used	
2.3	**Testing procedure**		
2.3.1	Test population / inoculum / test organism	Field trial conditions Cooling towers had bacterial, fungal and algal contamination. No identification of the species was performed. *(See Table 1.1 and Table 1.2)*	x
2.3.2	Test system	3 cooling towers [redacted] *See Table 1.3*	x
2.3.3	Application of TS	*See Table 1.4*	x

2.3.4	Test conditions	Temperature range: 70 C to 75C pH: 8.5 to 9 Cooling towers was allowed to foul for 1 week before start of glutaraldehyde treatment. *(See Table 1.5)*
2.3.5	Duration of the test / Exposure time	[redacted]
2.3.6	Number of replicates performed	1
2.3.7	Controls	Single control used i.e. without the test substance
2.4	**Examination**	
2.4.1	Effect investigated	The biocidal & biostatic effects of Glutaraldehyde in cooling towers under field trial conditions.
2.4.2	Method for recording / scoring of the effect	Counts of surviving organisms (cfu/ml) after each contact time were taken and all results were compared to the control.
2.4.3	Intervals of examination	[redacted]
2.4.4	Statistics	None were performed due to insufficient replicates.
2.4.5	Post monitoring of the test organism	No

		3 RESULTS
3.1	**Efficacy**	Glutaraldehyde [redacted] active substance was able to control the microbial population in all 3 cooling towers.
3.1.1	Dose/Efficacy curve	[redacted]
3.1.2	Begin and duration of effects	[redacted]
3.1.3	Observed effects in the post monitoring phase	No post observation monitoring was performed.
3.2	**Effects against organisms or objects to be protected**	None observed
3.3	**Other effects**	None
3.4	**Efficacy of the reference substance**	None used
3.5	**Tabular and/or graphical presentation of the summarised results**	Graph below shows the results obtained from one cooling tower and this was representative of the results observed in 2 other cooling towers. [redacted]

[redacted]

3.6	**Efficacy limiting factors**	None observed
3.6.1	Occurrences of resistances	Not observed
3.6.2	Other limiting factors	None

4 RELEVANCE OF THE RESULTS COMPARED TO FIELD CONDITIONS

4.1	**Reasons for laboratory testing**	To demonstrate the efficacy of Glutaraldehyde in cooling towers under field trial conditions.
4.2	**Intended actual scale of biocide application**	Test was performed to demonstrate that [redacted] Glutaraldehyde active substance controlled the microbial population.
4.3	**Relevance compared to field conditions**	
4.3.1	Application method	Field trial
4.3.2	Test organism	Not identified.
4.3.3	Observed effect	Glutaraldehdye controlled the microbial population in 3 different cooling towers. [redacted]
4.4	**Relevance for read-across**	Yes

x

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	[redacted]
5.2	**Reliability**	Field trial conditions.
5.3	**Assessment of efficacy, data analysis and interpretation**	Glutaraldehyde was shown to control the microbial population present in 3 different cooling towers. Glutaraldehyde was effective [redacted], this was visually observed by the improvement of water clarity in the cooling tower sump due to biofilm removal and sloughing.
5.4	**Conclusion**	Glutaraldehyde at [redacted] was able to control the organisms present in 3 different cooling towers.
5.5	**Proposed efficacy specification**	Glutaraldehyde dosed at [redacted] provided excellent efficacy and controlled all microbes present in 3 different cooling tower field trials.

x

Section B5.10
Annex Point IIB5.10
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Efficacy Data
PT 11

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	July 16, 2012
Materials and methods	2.3.1 Test population The initial numbers of bacterial, fungal and algal contaminants at each of the three trial sites should be given in Table 1.1 and 1.2. Where applicable, estimates of the initial counts at each site available from graphs provided in the original study report. In the original study report the methods are referred only by method codes [redacted], at least media and incubation parameters used in the quantitative examination should be available in Table 1.2. 2.3.2 Test system Information provided under 2.3.2 should be made available in Table 1.3 as well. 2.3.3. Application of TS The dosage regime of [redacted] applied at all three trial sites should be provided in Table 1.4 (Application procedure, delivery method, dosage rate). Dosage rates should be expressed both in terms of [redacted] dosage and dosage of active substance. 2.3.4 Test conditions In the original study report the temperatures of the cooling towers were given without specifying the temperature units: °F or °C? Under 2.3.4 and in table 1.5. the temperature is reported as °C. Whether or not this a correct assumption, should be checked and recorded in Table 1.5. Furthermore, other conditions such as pH, fouling period before the first slug dose, duration of experiment, etc. should be specified in Table 1.5. 2.4.3. Intervals of examination Text suggested to be slightly modified: The samples were examined for surviving organisms (heterotrophic plate count, fungi and yeasts, sulphate reducing bacteria, algae) [redacted] In the original study report, no evidence was provided whether the study was conducted following to GLP.
Results	General note As the initial contamination status of the cooling towers at the three trial sites studied was not identical, the results obtained in the efficacy assessment at each of the trial sites should be separately reported in the summary. If any conclusion on the efficacy against a specific part of the microbial population (heterotrophic bacteria, SRB, fungi, yeasts, algae, biofilm) would be presented, respective results should be provided for evidence in Results. Any results based on visual observation alone remain at highest as indication of potential capacity. Similarly, if no growth results have reported for a specific microbial group throughout the trial, evidence for capability of controlling the growth remains to certain extent uncertain: it is possible that such contaminants would not occur in the process flow.

	3.1 Efficacy According to the original study report, the biocide assessed for efficacy was [redacted]. The text under 3.1. should read as: [redacted] glutaraldehyde as the active substance, respectively, was able to control microbial population in the cooling towers studied at a regularly repeated dosage scheme. 3.5. Tabular and/or graphical presentation of the summarised results The graph provided in 3.5 is intended to illustrate the efficacy results obtained against heterotrophic bacteria. On the basis of the original study report, it is not clear to which of the three different trial sites these results refer. As the trial sites largely differed from each other, it is not likely that the results obtained at one site would directly represent the other sites as well. The efficacy results of each trial site should be presented from each of trial sites, for each target population (heterotrophic bacteria, SRB, fungi and yeasts, algae) numerically and/or graphically.
Relevance of results	4.3.2 Test organism The text should read as: Mixed population of not identified process contaminants in cooling tower water (aerobic bacteria and anaerobic SRB, yeasts and moulds, algae).
Applicant's summary and conclusion	Text should read as follows: [redacted] was capable of controlling the growth of heterotrophic bacteria and algae in three different cooling towers and indicated capability of controlling fungi and anaerobic SRB as well. 5.5. Proposed efficacy specification [redacted] provided good efficacy against heterotrophic bacteria and algae, and indicated capability of controlling fungi and anaerobic SRB.
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted] Concentrations, if expressed as %, should be given in terms of mass per volume (m/v) or volume per volume (v/v). Instead of using ppm as the concentration unit, SI units should be preferred..
	COMMENTS FROM ... *(specify)*
Date	*Give date of comments submitted*
Comments	*Discuss if deviating from view of rapporteur member state*
Summary and conclusion	*Discuss if deviating from view of rapporteur member state*

Tables for Method

1.1 (mixed) Population / Inoculum ***(if necessary; include separate table for different samples)***

Criteria	Details
Nature	Not done – field trial.
Origin	[redacted]
Initial biomass	No
Reference of methods	Field trial
Collection / storage of samples	Not done – field trial.
Preparation of inoculum for exposure	Not done – field trial.
Pretreatment	No
Initial density of test population in the test system	Not done – field trial

1.2 Test organism ***(if applicable)***

Criteria	Details
Species	Not applicable – field trial.
Strain	Not applicable – field trial.
Source	Not applicable – field trial.
Laboratory culture	No
Stage of life cycle and stage of stadia	Not applicable – field trial.
Mixed age population	No
Other specification	No
Number of organisms tested	Not applicable – field trial.
Method of cultivation	Not applicable – field trial.
Pretreatment of test organisms before exposure	None
Initial density/number of test organisms in the test system	Not applicable – field trial.

1.3 Test system

Criteria	Details
Culturing apparatus / test chamber	Not applicable – field trial.
Number of vessels / concentration	Not applicable – field trial.
Test culture media and/or carrier material	Not applicable – field trial.
Nutrient supply	Not applicable – field trial.
Measuring equipment	Not applicable – field trial.

1.4 Application of test substance

Criteria	Details
Application procedure	Glutaraldehyde added as a shock dose and intermittent dose via a metered pump.
Delivery method	Not applicable – field trial.
Dosage rate	[redacted]
Carrier	Cooling tower water
Concentration of liquid carrier	99.9%
Liquid carrier control	Cooling tower water
Other procedures	None

1.5 Test conditions

Criteria	Details
Substrate	Cooling tower water
Incubation temperature	Cooling tower temperature 70C
Moisture	Not known
Aeration	Not known
Method of exposure	Not known
Aging of samples	None
Other conditions	None

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Annex Point IIB5.10
TNsG: Pt. I-B5.10, Pt. III-Ch. 6

Efficacy Data
PT 11

1 REFERENCE

1.1	**Reference**	Title: The use of [redacted] in the treatment of reverse osmosis membranes [redacted] Author: [redacted] [redacted] [redacted] Report date: 17th November 2005
1.2	**Data protection**	Yes
1.2.1	Data owner	BASF [redacted] [redacted] [redacted] [redacted] [redacted]
1.2.2	Companies with letter of access	[redacted]
1.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing [a.s. / b.p.] for the purpose of its [entry into Annex I/IA / authorisation]
1.3	**Guideline study**	In-House Method
1.4	**Deviations**	No

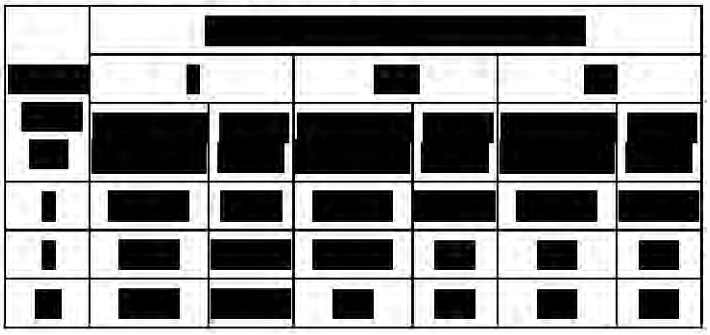
2 METHOD

2.1	**Test Substance (Biocidal Product)**	Glutaraldehyde	
2.1.1	Trade name/ proposed trade name	[redacted]	
2.1.2	Composition of Product tested	[redacted] active substance	
2.1.3	Physical state and nature	Clear liquid.	
2.1.4	Monitoring of active substance concentration	No	
2.1.5	Method of analysis	Certificate of Analysis for batch number [redacted]	
2.2	**Reference substance**	No	
2.2.1	Method of analysis for reference substance	None used	
2.3	**Testing procedure**		
2.3.1	Test population / inoculum / test organism	[redacted] *(See Table 1.1 and Table 1.2)*	x
2.3.2	Test system	*See Table 1.3*	x
2.3.3	Application of TS	*See Table 1.4*	x
2.3.4	Test conditions	A closed circuit reverse osmosis system was connected to a pump with a flow rate of 400 ml/min or 24 l/hr. An in-test inoculum of [redacted] approximately 1.0 x 10^5 cfu/ml was added to the system and left recirculating for 5 days. After which Glutaraldehyde was added at [redacted] for in line cleaning and membranes were taken from the system and soaked in Glutaraldehyde solutions at [redacted] The reverse osmosis membranes were evaluated at ambient over [redacted] for the reduction in the microbe level. *(See Table 1.5)*	x

2.3.5	Duration of the test / Exposure time	[redacted]
2.3.6	Number of replicates performed	1
2.3.7	Controls	Single control used i.e. without the test substance
2.4	**Examination**	
2.4.1	Effect investigated	Effect of Glutaraldehdye against [redacted] in a reverse osmosis membrane system.
2.4.2	Method for recording / scoring of the effect	Counts of surviving organisms (cfu/ml) after the contact time were taken and all results were compared to the control.
2.4.3	Intervals of examination	[redacted]
2.4.4	Statistics	None were performed due to insufficient replicates.
2.4.5	Post monitoring of the test organism	No

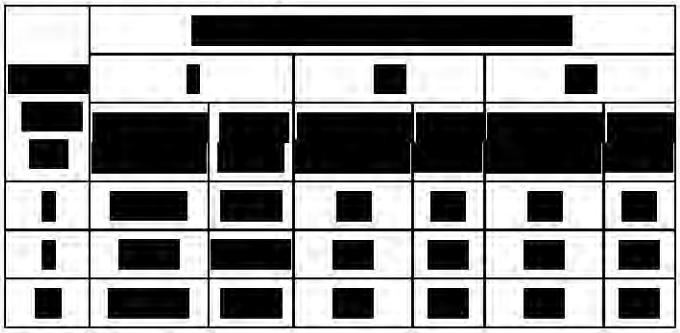
3 RESULTS

3.1	**Efficacy**	Glutaraldehyde was effective against [redacted] for in line and soak cleaning methods for reverse osmosis membranes.
3.1.1	Dose/Efficacy curve	[redacted]
3.1.2	Begin and duration of effects	[redacted]
3.1.3	Observed effects in the post monitoring phase	No post observation monitoring was performed.
3.2	**Effects against organisms or objects to be protected**	Reduction in microbe population.
3.3	**Other effects**	None
3.4	**Efficacy of the reference substance**	None used
3.5	**Tabular and/or graphical presentation of the summarised results**	Surviving [redacted] (cfu/ml) recovered 1. After in-line cleaning by recirculation



Surviving *Pseudomonas aeruginosa* (cfu/ml) recovered

2. After membrane soaking



NT – Not tested

3.6	**Efficacy limiting factors**	None observed
3.6.1	Occurrences of resistances	Not observed
3.6.2	Other limiting factors	None

4 RELEVANCE OF THE RESULTS COMPARED TO FIELD CONDITIONS

4.1	**Reasons for laboratory testing**	The aim of this experiment was to demonstrate the efficacy of [redacted] in controlling marker organisms associated with reverse osmosis membranes e[redacted]	
4.2	**Intended actual scale of biocide application**	Test was performed to demonstrate that [redacted] Glutaraldehyde active substance controlled the bacteria in a reverse osmosis membrane system.	x
4.3	**Relevance compared to field conditions**		
4.3.1	Application method	Laboratory test.	
4.3.2	Test organism	The organism tested is considered to be a typical organism for the intended use of Glutaraldehyde.	x
4.3.3	Observed effect	Glutaraldehyde at [redacted] active substance controlled microbe level in the reverse osmosis membrane system [redacted]	
4.4	**Relevance for read-across**	Yes The laboratory test is comparable with the field conditions.	

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	[redacted] In-House Method	x
5.2	**Reliability**	The method has been validated using an in-house method.	
5.3	**Assessment of efficacy, data analysis and interpretation**	Glutaraldehyde [redacted] active substance was shown to control [redacted]	x
5.4	**Conclusion**	Based upon the results shown above (section 3.5), Glutaraldehyde was shown to control [redacted]	x
5.5	**Proposed efficacy specification**	Glutaraldehyde tested at [redacted] provided excellent efficacy against [redacted]	x

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Efficacy Data
PT 11

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	July 13, 2012
Materials and methods	2.3.1 Test population As the efficacy of [redacted] was only assessed against aerobic [redacted], description of protocol for preparation of anaerobic target bacteria in Table 1.1 confusing. Description recommended to be removed. 2.3.2 Test system Table 1.3.: Number of vessels per concentration: data not from the original study report. 2.3.3 Application of TS Table 1.4.: To be more accurate, in accordance with the original study report in the details of application procedure: [redacted] Table 1.4.: Delivery method. According to the original study report paper slurry was not used as the matrix for delivery. Misleading data to be removed. 2.3.4 Test conditions [redacted] of glutaraldehyde were added for in-line cleaning. Thereafter, the membranes were taken from the system and soaked in [redacted]. Application of GLP was not reported.
Results	3.5 Tabular or graphical presentation of the results According to the original study report, in the table presenting the [redacted] recovered after membrane soaking, control value for water phase sample should be $5x10^7$, not $5x10^8$ cfu/ml.
Relevance of results	4.2 Intended actual scale of biocide application Text should read as: Test was performed to demonstrate that [redacted] glutaraldehyde as the active substance controlled the growth of [redacted] in a reverse osmosis membrane system. 4.3.2 Test organism Text should read as: [redacted].
Applicants summary and conclusion	5.1. Materials and methods Brief description of the in-house method should be provided in this chapter.

Evaluation by Competent Authorities	
	5.3 Assessment of efficacy [redacted] 5.4. Conclusion After a contact time of [redacted] active substance was shown to control [redacted] in a ROM system. 5.5. Proposed efficacy specification [redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	Concentrations, if expressed as %, should be given in terms of mass per volume (m/v) or volume per volume (v/v). Instead of using ppm as the concentration unit, SI units should be preferred.
	COMMENTS FROM ... *(specify)*
Date	*Give date of comments submitted*
Comments	*Discuss if deviating from view of rapporteur member state*
Summary and conclusion	*Discuss if deviating from view of rapporteur member state*

Tables for Method

1.1 (mixed) Population / Inoculum (*if necessary; include separate table for different samples*)

Criteria	Details
Nature	Freeze dried cultures
Origin	[redacted]
Initial biomass	No
Reference of methods	EN 12353 Storage of Test Strains
Collection / storage of samples	A number of colonies are suspended on beads in cryogenic protective media prior to freezing at -70^{0}C as per EN 12353 Storage of Test Strains.
Preparation of inoculum for exposure	From a freeze dried culture, the aerobic organism is reconstituted onto Tryptone Soya Broth (TSB) plates and incubated for at least 1 day. The mixed anaerobic organisms were reconstituted onto Postgate's Anaerobic Medium and incubated for at least 14 days. A number of colonies of typical morphology are selected and a further subculture (passage) is performed. A number of colonies of typical morphology are again selected and suspended on beads in cryogenic protective media prior to freezing at -70^{0}C as per EN 12353 Storage of Test Strains.
Pretreatment	No
Initial density of test population in the test system	Aerobic single strain approx. 1.0 x 10^7 cfu/ml

1.2 Test organism (*if applicable*)

Criteria	Details
Species	[redacted]
Strain	[redacted]
Source	[redacted]
Laboratory culture	Yes
Stage of life cycle and stage of stadia	24hr 2nd passage culture
Mixed age population	No
Other specification	No
Number of organisms tested	1.0 x 10^7 cfu/ml
Method of cultivation	Incubated at 30±2°C on Tryptone Soya Agar
Pretreatment of test organisms before exposure	NONE
Initial density/number of test organisms in the test system	1.0 x 10^5 cfu/ml

1.3 Test system

Criteria	Details
Culturing apparatus / test chamber	Incubation in laboratory incubators at 30±2°C.
Number of vessels / concentration	17
Test culture media and/or carrier material	Tryptone Soya Agar
Nutrient supply	None added
Measuring equipment	Total Viable Count

1.4 Application of test substance

Criteria	Details
Application procedure	[redacted]
Delivery method	[redacted]
Dosage rate	[redacted]
Carrier	Sterile Distilled Water
Concentration of liquid carrier	99.9%
Liquid carrier control	Sterile distilled water
Other procedures	None

1.5 Test conditions

Criteria	Details
Substrate	Reverse osmosis membrane system inoculated with [redacted]
Incubation temperature	20±1°C
Moisture	Aqueous suspension test
Aeration	No (shaken @ 100 rpm)
Method of exposure	Individual samples
Aging of samples	None
Other conditions	None

Section B5.10
Annex Point IIB5.10
TNsG: Pt. I-B5.10, Pt. III-Ch. 6

Efficacy Data
PT 11

1 REFERENCE

1.1	**Reference**	Title: The use of [redacted] in Water Treatment Plants [redacted] Author: [redacted] Report date: 17th November 2005
1.2	**Data protection**	Yes
1.2.1	Data owner	BASF [redacted]
1.2.2	Companies with letter of access	[redacted]
1.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing [a.s. / b.p.] for the purpose of its [entry into Annex I/IA / authorisation]
1.3	**Guideline study**	In-House Method
1.4	**Deviations**	No

		2 METHOD
2.1	**Test Substance (Biocidal Product)**	Glutaraldehyde
2.1.1	Trade name/ proposed trade name	[redacted]
[redacted]	Product tested	[redacted] active substance
2.1.3	Physical state and nature	Clear liquid.
2.1.4	Monitoring of active substance concentration	No
2.1.5	Method of analysis	Certificate of Analysis for batch [redacted]
2.2	**Reference substance**	No
2.2.1	Method of analysis for reference substance	None used
2.3	**Testing procedure**	
2.3.1	Test population / inoculum / test organism	[redacted] *(See Table 1.1 and Table 1.2)*
2.3.2	Test system	*See Table 1.3*
2.3.3	Application of TS	*See Table 1.4*
2.3.4	Test conditions	Shredded waste paper 1% (w/v) in sterile distilled water and allowed to stand for 7 days. Glutaraldehdye was added and the resulting test matrix evaluated at ambient. *(See Table 1.5)*
2.3.5	Duration of the test / Exposure time	[redacted]
2.3.6	Number of replicates performed	1
2.3.7	Controls	Single control used i.e. without the test substance

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TNsG: Pt. I-B5.10, Pt. III-Ch. 6

Efficacy Data
PT 11

2.4	**Examination**		
2.4.1	Effect investigated	Effect of Glutaraldehdye against [redacted] within a simulated waste-water system (water plus 1% waste paper pulp), in both the water phase and the pressed pulp phase.	
2.4.2	Method for recording / scoring of the effect	Counts of surviving organisms (cfu/ml) after the contact time were taken and all results were compared to the control.	x
2.4.3	Intervals of examination	[redacted]	
2.4.4	Statistics	None were performed due to insufficient replicates.	
2.4.5	Post monitoring of the test organism	No	

3 RESULTS

3.1	**Efficacy**	Glutaraldehyde at [redacted] active substance reduced the microbe population versus the non biocide control sample.
3.1.1	Dose/Efficacy curve	[redacted]
3.1.2	Begin and duration of effects	[redacted]
3.1.3	Observed effects in the post monitoring phase	No post observation monitoring was performed.
3.2	**Effects against organisms or objects to be protected**	Reduction in microbe population.
3.3	**Other effects**	None
3.4	**Efficacy of the reference substance**	None used
3.5	**Tabular and/or graphical presentation of the summarised results**	[redacted]
3.6	**Efficacy limiting factors**	None observed in this experimental series
3.6.1	Occurrences of resistances	Not observed
3.6.2	Other limiting factors	None

4 RELEVANCE OF THE RESULTS COMPARED TO FIELD CONDITIONS

4.1	**Reasons for laboratory testing**	To demonstrate the efficacy of Glutaraldehyde in controlling marker organisms commonly associated with waste-water e[redacted]
4.2	**Intended actual scale of biocide application**	Test was performed to demonstrate that [redacted] Glutaraldehyde active substance controlled bacteria in a waste water scenario.
4.3	**Relevance compared to field conditions**	
4.3.1	Application method	Laboratory test.
4.3.2	Test organism	The organisms tested are indicator organisms and considered to be typical organism(s) for the intended use of Glutaraldehyde.
4.3.3	Observed effect	Glutaraldehyde [redacted] active substance controlled the growth of problematic aerobic and anaerobic microorganisms in the waste water and suspended solids [redacted]
4.4	**Relevance for read-across**	Yes The laboratory test is comparable with the field conditions.

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	[redacted] In-House Method	
5.2	**Reliability**	The method has been validated using an in-house method.	
5.3	**Assessment of efficacy, data analysis and interpretation**	Glutaraldehyde at [redacted] active substance was shown to eliminate both aerobic and anaerobic organisms [redacted] when compared to the control.	
5.4	**Conclusion**	Based upon the results shown above (section 3.5), Glutaraldehyde was shown to control both type of organisms at [redacted]	x
5.5	**Proposed efficacy specification**	Glutaraldehyde [redacted] provided excellent efficacy against both aerobic and anaerobic bacteria when compared to the control [redacted]	x

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Efficacy Data
PT 11

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	July 13, 2012
Materials and methods	2.3.2 Test system Table 1.3.: Number of vessels per concentration: data not from the original study report. 2.3.4 Test conditions Whether the tests were conducted at ambient temperature was not reported in the original study report. 2.4.2 Method for recording/scoring of the effect According to description of materials and methods in the original study report, the test mixtures were examined for surviving target organisms after inactivating the active substance. Inactivation was conducted by preparing serial dilutions of the test mixtures into an inactivator solution. Information to be inserted into the summary report. Whether or not the diluents used for examination of anaerobic bacteria were appropriately deaerated/reduced before use, was not reported. Application of GLP was not reported.
Results	3.5 Tabular or graphical presentation of the results [redacted]
Applicants summary	5.4. Conclusion [redacted] was capable of controlling the growth of aerobic and anaerobic bacteria in both phases (water phase, solid phase) of the waste water. 5.5. Proposed efficacy specification Glutaraldehyde tested [redacted]
Reliability	[redacted]
Acceptability	Acceptable
Remarks	Concentrations, if expressed as %, should be given in terms of mass per volume (m/v) or volume per volume (v/v). Instead of using ppm as the concentration unit, SI units should be preferred.
	COMMENTS FROM ... *(specify)*
Date	*Give date of comments submitted*
Comments	*Discuss if deviating from view of rapporteur member state*
Summary and conclusion	*Discuss if deviating from view of rapporteur member state*

Tables for Method

1.1 (mixed) Population / Inoculum ***(if necessary; include separate table for different samples)***

Criteria	Details
Nature	Freeze dried cultures
Origin	[redacted]
Initial biomass	No
Reference of methods	EN 12353 Storage of Test Strains
Collection / storage of samples	A number of colonies are suspended on beads in cryogenic protective media prior to freezing at -70^{0}C as per EN 12353 Storage of Test Strains.
Preparation of inoculum for exposure	From a freeze dried culture, the aerobic organism is reconstituted onto Tryptone Soya Broth (TSB) plates and incubated for at least 1 day. The mixed anaerobic organisms were reconstituted onto Postgate's Anaerobic Medium and incubated for at least 14 days. A number of colonies of typical morphology are selected and a further subculture (passage) is performed. A number of colonies of typical morphology are again selected and suspended on beads in cryogenic protective media prior to freezing at -70^{0}C as per EN 12353 Storage of Test Strains.
Pretreatment	No
Initial density of test population in the test system	Aerobic single strain approx. 1.0 to 5.0 x 10^6 cfu/ml Anaerobic mixed population 5.0 x 10^4 cfu/ml

1.2 Test organism ***(if applicable)***

Criteria	Details
Species	[redacted]
Strain	[redacted]
Source	[redacted]
Laboratory culture	Yes
Stage of life cycle and stage of stadia	24hr 2nd passage culture
Mixed age population	No
Other specification	No
Number of organisms tested	1.0 x 10^8 cfu/ml
Method of cultivation	Incubated at 30±2°C on Tryptone Soya Agar
Pretreatment of test organisms before exposure	NONE
Initial density/number of test organisms in the test system	1.0 x 10^6 to 5.0 x 10^6 cfu/ml

Criteria	Details
Species	[redacted]
Strain	[redacted]
Source	[redacted]
Laboratory culture	Yes
Stage of life cycle and stage of stadia	14 days, 2nd passage culture
Mixed age population	Yes
Other specification	No
Number of organisms tested	1.0 x 10^5 cfu/ml
Method of cultivation	Incubated at 30±2°C on Postgate's Anaerobic Medium
Pre-treatment of test organisms before exposure	None
Initial density/number of test organisms in the test system	5.0 x 10^4 cfu/ml

1.3 Test system

Criteria	Details
Culturing apparatus / test chamber	Incubation in laboratory incubators at 30±1°C.
Number of vessels / concentration	17
Test culture media and/or carrier material	Tryptone Soya Agar
Nutrient supply	None added
Measuring equipment	Total Viable Count

1.4 Application of test substance

Criteria	Details
Application procedure	[redacted]
Delivery method	[redacted]
Dosage rate	[redacted]
Carrier	Sterile Distilled Water
Concentration of liquid carrier	99.9%
Liquid carrier control	Sterile distilled water
Other procedures	None

1.5 Test conditions

Criteria	Details
Substrate	Shredded waste paper in sterile distilled water at a concentration of 1% (w/v) and allowed to stand for 7 days.
Incubation temperature	20±1°C
Moisture	Aqueous suspension test
Aeration	No (shaken @ 100 rpm)
Method of exposure	Individual samples
Aging of samples	None
Other conditions	None

Section A5.3.2_06 Efficacy Data
Laboratory study, Antimicrobial efficacy

			Official use only
		1 REFERENCE	
1.1	**Reference**	Efficacy of slimicides for the paper industry bacterial slime [redacted] BPD ID A5.3.2_06, [redacted], done to GLP, Unpublished.	x
1.2	**Data protection**	Yes	
1.2.1	Data owner	BASF	
1.2.2	Companies with letter of access	None	
1.2.3	Criteria for data protection	Data on new [a.s. / b.p.] for [first entry to Annex I/IA / authorisation]	
1.3	**Guideline study**	Test method outlined in the ASTM Standards on Materials and Environmental Microbiology, Second Edition, 1993, E 600-91	
1.4	**Deviations**	The pulp slurry was prepared one day before the test, it was not made and used on the same day; however the addition of the 1% size solution and the test material as well as the adjustment of the pH were done on the day of the test. The study director was satisfied that this deviation did not adversely affect the study. The inoculum counts were higher than expected, leading to the actual populations being used to be higher than that allowed in the test method. 10^7 was maximum allowed, but up to 9.5×10^8 was used. The study director was satisfied that these deviations did not invalidate the test results.	
		2 METHOD	
2.1	**Test Substance (Biocidal Product)**	Glutaraldehyde [redacted]	
2.1.1	Trade name/ proposed trade name	[redacted]	x
2.1.2	Composition of Product tested	Freshly prepared ground wood pulp suspension (20 g/l solids) adjusted to pH 5.0 to 5.5. Biocide was added [redacted]	
2.1.3	Physical state and nature	Liquid	
2.1.4	Monitoring of active substance concentration	Not reported.	
2.1.5	Method of analysis	Not reported	
2.2	**Reference substance**	Not reported	
2.2.1	Method of analysis for reference substance	Not reported	

Section A5.3.2_06 **Efficacy Data**
Laboratory study, Antimicrobial efficacy

2.3	**Testing procedure**	The test material was evaluated by adding [redacted] to slurries of groundwood pulp. Various concentrations of the test material was added to each slurry, the slurries maintained at 37 ±2 °C for three hours and the number of surviving bacteria determined by standard microbiological techniques.
2.3.1	Test population / inoculum / test organism	Each sample was inoculated with 1.0 ml of the test organism suspension to give a concentration of between 2 x 10^6 and 1 x10^7 colony forming units (c.f.u's) ml^{-1} in the pulp to be tested. Organisms tested: [redacted] The actual inoculum counts were higher than expected, leading to the actual populations being used to be higher than that allowed for in the test method. Between 1.25 x 10^8 and 9.5 x 10^8 were used, this is noted in the deviations from method.
2.3.2	Test system	40 ml of steam sterilised [redacted] Pulp Slurry (~2.5% w/v of solids) was made up to 50 ml with sterile DI water (~2% w/v of solids). 1ml of sterile Rosin Size (~0.02% v/w) was added and the system pH adjusted to between 5.0 and 5.5 using a predetermined volume of 0.4% Aluminium sulphate solution.
2.3.3	Application of TS	The desired amount of the biocide was dosed into the Pulp Slurry on the day of the test, prior to the addition of the inoculum.
2.3.4	Test conditions	The inoculated test preparations were incubated at 37 ± 2°C during the test period.
2.3.5	Duration of the test / Exposure time	The samples were inoculated and checked for test organism survival after the [redacted] period.
2.3.6	Number of replicates performed	Two batches tested and two replicates performed for each batch.
2.3.7	Controls	Control (initial time) count: Two pulp cultures for each challenge organism ware prepared in the same manner as the test cultures, but without any biocide addition. Immediately following the addition of the challenge organism, the bottles were shaken vigorously, samples were enumerated and the colony forming units per ml (cfu/ml) calculated using the standard microbiological techniques detailed in 2.4.2 below. All plates were incubated together with the test material plates. Inoculum confirmation counts: The cfu/ml of the standardised inoculum was confirmed by serial dilution the bacterial suspension in Phosphate Buffered Saline (PBS) and plating selected dilutions on Tryptone Glucose Extract Agar (TGEA). All plates were incubated together with the test material plates. Neutraliser effectiveness control: Pulp slurry was prepared in the same manner as the test using the highest concentration of the test material and omitting the challenge

organism. The plating procedure used for the test was performed and fewer than 10^2 cfu of the challenge organism was added to each plate. The dilution tubes were allowed to sit at room temperature for 30 minutes, the plating procedure was repeated and again fewer than 10^2 cfu of the challenge organism was added to each plate. Duplicate TGEA plates without the test material were plated with the same inoculum. All plates were incubated together with the test material plates. The colonies counted and the cfu determined. The initial and 30 minute sample times were compared to the control plates without the test material.

Viability control:

Fewer than 10^2 cfu of the challenge organism were spread on TGEA plates in triplicate. All plates were incubated together with the test material plates.

2.4 Examination

2.4.1 Effect investigated

Effectiveness of Glutaraldehyde against slime forming bacteria in simulated paper mill conditions.

2.4.2 Method for recording / scoring of the effect

Monitoring levels of microbial contamination in slurries of ground wood pulp via Total Viable Counts (TVC's) three hours after deliberate contamination of the slurry. The slurries were maintained at 37 ± 2°C during the test period.

After incubation, the bottles were shaken vigorously and one ml samples were plated in duplicate using Tryptone Glucose Extract Agar (TGEA).The cfu/ml of each sample were confirmed by serial dilution of the system in Phosphate Buffered Saline with 1% Glycine (PBS+) and plating selected dilutions on Tryptone Glucose Extract Agar (TGEA). All plates were incubated together with the control plates at 37 ± 2°C for 48 ± 2 hours. The plates were enumerated and the cfu/ml calculated.

Preparations should show at least a 99% (2 log) reduction in bacterial numbers to show effectiveness of the test material.

$$\%\text{Kill} = \frac{(A - B)}{(A)} \times 100$$

where: A = Average count of initial control.
B = Average count after incubation.

2.4.3 Intervals of examination

The samples were inoculated and checked for test organism survival [redacted]

2.4.4 Statistics

Percentage reduction and the maximum possible number of cfu/ ml are given where no recovery occurred. Colony counts and % reduction in numbers are given. Simple pass / fail criteria are stated in the test method, at least a 99% reduction in bacterial numbers is required for a pass.

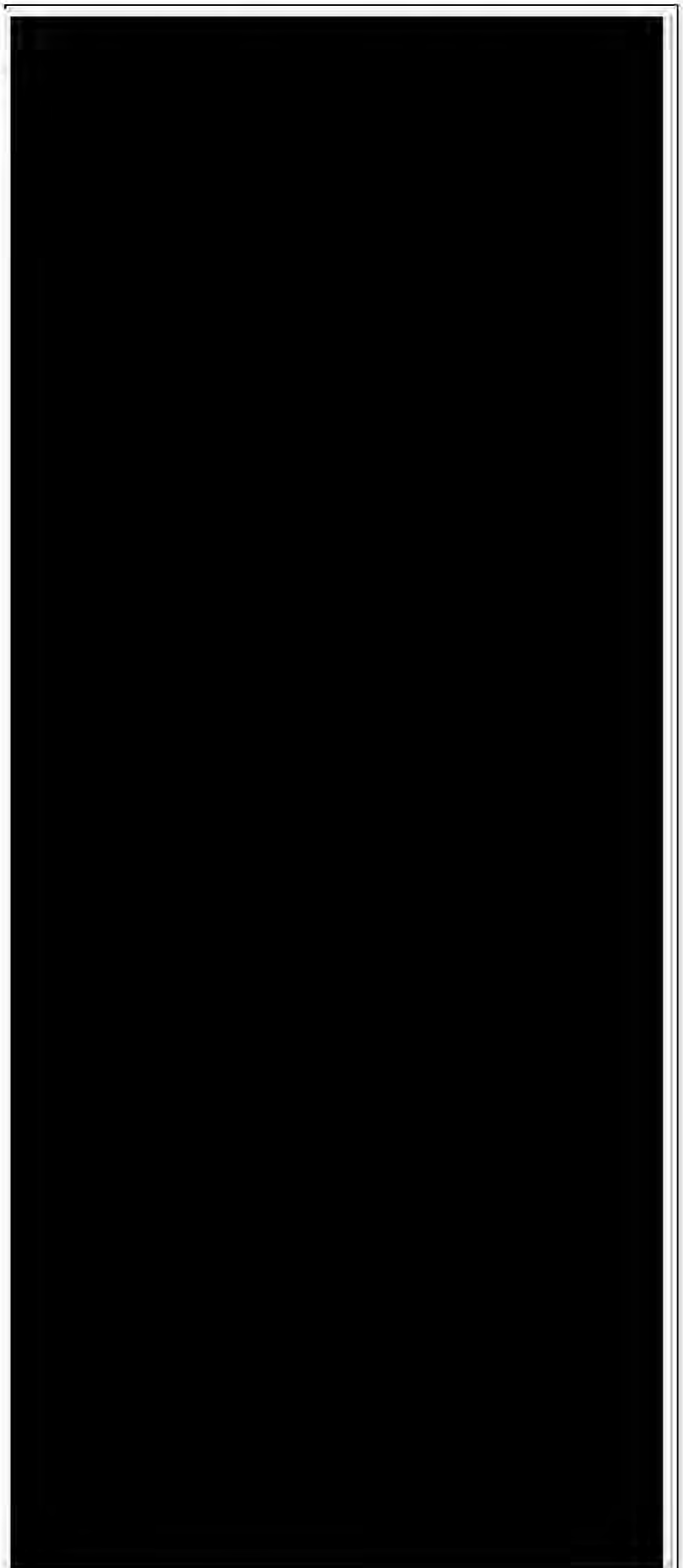
2.4.5 Post monitoring of the test organism

None

3 RESULTS

3.1	**Efficacy**	
3.1.1	Dose/Efficacy curve	[redacted]
3.1.2	Begin and duration of effects	[redacted]
3.1.3	Observed effects in the post monitoring phase	None tested
3.2	**Effects against organisms or objects to be protected**	The bacterial challenges [redacted] were effectively controlled by [redacted] tested.
3.3	**Other effects**	None
3.4	**Efficacy of the reference substance**	None tested

3.5 Tabular and/or graphical presentation of the summarised results



3.6	**Efficacy limiting factors**	None
3.6.1	Occurrences of resistances	None
3.6.2	Other limiting factors	None

4 RELEVANCE OF THE RESULTS COMPARED TO FIELD CONDITIONS

4.1	**Reasons for laboratory testing**	[redacted]
4.2	**Intended actual scale of biocide application**	[redacted]
4.3	**Relevance compared to field conditions**	This test was designed to demonstrate efficacy of [redacted] in highly contaminated systems in the presence of high levels of paper fibres. A dose of [redacted] was sufficient to pass the test in the presence of high levels of paper pulp; this dose represented [redacted] biocide. This test best mimics the conditions in an out of control paper mill, where slug dosing (maximum level added all at once) of biocide is appropriate. Whilst the test conditions have some relevance to the real life conditions in a paper mill (paper pulp, pH, size) the objective in use is to control slime build up in the presence of considerable amount of paper fibres, not vastly reduce bacterial numbers. Therefore lower levels of biocide than those used in this kill test are recommended for in use situations, especially once initial control has been exerted.
4.3.1	Application method	The desired amount of the biocide was dosed into the Pulp Slurry on the day of the test, prior to the addition of the inoculum. In a paper mill the biocide would be added via a metered pump, or via pouring.
4.3.2	Test organism	[redacted]
4.3.3	Observed effect	Adequate reduction in microbial count numbers following challenge.
4.4	**Relevance for read-across**	Organisms tested are standard representatives of microorgansms capable of growing in paper mills and contributing to slime. This test best mimics the conditions in an out of control paper mill and adequately demonstrates the effectiveness of the biocide in bringing the mill back under control, even in the presence of typical quantities of paper fibres.

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	On the day prior to the commencement of the test (see method deviation above) an [redacted] Wood Pulp typical of current production techniques produced when no slimicide was used in the pulp system for 24 hours was used. A slurry was prepared by disintegrating 25g of air-dried groundwood pulp in 976 ml of water. The slurry was mixed thoroughly by swirling 30 times. Aliquots of 40 ± 0.1g were dispensed

into bottles which were capped and steam sterilised on the day prior the date of the test (see deviation from test method in 1.4 above). Sterile deionised water was added aseptically to each bottle to bring the total weight of the contents of each bottle up to 50.0g. The addition of 1ml of the 1% size solution to the test material as well as the adjustment of the pH (to between 5.0 and 5.5 using a predetermined volume of 0.4% Aluminium sulphate solution) were made on the day of the test. Biocide was added at [redacted] prior to addition of the challenge organisms. The appropriate controls were carried out in order to validate the test. Samples were taken to evaluate the microbial count [redacted] and the % reduction in bacterial numbers during the test were evaluated using standard microbiological techniques (see above 2.4.2)

5.2	**Reliability**	[redacted]
5.3	**Assessment of efficacy, data analysis and interpretation**	Conducted to GLP. Deviations from the test method were noted. The study director was satisfied that these deviations did not invalidate the test results. The test results fit in with other similar studies and experience in use.
5.4	**Conclusion**	[redacted] is effective in controlling slime forming bacteria in simulated paper mill conditions.
5.5	**Proposed efficacy specification**	Treat the process water [redacted] Severely contaminated systems require the higher concentrations, after which the concentration can be gradually reduced until microbial growth is under control.

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	July 13, 2012
Materials and methods	General comments The method description of the original study report is much weaker than in the study summary and substantial amount of information is added to the summary. The source of the additional information provided (e.g. in chapters 2.3.2, 2.3.7, 2.4.2, 5.1) in the summary is unclear. [redacted] According to the original study report the assessment was conducted following GLP.
Results	4.3. Relevance compared to field conditions The results were obtained from an efficacy test using a suspension test. However, for the run-ability of the process slime formation on the process surfaces is often the major problem. The results now obtained do not provide any evidence about the efficacy of the biocide on surfaces. The results only show that the product has potential against slime forming bacteria when used in a suspension.
Applicant's summary and conclusion	5.4. Conclusion [redacted] is effective in controlling the growth of slime forming bacteria in a paper suspension simulating the matrix in the process flow of paper mill. The dosage scheme needs to be tailored process-wise.
Reliability	[redacted]
Acceptability	Acceptable
Remarks	Concentrations, if expressed as %, should be given in terms of mass per volume (m/v) or volume per volume (v/v). Instead of using ppm as the concentration unit, SI units should be preferred.
	COMMENTS FROM ... *(specify)*
Date	*Give date of comments submitted*
Comments	*Discuss if deviating from view of rapporteur member state*

Tables for Method

1.1 Population / Inoculum

Criteria	Details
Nature	Freeze dried cultures
Origin	[redacted]
Initial biomass	N/A
Reference of methods	Not reported
Collection / storage of samples	Received in post on request.
Preparation of inoculum for exposure	Each organism was incubated using Tryptone Glucose Extract Agar (TGEA) at 32±2°C for 24±2 hours. Following incubation, a one ml aliquot of sterile DI water was added to the agar surface and the bacterial cells were gently scraped off to produce a bacterial suspension.
Pretreatment	The bacterial suspension was transferred to a dilution bottle flat containing TGEA, spread evenly over the surface and incubated at 32±2°C for 24±2 hours. Ten ml of sterile DI water was added to the dilution bottle flat from a 99 ml DI water blank. By moving water over the agar surface the bacterial cells were removed. A five ml aliquot of the suspension produced was transferred to the remaining 89 ml sterile DI water blank and shaken vigorously, to produce the final inoculum culture.
Initial density of test population in the test system	1.0 ml of the test system strain was added to 51.5 ml of the test pulp system to give an in product concentration of between 2.0×10^6 to 1.0×10^6 cfu ml^{-1}. However the initial densities were higher than expected (see 1.4 deviations from method section) at 1.2×10^8 and 1.5×10^8 for [redacted]

1.2 Test organism

Criteria	Details
Species	[redacted]
Strain	[redacted]
Source	[redacted]
Laboratory culture	Yes
Stage of life cycle and stage of stadia	NA
Mixed age population	NA
Other specification	NA
Number of organisms tested	1.2×10^8 and 1.5×10^8 cfu ml^{-1}

Method of cultivation	The organism was incubated using Tryptone Glucose Extract Agar (TGEA) at 32±2°C for 24±2 hours. Following incubation, a one ml aliquot of sterile DI water was added to the agar surface and the bacterial cells were gently scraped off to produce a bacterial suspension.
Pretreatment of test organisms before exposure	The bacterial suspension was transferred to a dilution bottle flat containing TGEA, spread evenly over the surface and incubated at 32±2°C for 24±2 hours. Ten ml of sterile DI water was added to the dilution bottle flat from a 99 ml DI water blank. By moving water over the agar surface the bacterial cells were removed. A five ml aliquot of the suspension produced was transferred to the remaining 89 ml sterile DI water blank and shaken vigorously, to produce the final inoculum culture.
Initial density/number of test organisms in the test system	1.0ml of an inoculum was added to ~51.5ml of test system to give an *in situ* concentration of 1.2×10^8 and 1.5×10^8 cfu ml^{-1}

1.2 Test organism

Criteria	**Details**
Species	[redacted]
Strain	[redacted]
Source	[redacted]
Laboratory culture	[redacted]
Stage of life cycle and stage of stadia	N/A
Mixed age population	N/A
Other specification	N/A
Number of organisms tested	7.3×10^8 and 9.5×10^8
Method of cultivation	The organism was incubated using Tryptone Glucose Extract Agar (TGEA) at 32±2°C for 24±2 hours. Following incubation, a one ml aliquot of sterile DI water was added to the agar surface and the bacterial cells were gently scraped off to produce a bacterial suspension.
Pretreatment of test organisms before exposure	The bacterial suspension was transferred to a dilution bottle flat containing TGEA, spread evenly over the surface and incubated at 32±2°C for 24±2 hours. Ten ml of sterile DI water was added to the dilution bottle flat from a 99 ml DI water blank. By moving water over the agar surface the bacterial cells were removed. A five ml aliquot of the suspension produced was transferred to the remaining 89 ml sterile DI water blank and shaken vigorously, to produce the final inoculum culture.
Initial density/number of test organisms in the test system	1.0ml of an inoculum was added to ~51.5ml of test system to give an *in situ* concentration of 7.3×10^8 and 9.5×10^8 cfu ml^{-1}

1.3 Test system

Criteria	Details
Culturing apparatus / test chamber	Sterile borosilicate glass bottles with caps. Sterile culture tubes. Blender with sterile container, balance and miscellaneous supplies and general microbiological equipment.
Number of vessels / concentration	Two vessels per organism per concentration tested.
Test culture media and/or carrier material	Test system: 40 ml of steam sterilised [redacted] Wood Pulp Slurry (~2.5% w/v of solids) was made up to 50 ml with sterile deionised water (~2% w/v of solids). 1ml of a 1% sterile Rosin Size solution (~0.02% v/w) was added and the system pH adjusted to between 5.0 and 5.5 using a predetermined volume of 0.4% Aluminium sulphate solution. Diluent and neutraliser: Phosphate buffered saline containing 1% glycine Nutrient agar for enumeration: Tryptone glucose extract agar (TGEA)
Nutrient supply	For test none other than that offered by simulated paper mill conditions (Pulp slurry and size). For enumeration, TGEA Media.
Measuring equipment	Simple plate count. cfu's per dilution plate is calculated into surviving cfu's of test system

1.4 Application of test substance

Criteria	Details
Application procedure	Stock solutions of the antimicrobial were prepared such that the volume of the antimicrobial added [redacted] sufficient was added to the test system to give the desired concentration in ppm.
Delivery method	Mixing
Dosage rate	[redacted]
Carrier	Deionised water
Concentration of liquid carrier	N/A
Liquid carrier control	N/A
Other procedures	N/A

1.5 Test conditions

Criteria	Details
Substrate	Freshly prepared ground wood pulp suspension (20 g/l solids) adjusted to pH 5.0 to 5.5.
Incubation temperature	The test preparations were stored at 37 ± 1°C during the test period.
Moisture	Not measured
Aeration	Not measured
Method of exposure	Inoculum added with vigorous shaking
Ageing of samples	Fresh samples not aged.
Other conditions	N/A

Section B5.10 **Efficacy Data**
Annex Point IIB5.10
TNsG: Pt. I-B5.10, Pt. III-Ch. 6

			Official use only
		1 REFERENCE	
1.1	**Reference**	Evaluation of [redacted]% Glutaraldehyde) at use concentrations in aqueous systems, [redacted], BPD ID A5.3.2_10, 5th August 2003, Unpublished, Not GLP	
1.2	**Data protection**	Yes	
1.2.1	Data owner	BASF	
1.2.2	Companies with letter of access	None	
1.2.3	Criteria for data protection	Data on new [a.s. / b.p.] for [first entry to Annex I/IA / authorisation]	
1.3	**Guideline study**	In house kill test	
1.4	**Deviations**	Not applicable	
		2 METHOD	
2.1	**Test Substance (Biocidal Product)**	[redacted] (Glutaraldehyde) [redacted] aqueous Glutaraldehyde active substance	
2.1.1	Trade name/ proposed trade name	[redacted]	
2.1.2	Composition of Product tested	[redacted] solutions of glutaraldehyde active substance ([redacted]) in instant ocean water ([redacted]) for the aerobic bacterial strains. [redacted] solutions of glutaraldehyde active substance ([redacted]) in ¼ Ringer's solution for the mixed anaerobic bacterial inoculum.	x
2.1.3	Physical state and nature	Solution	
2.1.4	Monitoring of active substance concentration	No	
2.1.5	Method of analysis	Quantitative Suspension Test. Contact times were: [redacted]	
2.2	**Reference substance**	No	

Section B5.10 **Efficacy Data**
Annex Point IIB5.10
TNsG: Pt. I-B5.10, Pt. III-Ch. 6

2.2.1	Method of analysis for reference substance	Not tested	
2.3	**Testing procedure**		
2.3.1	Test population / inoculum / test organism	Aerobic; 24 hr, 2nd passage cultures of [redacted] in test concentrations of approximately 1.0 x 10^5 cfu/ml. Anaerobic; a mixed inoculum of14 day old, 2nd passage of the following [redacted] in a test concentration of the mixture of approximately 1.0 x 10^5 cfu/ml.	
2.3.2	Test system	Aerobic: [redacted] x [redacted]) using instant ocean water ([redacted]). 9 ml aliquots of these dilutions were challenged separately using 24 hr, 2nd passage cultures of [redacted] to give in test concentrations of approximately 1.0 x 10^5 cfu/ml. The surviving numbers of organisms were determined after 0, 0.5, 1, 3 and 6 hours contact by Total Viable Count. A serial dilution series of the sample was made in ¼ Ringers. 1ml volumes of these dilutions were plated into Tryptone Soya Agar (TSA) to enumerate aerobic bacteria. The plates were incubated at (30±2)°C for at least 5 days. Anaerobic: [redacted] solutions of glutaraldehyde active substance ([redacted]) using ¼ Ringer's solution and 19 ml aliquots were challenged with a mixed inoculum of 14 day old, 2nd passage of [redacted] strains to give in test concentrations of approximately 1.0 x 10^5 cfu/ml (see above for strain details). The surviving numbers of organisms were determined after 0.5, 1 and 2 hours by Total Viable Counts. A serial dilution series of the sample was made in ¼ Ringers. 2ml volumes of these dilutions were dispensed into 18 ml Postgates Medium for Marine Sulphate Reducers to enumerate surviving sulphate reducing bacteria. 10 µl of the sample was also streaked onto an Iron Sulphite Agar (ISA) plate. The plates and broths were incubated anaerobically at (30 ± 2)°C for at least 21 days.	
2.3.3	Application of TS	See test system section above.	
2.3.4	Test conditions	The test was conducted at room temperature.	x
2.3.5	Duration of the	Contact times were:	

	test / Exposure time	[redacted]	
2.3.6	Number of replicates performed	The methods used in this study were internally developed methods and were carried out at least in duplicate. The results shown are means of those results.	
2.3.7	Controls	0ppm glutaraldehyde	
2.4	**Examination**		
2.4.1	Effect investigated	Kill	
2.4.2	Method for recording / scoring of the effect	By comparing the decrease in cell numbers over time achieved by the various concentrations of the test substance against those achieved in the absence of the test substance.	
2.4.3	Intervals of examination	[redacted]	x
2.4.4	Statistics	None	
2.4.5	Post monitoring of the test organism	None	
		3 RESULTS	
3.1	**Efficacy**	The challenge organisms were chosen because they are common spoilage organisms associated with environments such as production fluids, hydrostatic test fluids and water associated with oil and gas production and transport. Against [redacted]	x
3.1.1	Dose/Efficacy curve	Efficiency was shown to depend [redacted]	
3.1.2	Begin and duration of effects	[redacted]	

Section B5.10 **Efficacy Data**
Annex Point IIB5.10
TNsG: Pt. I-B5.10, Pt. III-Ch. 6

3.1.3	Observed effects in the post monitoring phase	There was no post monitoring phase
3.2	**Effects against organisms or objects to be protected**	No adverse effects were observed
3.3	**Other effects**	No other effects were observed
3.4	**Efficacy of the reference substance**	A reference substance was not tested
3.5	**Tabular and/or graphical presentation of the summarised results**	[redacted]
3.6	**Efficacy limiting factors**	There were no limiting factors observed during the test. [redacted] '<10cfu/ml' to be recorded. [redacted]
3.6.1	Occurrences of resistances	There was no evidence or observance of resistance

3.6.2	Other limiting factors	None observed	
		4 RELEVANCE OF THE RESULTS COMPARED TO FIELD CONDITIONS	
4.1	**Reasons for laboratory testing**	To demonstrate the broad spectrum bactericidal activity of Glutaraldehyde at low concentrations and to demonstrate that its activity is not significantly affected by salts found in sea water.	x
4.2	**Intended actual scale of biocide application**	The testing was carried out using intended use dilutions into test conditions recognised as acceptable for the field of use (see 4.1 above).	
4.3	**Relevance compared to field conditions**	The challenge organisms were chosen because they are common spoilage organisms associated with environments such as production fluids, hydrostatic test fluids and water associated with oil and gas production and transport.The use concentrations and contact time [redacted]) were chosen as typical and representative of field conditions.	
4.3.1	Application method	In the field, the biocidal product would be applied in a liquid medium, the target organisms would be resuspended and kill would take place in such a medium.	
4.3.2	Test organism	The test organisms were relevant to the field of use.	
4.3.3	Observed effect	The observed effect has been achieved under conditions similar to those expected in the field and therefore it is reasonable to assume that the effect is similar to that which would be observed in the field.	
4.4	**Relevance for read-across**	Yes, activity is relevant to both PT 11 (hydrotesting) and PT 12 (oilfield) applications	
		5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	The test method was developed especially to determine the performance of glutaraldehyde against bacteria relevant to the field of use. The concentrations tested were similar to actual biocidal levels used in the field.	x
5.2	**Reliability**	[redacted].	x
5.3	**Assessment of efficacy, data analysis and interpretation**	The results showed that the active substance, glutaraldehyde, could be used at levels similar to those expected in the field. The results showed that the substance was active against an organism relevant to the field under conditions expected in the field.	
5.4	**Conclusion**	The test concentrations and typical contact times reflect well the conditions expected in the field and therefore in-situ efficacy can be estimated as similar to the efficacy exhibited in the test.	x

5.5	**Proposed efficacy specification**	Glutaraldehyde is added to injection water associated with oil and gas production at concentrations between [redacted] Glutaraldehyde is added directly to the water used in the hydrotesting process. It is used once, at the initial charging of the system. It is used predominantly to inhibit the growth of sulphate reducing bacteria and is used at or above the [redacted]	x

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	July 11, 2012
Materials and methods	2.1.2. Composition of product tested Bactericidal activity was tested under sea water simulating conditions only against aerobic bacteria. [redacted] 2.3.2 Test system In the original study report, no information is provided whether the active substance was properly inactivated after the fixed contact time and enumeration of surviving target organisms after the treatment. If inactivation was neglected, the results of microbiological examinations cannot be considered reliable. In the original study report, Letheen broth is listed among the materials used. However, it should primarily be used for inactivating quaternary ammonium compounds, not compounds as GA. For enumerating of anaerobic bacteria, serial dilutions were made from the test mixture in ¼ Ringer's solution not at all optimal for anaerobic bacteria, in particular, if it was not properly de-aerated/reduced before being used. Whether or not this was carried out was not reported in the original study report. Iron Sulphite Agar used for SRB streaks is not optimal for these organisms. 2.3.4 Test conditions Whether the tests were conducted at RT was not reported in the original study report 2.4.3 Intervals of examination According to description of materials and methods in the original study report, test solutions were examined for surviving target organisms after a contact time of [redacted] Application of GLP was not reported.

Results	3.1. Efficacy The results reported for the efficacy against [redacted]. The text should be changed as follows: [redacted] **4. Relevance of the results** 4.1 Reasons for laboratory testing In the current study, the efficacy of GA against anaerobic bacteria was not demonstrated in a sea water system. However, as GA is predominantly intended to inhibit anaerobic SRB in the field conditions (see study summary, point 5.5), results from a more solid simulation test would be desirable. In the current study, the efficacy of [redacted] against SRB was only assessed in a suspension test conducted in a lab diluent.
Applicant's summary and conclusion	5.1 Materials and methods Brief description of the experimental set-up and methods should be provided here. 5.4 Conclusion Providing evidence could be provided that active substance was appropriately inactivated after the fixed contact time: [redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted] Concentrations, if expressed as %, should be given in terms of mass per volume (m/v) or volume per volume (v/v). Instead of using ppm as the concentration unit, SI units should be preferred.

	COMMENTS FROM ... *(specify)*
Date	*Give date of comments submitted*
Comments	*Discuss if deviating from view of rapporteur member state*
Summary and conclusion	*Discuss if deviating from view of rapporteur member state*

Tables for Method

1.1 (mixed) Population / Inoculum (*if necessary; include separate table for different samples*)

Criteria	Details
Nature	Freeze dried cultures
Origin	[redacted]
Initial biomass	N/A
Reference of methods	European norm method EN 12353 Storage of Test Strains
Collection / storage of samples	Received in post on request.
Preparation of inoculum for exposure	2nd passage cultures were used to prepare the inoculum
Pretreatment	The challenge organisms were subcultured under suitable conditions: Aerobic bacteria – cultured on TSA, at 30°C±2°C for 24 hours. Anaerobic bacteria – cultured in NCIMB Postgates Medium for Marine Sulphate Reducers and incubated anaerobically at 30°C±2°C for 14 days.
Initial density of test population in the test system	Each test system was dosed to achieve an in test microbial concentration of approximately 1.0×10^5 cfu/ml.

1.2 Test organism (*if applicable*)

Criteria	Details
Species	**Aerobic bacteria**
Strain	[redacted] **Anaerobic bacteria** [redacted]
Source	[redacted]
Laboratory culture	Yes
Stage of life cycle and stage of stadia	N/A

Mixed age population	N/A
Other specification	For the anaerobic mixed inoculum, approximately equal quantities of each culture were used
Number of organisms tested	Approximately 1.0×10^5 cfu/ml
Method of cultivation	The challenge organisms were sub cultured under suitable conditions:
Pretreatment of test organisms before exposure	Aerobic bacteria – cultured on TSA, at 30°C±2°C for 24 hours. Anaerobic bacteria – cultured in NCIMB Postgates Medium for Marine Sulphate Reducers and incubated anaerobically at 30°C±2°C for 14 days.
Initial density/number of test organisms in the test system	[redacted]

1.3 Test system

Criteria	Details
Culturing apparatus / test chamber	Test organisms/test substance suspended in fluid media at the temperature specified in the method. Recovery incubation was at 30C for at least 5 days (no additional humidity) in dry air incubators for aerobes and 30C for at least 21 days in dry anaerobic conditions for anaerobes.
Number of vessels / concentration	The tests were carried out at least in duplicate. The results shown are means of those results. [redacted] were tested in each case.
Test culture media and/or carrier material	Test material: instant ocean water (Hawaiian sea) for aerobes and ¼ Ringers for anaerobes Diluent: ¼ Ringers Culture media: Petri dishes (90 ml triple vented) containing approximately 19ml Tryptone Soya Agar for aerobes. Petri dishes (90 ml triple vented) containing approximately 19ml Iron Sulphite Agar for streaks and broths were NCIMB Postgate's Medium for Marine Sulphate Reducers for the anaerobes.
Nutrient supply	Not applicable, batch culture employed
Measuring equipment	Manual plate reading and assessing broth growth

1.4 Application of test substance

Criteria	Details
Application procedure	Test substance applied as an aqueous solution
Delivery method	Not reported
Dosage rate	Non variable discreet tests. [redacted]
Carrier	Ringers solution (oxoid)
Concentration of liquid carrier	¼ strength
Liquid carrier control	Not reported
Other procedures	None reported

1.5 Test conditions

Criteria	Details
Substrate	Artificial ocean water (Instant ocean water, [redacted]) for aerobes and ¼ Ringers for anaerobes
Incubation temperature	Room temperature
Moisture	Not reported
Aeration	None reported, although vented petri dishes were used for aerobes and anaerobic conditions were reported for the anaerobic bacteria.
Method of exposure	individual subsamples
Aging of samples	None
Other conditions	Anaerobic conditions where required.

Section A5 Annex Point IIA,V.	Effectiveness against target organisms and intended uses General Part C submission for PT 2, 3, 4, and 6	
Subsection (Annex Point)		**Official use only**
5.1 Function (IIA5.1)	Active substance that is a key component in products used in Disinfection. Product and process preservative, used to control the growth of spoilage and potentially pathogenic microorganisms during the shelf life of the products and during the industrial processes. Glutaraldehyde is being supported in phase three for product types 2, 3, 4 and 6. The first 3 pages cover general aspects of the efficacy of Glutaraldehyde and then the same template is used to cover the 14 specific use scenarios for the phase 3 submission. Only those sections are completed where information is additional to, or, different from this general section. A separate dossier will be submitted for product types 11 and 12 in phase 4.	
5.2 Organism(s) to be controlled and products, organisms or objects to be protected		
5.2.1 Organism(s) to be controlled (IIA5.2)	Glutaraldehyde effectively controls the growth of bacteria, bacterial spores, fungi (yeast and mould) and viruses. For preservation, typical water borne contaminants are Gram-negative aerobic rods such as [redacted] Other problematic Gram-negative, facultative bacteria such as [redacted] are typically introduced from poor operator practice and poor plant hygiene. Gram positive cocci such as [redacted] can also be conferred to the product via handling (these are normally associated with the skin) and spores of Gram positive organisms such as [redacted] can contaminate the product via dust and dry manufacturing materials. Typical fungal spoilage contaminants are [redacted] For disinfection purposes, typical target organisms include the organisms listed above and, additionally, [redacted]a. For the disinfection of cooling towers the specific target organism is [redacted]	
5.2.2 Products, organisms or objects to be protected (IIA5.2)	For the disinfection of industrial and institutional premises (floors, walls and infrastructure), machinery (including farm machinery), medical instruments, kitchen surfaces, sanitary ware, chemical toilet waste (though incorporation in the toilet fluid), air conditioning systems (though incorporation in the cooling water) and laundry. For the disinfection of areas in which animals are housed, kept and transported and the utensils, pipes and surfaces contained within such areas as well as transport vehicles, machinery and footwear, including dipping troughs. For the disinfection of working areas surfaces such as floors, walls, conveyer lines as well as food contact surfaces such as preparation areas, display areas, production surfaces such as pipelines, mixing vessels and storage tanks including food preparation and consumption areas such as catering facilities and dining area surfaces For preservation during the manufacture, distribution, storage and use of industrial, consumer, household and institutional products.	
5.3 Effects on target organisms, and likely concentration at which the active substance will be used		

Section A5 Annex Point IIA,V.	Effectiveness against target organisms and intended uses General Part C submission for PT 2, 3, 4, and 6	
5.3.1 Effects on target organisms (IIA5.3)	Glutaraldehyde will control the growth of microorganisms by killing actively growing cells. Where cells are not actively growing (e.g. spores) they will be killed provided that there is exposure to sufficient concentration for a suitable time period	
5.3.2 Likely concentrations at which the A.S. will be used (IIA5.3)	Preservation requires lower concentrations and exposure times than disinfection. Glutaraldehyde should be dosed above the recorded MIC [redacted] in products to be preserved under product type 6. See References: BPD ID A5.3.1_01; BPD ID A5.3.1_17	
	For medical instrument disinfection Glutaraldehyde should be dosed at between [redacted] See Reference: BPD ID A5.3.1_02 to BPD ID A5.3.1_10; BPD ID A5.3.1_13; BPD ID A5.3.1_20	x
	For institutional hard surface disinfectant applications (e.g. floors and counter tops), veterinary machinery, means of transport, footwear etc. Glutaraldehyde should be dosed at between [redacted] (ppm). See References: BPD ID A5.3.1_09; BPD ID A5.3.1_10; BPD ID A5.3.1_12; BPD ID A5.3.1_21	x
	For the disinfection of animal houses and other associated farm buildings Glutaraldehyde should be dosed at between [redacted], either alone or, more commonly in the presence of another active substance. See References: BPD ID A5.3.1_11; BPD ID A5.3.1_18	x
	For the disinfection of air-conditioning systems (though incorporation in the cooling water), in particular the control of *Legionellae*, Glutaraldehyde should be dosed [redacted] See References: BPD ID A5.3.1_14. BPD ID A5.3.1_15	?
	In Chemical Toilets, for odour control, where cidal activity is unnecessary, use concentrations at or above typical bacterial MIC value, once in-use dilution has been accounted for. An example target final application rate of [redacted] Glutaraldehyde in the toilet should suffice. In Chemical Toilets, where public health requirements demand a cidal effect, a final concentration of [redacted] in the toilet, once in-use dilution has been accounted for, is required. See Reference: BPD ID A5.3.1_19	
5.4 Mode of action (including time delay) (IIA5.4)		
5.4.1 Mode of action	Glutaraldehyde – protein interactions indicate an effect of the dialdehyde on the bacterial cell surface leading to a sealing of the outer layer. This activity is supplemented by cell enzyme inactivation. Inhibition of the germination, spore swelling, mycelial growth and sporulation in fungal species has been demonstrated. It has been suggested that antiviral activity is by "fixing" the particles	

Section A5 Annex Point IIA,V.	Effectiveness against target organisms and intended uses General Part C submission for PT 2, 3, 4, and 6	
	in a similar manner to that of the bacterial surface. Re-arrangement of RNA has also been cited as a mechanism for antiviral activity. See References: BPD ID A5.4.1_01; BPD ID A5.4.1_02	
5.4.2 Time delay	Glutaraldehyde exhibits a rapid rate of kill against a wide range of microorganisms ranging from less than [redacted] See Reference: BPD ID A.5.3.1_02	
5.5 Field of use envisaged (IIA5.5)	Product Types 2, 3, 4 and 6 in Part C	
5.6 User (IIA5.6)		
Industrial	Glutaraldehyde is used in the manufacture of disinfectant products and to preserve consumer and industrial products	
Professional	Glutaraldehyde may be used in specific scenarios directly by professional users, such as the offshore oil industry and in disinfection applications.	
General public	Glutaraldehyde is not used directly by the general public. The general public will use biocidal products containing the active substance and products preserved with Glutaraldehyde.	
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	There is a suggestion of increased tolerance to Glutaraldehyde of strains of *Mycobacterium chelonei*. See Reference: BPD ID A5.7.1_01. This intrinsic organism tolerance has not been reported for other species. See Reference: BPD ID A5.7.1_02; BPD ID A5.7.1_03; BPD ID A5.7.1_04; BPD ID A5.3.1_13	
5.7.2 Management strategies	To prevent development of resistant bacteria it is common to dose products or systems with more than one biocide at once or to alternate treatment regimes.	
5.8 Likely tonnage to be placed on the market per year (IIA5.8)	Please see confidential Doc V	

Section 5.3: Summary table of experimental data on the effectiveness of the active substance against target organisms at different fields of use envisaged, where applicable

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference
Bacteristat	General	Glutaraldehyde	[redacted]	Internal Methodology EVD/MM/MS/009.SEP	The bacteria were inoculated using a Denley Automatic Multipoint Inoculator in duplicate onto Minerals Modified Medium (MMM+) plates containing the test compound. Incubated (in contact with the test compound) at 32°C±1°C for at least 3 d The MIC was recorded as the minimum concentration of test compound to inhibit growth.	[redacted]	BPD ID A5.3.1_01 Supportive information - no study summary available

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference
						[redacted]	
Bacteristat	General	Glutaraldehyde	[redacted]	Internal Methodology EVD/MM/MS/009.SEP	The bacteria were inoculated using a Denley Automatic Multipoint Inoculator in duplicate onto Legionella BCYE Agar plates. Incubated (in contact with the test compound) at 37°C±1°C for 7 d The MIC was recorded as the minimum concentration of test compound to inhibit growth.	[redacted]	BPD ID A5.3.1_01 Supportive information - no study summary available

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference
Bacteristat	General	Glutaraldehyde	[redacted]	Internal Methodology EVD/MM/MS/009.SEP	The test compound was incorporated into 19ml Postgate's medium into which test organism was inoculated and incubated anaerobically at 32°C±1°C for at least 14 d. The MIC was recorded as the minimum concentration of test compound to inhibit growth.	[redacted]	BPD ID A5.3.1_01 Supportive information - no study summary available
Bacteristat	General	Glutaraldehyde	[redacted]	Internal Methodology EVD/MM/MS/009.SEP	The bacteria were inoculated using a Denley Automatic Multipoint Inoculator in duplicate TBA plates. Incubated (in contact with the test compound) at 30°C±1°C for at least 3 d The MIC was recorded as the minimum concentration of test compound to inhibit growth.	[redacted]	BPD ID A5.3.1_01 Supportive information - no study summary available

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference
Fungistat	General	Glutaraldehyde	[redacted]	Internal Methodology EVD/MM/MS/009.SEP	The fungi were inoculated using a Denley Automatic Multipoint Inoculator in duplicate onto Czapek Dox Agar. Incubated (in contact with the test compound) at 25°C±1°C for at least 5 d The MIC was recorded as the minimum concentration of test compound to inhibit growth.	[redacted]	BPD ID A5.3.1_01 Supportive information - no study summary available
Bactericide	PT2	Glutaraldehyde	[redacted]	EN 1276	Test Temperature: 20°C Contact Time: [redacted] requirement: 5 log reduction Clean conditions: 0.3 g/l Bovine albumin (BA) Dirty conditions: 3.0 g/l BA	[redacted]	BPD ID A5.3.1_12 Key study

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference
Fungicide	PT2	Glutaraldehyde	[redacted]	EN 1650 Modified (*Aspergillus* only)	Test Temperature: 20°C Contact Times: [redacted] min Requirement: 4 log reduction Clean conditions: 0.3 g/l BA Dirty conditions: 3.0 g/lBA	[redacted]	BPD ID A5.3.1_21 Key study
Fungicide	PT2	Glutaraldehyde	[redacted]	EN 1275	Test Temperature: 20°C Contact Time: [redacted] Requirement: 4 log reduction	[redacted]	BPD ID A5.3.1_16 Supportive information - no study summary available

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test conditions	[redacted]	Reference
Fungicide	PT2	Glutaraldehyde	[redacted]	EN 1275	Test Temperature: 20°C Contact Time: [redacted] min Requirement: 4 log reduction	[redacted]	BPD ID A5.3.1_21 Key study
Bactericide	PT3	Glutaraldehyde	[redacted]	EN 1656	Test Temperature: 10°C Contact Time: [redacted] requirement: 5 log reduction Clean conditions: 3 g/l BA Dirty conditions: 10 g/l BA plus 10% Yeast Extract	[redacted]	BPD ID A5.3.1_11 Key study

Fungicide	PT3	Glutaraldehyde	[redacted]	EN 1657	Test Temperature: 10°C Contact Time: [redacted] requirement: 4 log reduction Clean conditions: 3% BA Dirty conditions: 10% BA plus 10% Yeast Extract	[redacted]	BPD ID A5.3.1_11 Key study
Sporicide	PT2	Glutaraldehyde	[redacted]	prEN216003	Basic suspension test at 25°C	[redacted]	BPD ID A5.3.1_20 Key study
Sporicide	PT2.1.1	Glutaraldehyde	[redacted]	prEN216003	Basic suspension test at 25°C EN 13704: 20°C, contact time [redacted]	[redacted]	BPD ID A5.3.1_10 Supportive information - no study summary available

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference
Sporicide	PT2.1.1	Glutaraldehyde	[redacted]	Modified prEN216003	Basic suspension test at 20°C	[redacted]	BPD ID A5.3.1_09 Supportive information - no study summary available
Sporicide	PT2.1.1	Glutaraldehyde	[redacted]	Modified prEN 13704	Sporicidal efficacy test Test temperature: 20°C±2°C Anaerobic incubation @37°C±2°C Contact Times [redacted]	[redacted]	BPD ID A5.3.1_08 [redacted] Supportive information - no study summary available

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference
Bactericide	PT2.1.1	Glutaraldehyde	[redacted]	Modified EN 1040	Modified Basic suspension to include media (Middlebrookes) suitable for the growth of Mycobacteria. Modified to include "dirty" conditions by adding 0.3 g/l bovine albumin. Contact times of [redacted]	[redacted]	BPD ID A5.3.1_13 Key study

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference
Antimicrobial	PT2.4	Glutaraldehyde	*Escherichia coli* NCTC 8196	BS 2893: 1989 Chemical preparations for portable and transportable chemical closets.	[redacted]	[redacted]	BPD ID A5.3.1_19 Supportive information - no study summary available
Antibacterial	PT3	Glutaraldehyde and [redacted]	[redacted]	Modified EN 1656 Standard soilent level of 3 g /litre Bovine Albumin (clean veterinary conditions) Additionally efficacy against *E. coli* was tested using a high organic loading of BA + Yeast Extract (dirty veterinary conditions) Additionally The method was modified by using a 4°C test temperature and a [redacted] contact time to demonstrate the effects of low temperature on the system	Product description: A combination concentrate containing [redacted]	[redacted]	BPD ID A5.3.1_18 Supportive information - no study summary available

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference
Antifungal	PT3	Glutaraldehyde and [redacted]	[redacted]	EN 1657 Standard soilent level of 3 g/ litre Bovine Albumin Additionally The method was modified by using a 4°C test temperature and a [redacted] time to demonstrate the effects of low temperature on the system	Product description: A combination concentrate containing [redacted]	[redacted]	BPD ID A5.3.1_18 Supportive information - no study summary available

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference
Sporicide	PT2.1.1	Glutaraldehyde	[redacted]	AOAC Sporicidal Efficacy Test	Range of pH (5,7,9) Range of exposure ([redacted] aqueous soln	[redacted]	BPD ID A5.3.1_02 BPD ID A5.3.1_03 Key study
Sporicide	PT2.1.1	Glutaraldehyde	[redacted]	Modified AOAC Sporicidal test Test was modified to explore the parameters affecting spore tolerance.	[redacted]% aqueous, alkaline solution	[redacted]	BPD ID A5.3.1_04 Supportive information - no study summary available
Sporicide	PT2.1.1	Glutaraldehyde	[redacted]	AOAC sporicidal Efficacy test 1975	[redacted] aqueous glutaraldehyde solution. (Efficacy [redacted]	[redacted]	BPD ID A5.3.1_05 Supportive information - no study summary available

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference
						[redacted]	
Bactericide	PT2.1.1	Glutaraldehyde	[redacted]	Ortenzio & Stuart Bactericidal Efficacy Test (Carrier method)	[redacted]% aqueous, alkaline solution	[redacted]	BPD ID A5.3.1_02 BPD ID A5.3.1_03 Key study
Bactericide	PT2.1.1	Glutaraldehyde	[redacted]	Orsi Method	[redacted]% aqueous, alkaline solution	[redacted]	BPD ID A5.3.1_06 Supportive information - no study summary available
Bactericide	PT2.1.1	Glutaraldehyde	[redacted]	Bactericidal efficacy test. Presence and absence of organic matter	[redacted]% aqueous, solution	[redacted]	BPD ID A5.3.1_07 Supportive information - no study summary available
Bactericide	General 5.2.1	Glutaraldehyde	[redacted]	Aqueous Efficacy Test	[redacted]) aqueous Glutaraldehyde solution	[redacted]	BPD ID A5.3.1_14 Key study
Bactericide	General 5.2.1	Glutaraldehyde	[redacted]	ASTM 645-91 Aqueous Efficacy Test	[redacted] Glutaraldehyde [redacted] Glutaraldehyde	[redacted]	BPD ID A5.3.1_15 Supportive information - no study summary available
Virucide	PT2.1.1	Glutaraldehyde	[redacted]	Virucidal Efficacy	[redacted]% aqueous,	[redacted]	BPD ID A5.3.1_02

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference
			[redacted]	Test	alkaline solution	[redacted]	BPD ID A5.3.1_03 Key study
Mycobactericide	PT2.1.1	Glutaraldehyde	[redacted]	Mycobactericidal efficacy Test	[redacted]% aqueous, alkaline solution	[redacted]	BPD ID A5.3.1_02 BPD ID A5.3.1_03 Supportive information - no study summary available
Fungicide	PT2.1.1	Glutaraldehyde	[redacted]	Fungicidal Efficacy Test	[redacted]% aqueous, alkaline solution	[redacted]	BPD ID A5.3.1_02 BPD ID A5.3.1_03 Key study
Fungicide	PT6	Glutaraldehyde	[redacted]	Preservative Efficacy Test Modified American Petroleum Institute (API) RP88	Oilfield Products – Workover fluids and Drilling Muds Aerobic conditions @25°C±2°C Contact Time [redacted]	[redacted]	BPD ID A5.3.1_17 Key study

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference
					[redacted] Glutaraldehyde		
Mode of Action	General 5.4.1	Glutaraldehyde	[redacted]	Chemical uptake study Cell desorption study Metabolic process effect study	[redacted] aqueous solution both unbuffered (pH6.0) and buffered (pH7.9)	[redacted]	BPD ID A5.4.1_01 Supportive information - no study summary available
Mode of Action	General 5.4.1	Glutaraldehyde	[redacted]	Cell wall cross-linking study	[redacted] Glutaraldehyde (pH7.0)	[redacted]	BPD ID A5.4.1_02 Supportive information - no study summary available
Development of resistance	General 5.7.1	Glutaraldehyde	[redacted]	Study to determine the effect of washing, flushing and chemically disinfecting flexible endoscopes	[redacted]	[redacted]	BPD ID A5.7.1_02 Supportive information - no study summary available
Development of resistance	General 5.7.1	Glutaraldehyde	[redacted]	Bacterial counts following both washing and washing and disinfecting processes	[redacted]	[redacted]	BPD ID A5.7.1_03 Supportive information - no study summary available
Development of resistance	General 5.7.1	Glutaraldehyde	[redacted]	[redacted]	[redacted]% aqueous, alkaline solution	[redacted]	BPD ID A5.7.1_01 Supportive information - no

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference
			[redacted]	[redacted]		[redacted]	study summary available
Development of resistance	General 5.7.1	Glutaraldehyde	[redacted]	Organisms isolated from hatcheries and exposed to levels of glutaraldehyde that were above, below and similar to the manufacturers recommended levels. Survivors were identified and enumerated	Organisms exposed [redacted] glutaraldehyde solution. Contact time was [redacted]	[redacted]	BPD ID A5.7.1_04 Supportive information - no study summary available

Section A5 Annex Point IIA,V. Disinfection	**Effectiveness against target organisms and intended uses** **PT 2 Private and Public Health Areas - Overview**	
Subsection (Annex Point)		**Official use only**
5.1 Function (IIA5.1)	Active substance conferring disinfectant activity in products used in the following fields: 2.1 Medical, Man, Industry 2.1.1 Medical Equipment 2.1.2 Accommodation and Industrial Areas 2.3 Air Conditioning 2.4 Chemical toilet additive to reduce odour	
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)	Gram +ve Bacteria, Gram –ve Bacteria, Fungi, Bacterial Spores Mycobacteria and Viruses. See general section 5.2.1	
5.2.2 Products, organisms or objects to be protected (IIA5.2)	Industrial and institutional premises (floors, walls and infrastructure), machinery (including farm machinery), kitchen and bathoom surfaces, chemical toilet waste (though incorporation in the toilet fluid) and air conditioning systems (though incorporation in the cooling water). Medical equipment such as used in hospitals, dental surgeries and consulting rooms. In this field the major use is for endoscope disinfection which falls under the medical devices directive and is therefore out of scope of the BPD. However, certain non-invasive heat sensitive instruments that are not classed as medical devices are subjected to disinfection with glutaraldehyde.	
5.3 Effects on target organisms, and likely concentration at which the active substance will be used		
5.3.1 Effects on target organisms (IIA5.3)	Glutaraldehyde will control the growth of microorganisms by killing actively growing cells. Where cells are not actively growing (e.g. spores) they will be killed provided that there is exposure to sufficient concentration for a suitable time period.	
5.3.2 Likely concentrations at which the A.S. will be used (IIA5.3)	For Product Type 2 purposes Glutaraldehyde will be used at concentrations between [redacted] This will differ depending on the application and further detail can be found in the relevant sub-section of the Product Type. See General Section A5.3.2 "For medical instrument disinfection"	x
5.4 Mode of action (including time delay) (IIA5.4)		
5.4.1 Mode of action	See general section	
5.4.2 Time delay	For Product Type 2 purposes Glutaraldehyde will be used for contact times between [redacted]. This will differ depending on the application and further detail can be found in the relevant sub-section of the Product Type.	
5.5 Field of use envisaged (IIA5.5)	PT 2	
5.6 User (IIA5.6)		
Industrial	Industrial users manufacture the disinfectant product use the active substance, Glutaraldehyde.	
Professional	Professional users can apply the disinfectants.	
General public	The active substance, Glutaraldehyde, is not used directly by the general public.	

Section A5 **Annex Point IIA,V.** **Disinfection**	**Effectiveness against target organisms and intended uses** **PT 2 Private and Public Health Areas - Overview**	
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	See general section.	
5.7.2 Management strategies	To prevent development of resistant bacteria it is common to dose products or systems with more than one biocide at once.	
5.8 Likely tonnage to be placed on the market per year (IIA5.8)	Please see confidential Doc V	

Section A5 Annex point IIA,V. Disinfection	Effectiveness against target organisms and intended uses PT2 Private and Public Health Areas PT2.1 Medical, Man, Industry 2.1.1. Medical equipment	Official use only
Subsection (Annex Point)		
5.1 Function (IIA5.1)	To disinfect medical equipment	
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)	Gram +ve bacteria, Gram-ve bacteria, Bacterial spores, Mycobacteria, viruses. See initial section.	
5.2.2 Products, organisms or objects to be protected (IIA5.2)	General medical equipment such as used in hospitals, dental surgeries and consulting rooms, excluding medical devices.	
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)	Target organisms are [redacted]. Intent is to kill the target organisms and spores.	
5.3.2 Likely concentrations at which the A.S. will be used (IIA5.3)	[redacted]	x
5.4 Mode of action (including time delay) (IIA5.4)		
5.4.1 Mode of action	See initial section	
5.4.2 Time delay	[redacted]	
5.5 Field of use envisaged (IIA5.5)	PT2.1.1	
5.6 User IIA5.6)		
Industrial	The active substance is used to manufacture the disinfectant product.	
Professional	The disinfectants can be applied by professional users.	
General public	None	
5.7 Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies (A5.7)		
5.7.1 Development of resistance	See general section	
5.7.2 Management strategies	See general section	
5.8 Likely tonnage to be placed on market per year (IIA5.8)	See confidential document V	

Section A5 **Annex point IIA,V.** **Disinfection**	**Effectiveness against target organisms and intended uses** **PT2 Private and Public Health Areas** **PT2.1 Medical, Man, Industry** **2.1.2 Accommodation and industrial areas**	
Subsection (Annex Point)		**Official use only**
5.1 Function (IIA5.1)	To disinfect floors, walls and other surfaces in institutional both in domestic premises and public and industrial areas	
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)	Gram +ve and Gram –ve Bacteria, Fungi and Viruses	
5.2.2 Products, organisms or objects to be protected IIA5.2)	Floors, walls, machinery (such as filling lines), utensils and other surfaces.	
5.3 Effects on target organisms, and concentration at which the active substance will be used (IIA5.3)		
5.3.1 Effects on target organisms IIA5.3)	Intent is to kill the target organisms in 5.2.1 above.	
5.3.2 Likely concentrations at which the A.S. will be used IIA5.3)	The likely concentration of Glutaraldehyde at which kill is achieved, [redacted]	x
5.4 Mode of action (including time delay) (IIA5.4)		
5.4.1 Mode of action	See initial section	
5.4.2 Time delay	Kill is effected within [redacted]	
5.5 Field of use envisaged (IIA5.5)	PT 2.1.2 – Medical, Man, Industry 2.1.2 Accommodation, Man	
5.6 User (IIA5.6)		
Industrial	Yes to manufacture the disinfectant product.	
Professional	The disinfectant can be applied by professional users.	
General public	No direct use of [redacted] public but there is use of biocidal products containing Glutaraldehyde.	
5.7 Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies IA5.7)		
5.7.1 Development of resistance	See general section.	
5.7.2 Management strategies	See general section.	
5.8 Likely tonnage to be placed on the market per year (IIA5.8)	See confidential document V	

Section A5 **Annex Point IIA,V.** **Disinfection**	**Effectiveness against target organisms and intended uses** **PT 2 Private and Public Health Areas** **2.3 Air Conditioning**	
Subsection (Annex Point)		**Official use only**
5.1 Function (IIA5.1)	Control of bacterial contamination in air conditioning units	
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: The main target organism from a public health standpoint is [redacted]	
5.2.2 Products, organisms or objects to be protected (IIA5.2)	To decontaminate or disinfect air conditioning units. Small personal air conditioning units are generally directly air-cooled and therefore require no treatment. Larger size units employ a recirculating closed water-cooling system, which may or may not be fed from an expansion tank of stored water.	
5.3 Effects on target organisms, and likely concentration at which the active substance will be used		
5.3.1 Effects on target organisms (IIA5.3)	See general section A5.3.1, and studies BPD ID A5.3.1_14. BPD ID A5.3.1_15	
5.3.2 Likely concentrations at which the A.S. will be used (IIA5.3)	See efficacy study BPD ID A5.3.1_01 (general section) for MIC data applicable to general (slime forming and corrosion implicated) organisms. See also efficacy studies BPD ID A5.3.1_14 and BPD ID A5.3.1_15 which provide information specific to target organisms within the [redacted]	
5.4 Mode of action (including time delay) (IIA5.4)		
5.4.1 Mode of action	See general section A5.4.1	
5.4.2 Time delay	See general section A5.4.2 and efficacy studies BPD ID A5.3.1_14; BPD ID A5.3.1_15 for speed of kill information against organisms within the family [redacted]	
5.5 Field of use envisaged (IIA5.5)	PT 2.3	
5.6 User (IIA5.6)		
Industrial	The active substance Glutaraldehyde is used by industrial users to manufacture their biocidal products for air conditioning units.	
Professional	Water contained within air conditioning units is generally serviced by professional users	
General public	The active substance, Glutaraldehyde, is not used directly by the general public for PT 2.3.	
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	See general section 5.7.1. [redacted] is not a significant organism for this use	
5.7.2 Management strategies	[redacted]	

Section A5 **Annex Point IIA,V.** **Disinfection**	**Effectiveness against target organisms and intended uses** **PT 2 Private and Public Health Areas** **2.3 Air Conditioning**	
	[redacted]	
5.8 Likely tonnage to be placed on the market per year (IIA5.8)	See confidential doc V	

Section A5 Annex Point IIA,V. Disinfection	Effectiveness against target organisms and intended uses PT 2 Private and Public Health Areas 2.4 Chemical Toilets	
Subsection (Annex Point)		**Official use only**
5.1 Function (IIA5.1)	The control of organisms within portable toilet systems	
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 that are significant to human health and / or responsible for product spoilage, slime production, odour formation and corrosion.	
5.2.2 Products, organisms or objects to be protected (IIA5.2)	Water associated with the toilet and excreta (waste) collected and contained within the toilet.	
5.3 Effects on target organisms, and concentration at which the active substance will be used (IIA5.3)		
5.3.1 Effects on target organisms (IIA5.3)	To reduce the microbiological load in order to control the production of odour from microbiological activity	
5.3.2 Likely concentrations at which the A.S. will be used (IIA5.3)	[redacted] See reference: BPD ID A5.3.1_19	x
5.4 Mode of action (including time delay) (IIA5.4)		
5.4.1 Mode of action	See initial section	
5.4.2 Time delay	Minimum contact time of 24 h, system replenishment required after seven days	
5.5 Field of use envisaged (IIA5.5)	PT 2 Private and Public Health Areas PT 2.4 Chemical Toilets	
5.6 User (IIA5.6)		
Industrial	Yes to manufacture the disinfectant product.	
Professional	The disinfectants can be applied by professional users.	
General public	The active substance is not used but there is use of biocidal products containing Glutaraldehyde.	
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	See general section	

Section A5 **Annex Point IIA,V.** **Disinfection**	**Effectiveness against target organisms and intended uses** **PT 2 Private and Public Health Areas** **2.4 Chemical Toilets**	
5.7.2 Management strategies	[redacted]. This intrinsic organism tolerance has not been reported for other species and unlikely to be of relevance in Chemical Toilets.	
5.8 Likely tonnage to be placed on the market per year (IIA5.8)	See confidential doc V	

Section A5 Annex Point IIA,V. Disinfection	Effectiveness against target organisms and intended uses PT3 Veterinary Hygiene -	
Subsection (Annex Point)		**Official use only**
5.1 Function (IIA5.1)	Active substance conferring disinfectant activity in products used in the following fields: 3.1 Animal housing including hatcheries and stables. 3.2 Means of transport, footwear and machinery	
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)	Gram +ve and Gram –ve bacteria, fungi, bacterial spores Mycobacteria and viruses	
5.2.2 Products, organisms or objects to be protected (IIA5.2)	Areas in which animals are housed, kept and transported and the utensils, pipes and surfaces contained within such areas. To disinfect areas in which animals hatched, including the disinfection of, by wiping or dipping, egg shells for chicken production where high densities occur. Transport vehicles, machinery and footwear, including dipping troughs.	
5.3 Effects on target organisms, and likely concentration of the active substance (IIA5.3)		
5.3.1 Effects on target organisms (IIA5.3)	Glutaraldehyde will control the growth of microorganisms by killing actively growing cells. Where cells are not actively growing (e.g. spores) they will be killed provided that there is exposure to sufficient concentration for a suitable time period. See Reference: BPD ID A5.3.1_11	
5.3.2 Likely concentrations at which the A.S. will be used (IIA5.3)	[redacted]	x
5.4 Mode of action (including time delay) (IIA5.4)		
5.4.1 Mode of action	See Doc IIIA 5 General Section 5.4.1	
5.4.2 Time delay	For Product Type 3 purposes Glutaraldehyde will be used for contact times between [redacted]	
5.5 Field of use envisaged (IIA5.5)	PT 3	
5.6 User(IIA5.6)		
Industrial	The active substance is used to manufacture the disinfectant product.	
Professional	The disinfectants can be applied by professional users.	
General public	No	
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	See general section	
5.7.2 Management strategies	See general section	
5.8 Likely tonnage to be placed on the market per year (IIA5.8)	See confidential document V	

Section A5 Annex Point IIA,V. Disinfection		Effectiveness against target organisms and intended uses PT4 Disinfectants used in Food and Feed Area	
Subsection (Annex Point)			Official use only
5.1	Function (IIA5.1)	Disinfection of floors, walls, equipment in plant, production, preparation and consumption. No direct use on food is intended.	
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)	Gram +ve and Gram –ve bacteria, fungi, bacterial spores Mycobacteria and viruses	
5.2.2	Products, organisms or objects to be protected (IIA5.2)	Working areas surfaces such as floors, walls and conveyer lines. Food contact surfaces such as preparation areas, display areas. Production surfaces such as pipelines. Mixing vessels and storage tanks. Food preparation and consumption areas such as catering facilities and dining area surfaces	
5.3	Effects on target organisms, and concentration at which the active substance will be used (IIA5.3)		
5.3.1	Effects on target organisms (IIA5.3)	See Doc IIIA 5.4.1 General Section	
5.3.2	Likely concentrations at which the A.S. will be used (IIA5.3)	For Product Type 4 purposes Glutaraldehyde will be used at concentrations [redacted] can be found in the relevant sub-section of Doc III B5.3 PT 4	x
5.4	Mode of action (including time delay) (IIA5.4)		
5.4.1	Mode of action	See Doc IIIA 5.4.1 General Section	
5.4.2	Time delay	For Product Type 4 purposes Glutaraldehyde will be used for contact times [redacted]. This will differ depending on the application .and further detail can be found in the relevant sub-section of Doc III B5.8 PT 4	
5.5	Field of use (IIA5.5)	PT 4	
5.6	User (IIA5.6)		
	Industrial	Yes, the active is used to manufacture the disinfectant product.	
	Professional	The disinfectants are applied by professional users.	
	General public	No	
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	See Doc IIIA 5.7.1 General Section	
5.7.2	Management strategies	To prevent development of resistant bacteria it is common to dose products or systems with more than one biocide at once.	
5.8	Likely tonnage to be placed on the market per year (IIA5.8)	See confidential doc V	

Section A5 Annex Point IIA,V.	Effectiveness against target organisms and intended uses Preservation PT6 In-Can Preservatives	
Subsection (Annex Point)		**Official use only**
5.1 Function (IIA5.1)	Product preservative, to control the growth of spoilage and potentially pathogenic microorganisms during the shelf life of the products.	
5.2 Organism(s) to be controlled and products, organisms or objects to be protected		
5.2.1 Organism(s) to be controlled (IIA5.2)	Glutaraldehyde is effective in controlling the growth of both bacteria, and fungi (yeast and mould). See general section.	
5.2.2 Products, organisms or objects to be protected (IIA5.2)	For preservation during the manufacture, distribution, storage and use of industrial, consumer, household and institutional products. Industrial products include materials such as mineral slurries, pigment slurries, drilling muds and packer fluids, emulsion systems such as acrylic, styrene-acrylic, polyvinyl acetate, other latex emulsions, latex emulsion based paints, adhesives, photographic emulsions and antifoam emulsion systems, textile and leather auxiliaries, lignosulphonates and other admix extenders and modifiers, inks and font solutions. Consumer, household and institutional products such as dishwashing liquids, surface cleaners and polishes. Surfactants and raw materials for the manufacture of industrial and consumer products. Without adequate preservation, susceptible products may become heavily contaminated with microorganisms, A significant number of microorganisms are pathogenic (harmful to humans) and if allowed to contaminate and proliferate in formulated products, the product can become a vector for disease and present a risk to the end user. Unchecked microbial growth within products can also negatively affect product performance and / or the physical parameters of the product (detergency properties, viscosity, colour, odour etc.).	
5.3 Effects on target organisms, and likely concentration at which the active substance will be used		
5.3.1 Effects on target organisms (IIA5.3)	Glutaraldehyde will control the growth of microorganisms within the product(s) to be preserved. Glutaraldehyde will first inhibit and eventually kill actively growing cells. Where cells are not actively growing (e.g. spores) they may be killed, or they will remain dormant within the product. See Doc IIIA General Section 5.3.1	
5.3.2 Likely concentrations at which the A.S. will be used (IIA5.3)	Glutaraldehyde should be dosed between [redacted] See Doc IIIA General Section 5.3.2 Tests to prove adequacy of preservation should be undertaken by the developer of the formulated product for every formulation in order to determine the actual dose of Glutaraldehyde required. The product type, pack and pattern of use should all be considered in this determination, the subtleties involved in such an assessment cannot be described as part of a label claim.	x
5.4 Mode of action (including time delay) (IIA5.4)		
5.4.1 Mode of action	See Doc IIIA General Section 5.4.1	
5.4.2 Time delay	See Doc IIIA General Section 5.4.2	
5.5 Field of use	**PT 6**	

Section A5 Annex Point IIA,V.		Effectiveness against target organisms and intended uses Preservation PT6 In-Can Preservatives	
	envisaged (IIA5.5)		
5.6	User (IIA5.6)		
	Industrial	The active substance, Glutaraldehyde, is used by industrial users	
	Professional	The active substance, Glutaraldehyde, is not used directly by professional users.	
	General public	The active substance, Glutaraldehyde, is not used directly by the general public	
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	See initial section	
5.7.2	Management strategies	See initial section	
5.8	Likely tonnage to be placed on the market per year (IIA5.8)	Please see confidential Doc V	

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
General comments	The general comments below summarize the comments of individual key studies. Comments on the individual key studies are provided more in detail in Doc III B.
Date	November 2012
Materials and methods	The efficacy testing methods applied in the ten key studies of dossier IIIA, were mostly based on EN standards (EN 1656, EN 1657, EN 1275, EN 1276, EN 1650, EN 14476) or in-house methods conducted in compliance with the principles of EN or other standards. All key studies were based on suspension test methods conducted with or without interfering organic load. For surface activity RMS asked additional information which was provided by two studies (EN 13697). However, the applicant did not provide study summaries of these studies. RMS has evaluated the studies and included the evaluations in the document. The reference numbers of the surface test studies and virucidal studies provided after this IIIA document was submitted should be added to the document at appropriate points. Inactivation methods applied were stated in most of the studies. The results obtained from the key studies demonstrated bactericidal effectiveness of glutaraldehyde against vegetative bacteria [redacted] spp. and sulphate reducing anaerobic bacteria. In addition, the studies showed evidence of sporicidal and fungicidal activity against both yeasts and moulds. Virucidal activity of the active substance against [redacted] 1was shown in two key studies. In the supportive study reports the broad spectrum activity of glutaraldehyde against a range of target organisms was extensively demonstrated.
Likely concentrations at which the a.s. will be used Point 5.3.2	Glutaraldehyde is suggested as an active ingredient applicable for four product types covering 14 use scenarios. Ideally, the likely use concentrations should be the minimum effective concentration, taking into account all relevant parameters that impact the efficacy. The likely concentrations for different product types and applications given should be justified with reference to individual studies attached to the dossier. The applicant should provide appropriate reference to the likely concentrations. This can be performed at product authorization stage.
Conclusion	Information provided in key studies demonstrate that glutaraldehyde exhibits bactericidal, fungicidal and sporicidal activity in suspension conditions with and without the presence of interfering organic load. Virucidal activity in clean and soiled conditions has also been demonstrated. Additional evidence of microbicidal activity on clean and dirty surfaces (EN 13697) was also provided but because the study summaries are missing they can not be considered as key studies.
Remarks	None

COMMENTS FROM...

Date

Section A5 Annex Point IIA, V.	Effectiveness against target organisms and intended uses General Part D submission for PT 11 and 12	
Subsection (Annex Point)		**Official use only**
5.1 Function (IIA5.1)	Active substance that is a key component in products and industrial processes. Glutaraldehyde has already been submitted for Part C relating to product types 2, 3, 4 and 6. Glutaraldehyde is now being submitted for product types 11 and 12 for Part D. The first section covers general aspects of the efficacy of Glutaraldehyde. The same template is used to include information specific to PT 11 and PT12. Only those sections are completed where information is additional to, or different from this general section.	
5.2 Organism(s) to be controlled and products, organisms or objects to be protected		
5.2.1 Organism(s) to be controlled (IIA5.2)	In general, glutaraldehyde is able to control the organisms responsible for slime, biofilms and biocorrosion conditions found in PT's 11 and 12.	x
	Glutaraldehyde effectively controls the growth of bacteria, bacterial spores, fungi (yeast and mould) and algae. Typical water borne contaminants are Gram-negative aerobic rods such as [redacted] can also be conferred to the product via handling (these are normally associated with the skin) and spores of Gram positive organisms such as [redacted] can contaminate the product via dust and dry manufacturing materials. Typical fungal spoilage contaminants are [redacted]	x
	For hydrotesting applications the specific target organisms are Sulphate Reducing Bacteria.	x

Section A5 Annex Point IIA,V.	Effectiveness against target organisms and intended uses General Part D submission for PT 11 and 12	
5.2.2 Products, organisms or objects to be protected (IIA5.2)	In general, glutaraldehyde is able to control the organisms responsible for slime, biofilms and biocorrosion conditions found in PT's 11 and 12. PT11: Recirculating cooling systems. Cooling towers. Water circuits in heat transfer systems including pasteurisers, retorts and evaporative condensers, humidifying systems. Industrial scrubbing systems and air washers. Reverse osmosis membranes, industrial waste water. Process water, stored non-potable water, service water and auxiliary systems. NB: Air conditioning has been covered under PT 2.5 as part of the phase 3 submission. Use in once through cooling systems is not expected. PT11: Hydrotesting. Glutaraldehyde is used as a water preservative to control microbially induced corrosion to the inner surfaces of transit pipes during hydrostatic pressure testing. PT12.1: Paper making as a process additive for continuous paper production as well as de-inking. PT12.2: For application into injection water during oil and gas production	x
5.3 Effects on target organisms, and likely concentration at which the active substance will be used		x
5.3.1 Effects on target organisms (IIA5.3)	Glutaraldehyde will control the growth of microorganisms by killing actively growing cells. Where cells are not actively growing (e.g. spores) they will be killed provided that there is exposure to sufficient concentration for a suitable time period	
5.3.2 Likely concentrations at which the A.S. will be used (IIA5.3)	In general, Glutaraldehyde is normally added above the recorded MIC's for the particular type of contaminant such as bacteria, fungi, algae and spores. See References: BPD ID A5.3.1_01[1] [redacted] PT 11: For the applications mentioned in A5.2.2 above, the concentration of Glutaraldehyde varies between [redacted] to treat water dosed either intermittently or by shock dose. The higher concentration is used to rapidly lower the microbial population. For the remedial treatment of reverse osmosis membranes the likely concentration is between [redacted] Waste water clean up the likely concentration is between [redacted] For use in hydrotesting applications the likely use [redacted] Continuous dosage is not expected (defined as application of GA, 24 hours a day, 7 days a week). Further information is given below under the section for PT11.	x

Section A5 Annex Point IIA,V.	Effectiveness against target organisms and intended uses General Part D submission for PT 11 and 12	
	NB: For the disinfection of air-conditioning systems (through incorporation in the cooling water), in particular the control of *Legionellae*, Glutaraldehyde should be dosed at [redacted] See References: BPD ID A5.3.1_14 [1], BPD ID A5.3.1_15 [1] PT12: Glutaraldehyde is added to treat the white water circuit either intermittently or by shock dose. Continuous dosage is not expected (defined as application of GA, 24 hours a day, 7 days a week). Further information is given below under the section for PT12. **Papermill slimicide:** **Shock dose:** Add Glutaraldehyde [redacted] microbial control. **Intermittent dose:** Add Glutaraldehyde [redacted] **Deinking:** Glutaraldehyde is added to control bacteria (e.g [redacted]) and the catalase enzymes released, which interfere with the deinking process using hydrogen peroxide. The effect is both microbiological and chemical. The chemical effect is shown in BPD ID 5.3.2_08. Glutaraldehyde dosage amount: [redacted]. **Mineral Oil:** Glutaraldehyde is added to injection water associated with oil and gas production at concentrations between [redacted] See References: BPD ID A5.3.2_09, BPD ID A5.3.2_10	x
5.4 Mode of action (including time delay) (IIA5.4)		
5.4.1 Mode of action	Glutaraldehyde – protein interactions indicate an effect of the dialdehyde on the microbial cell surface leading to a sealing of the outer layer. This activity is supplemented by cell enzyme inactivation. (Inhibition of the germination, spore swelling, mycelial growth and sporulation in fungal species has also been demonstrated.) See References: BPD ID A5.4.1_01 [1]; BPD ID A5.4.1_02 [1]	
5.4.2 Time delay	Glutaraldehyde exhibits a rapid rate of kill against a wide range of microorganisms ranging from less than [redacted] contact time for	

Section A5 Annex Point IIA, V.		Effectiveness against target organisms and intended uses General Part D submission for PT 11 and 12	
		bacteria. The inactivation of bacterial spores can take up [redacted]. See Reference: BPD ID A.5.3.1_02[1]	x
5.5	Field of use envisaged (IIA5.5)	Product Types 11 and 12.	
5.6	User (IIA5.6)		
	Industrial	Glutaraldehyde is used to treat the water circuits of PT11 and PT12 as well as clean up of RO membranes. Used by service companies.	
	Professional	Glutaraldehyde may be used in specific scenarios directly by professional users, such as the offshore oil industry and by service operators.	
	General public	Glutaraldehyde is not used directly by the general public in relation to PT11 and PT12.	
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	There is a suggestion of increased tolerance to Glutaraldehyde of strains of *Mycobacterium chelonei*. See Reference: BPD ID A5.7.1_01[1]. This intrinsic organism tolerance has not been reported for other species. See Reference: BPD ID A5.7.1_02[1]; BPD ID A5.7.1_03[1]; BPD ID A5.7.1_04[1]	x
5.7.2	Management strategies	To prevent development of resistant bacteria it is common to dose products or systems with more than one biocide at once or to employ alternate treatment regimes.	
5.8	Likely tonnage to be placed on the market per year (IIA5.8)	Please see confidential Doc V	

[1] This study was previously submitted in support of Product Types 2, 3, 4 & 6. This data has therefore not been re-submitted but is cross referenced to the Part C dossier, where it can be found in Document IVA.

Section 5.3: Summary table of experimental data on the effectiveness of the active substance against target organisms at different fields of use envisaged, where applicable

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference
Bacteristat	General	Glutaraldehyde	[redacted]	Internal Methodology EVD/MM/MS/009 .SEP	The bacteria were inoculated using a Denley Automatic Multipoint Inoculator in duplicate onto Minerals Modified Medium (MMM+) plates containing the test compound. Incubated (in contact with the test compound) at 32°C±1°C for at [redacted] The MIC was recorded as the minimum concentration of test compound to inhibit growth.	[redacted]	BPD ID A5.3.1_01[1] Supportive information only
Bacteristat	General	Glutaraldehyde	[redacted]	Internal Methodology EVD/MM/MS/009	The bacteria were inoculated using a Denley Automatic Multipoint Inoculator in	[redacted]	BPD ID A5.3.1_01[1]

[1] This study was previously submitted in support of Product Types 2, 3, 4 & 6. This data has therefore not been re-submitted but is cross referenced to the Part C dossier, where it can be found in Document IVA.

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference
			[redacted]	.SEP	duplicate onto Legionella BCYE Agar plates. Incubated (in contact with the test compound) at 37°C±1°C [redacted]. The MIC was recorded as the minimum concentration of test compound to inhibit growth.	[redacted]	Supportive information only
Bacteristat	General Including hydrotest app's.	Glutaraldehyde	[redacted]	Internal Methodology EVD/MM/MS/009 .SEP	The test compound was incorporated into 19ml Postgate's medium into which test organism was inoculated and incubated anaerobically at 32°C±1°C for at least [redacted] The MIC was recorded as the minimum concentration of test compound to inhibit growth.	[redacted]	BPD ID A5.3.1_01[1] Supportive information only
Bacteristat	General	Glutaraldehyde	[redacted]	Internal Methodology EVD/MM/MS/009 .SEP	The bacteria were inoculated using a Denley Automatic Multipoint Inoculator in duplicate TBA plates. Incubated (in contact with the test compound) at	[redacted]	BPD ID A5.3.1_01[1] Supportive information only

[1]This study was previously submitted in support of Product Types 2, 3, 4 & 6. This data has therefore not been re-submitted but is cross referenced to the Part C dossier, where it can be found in Document IVA.

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference
					30°C±1°C for at least [redacted] The MIC was recorded as the minimum concentration of test compound to inhibit growth.		
Bacteristat	Water associated with Mineral Oil Recovery	Glutaraldehyde	[redacted]	In situ monitoring of the effect of biocide addition on both sessile and planktonic bacteria associated with topside water flow lines. Glutaraldehyde (1200ppm /25%solution)was added downstream of the dearator	Weekly monitoring of the planktonic population, before and after a deaerator using MPN technique for SRB and monthly monitoring for GAB. Sessile populations were enumerated by first exposing a bioprobe to the internal flow for a period of three months	[redacted]	BPD ID A5.3.2_09 Supportive information only
Fungistat	General	Glutaraldehyde	[redacted]	Internal Methodology EVD/MM/MS/009 .SEP	The fungi were inoculated using a Denley Automatic Multipoint Inoculator in duplicate onto Czapek Dox Agar. Incubated (in contact with the test compound) at		BPD ID A5.3.1_01[1] Supportive information only

[1] This study was previously submitted in support of Product Types 2, 3, 4 & 6. This data has therefore not been re-submitted but is cross referenced to the Part C dossier, where it can be found in Document IVA.

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference
					25°C±1°C for at least [redacted] The MIC was recorded as the minimum concentration of test compound to inhibit growth.		
Algistatic / Algicidal	General 5.2.1	Glutaraldehyde	[redacted]	Internal Methodology for MIC and MBC Broth MIC, centrifugation and reinoc of negatives into fresh media to determine MBC	[redacted]	[redacted]	BPD ID A5.3.1_01[1]
Bactericide	General 5.2.1	Glutaraldehyde	[redacted]	Aqueous Efficacy Test	[redacted]	[redacted]	BPD ID A5.3.1_14[1] Key study
Bactericide	General 5.2.1	Glutaraldehyde	[redacted]	ASTM 645-91 Aqueous Efficacy Test Speed of kill	[redacted]	[redacted]	BPD ID A5.3.1_15[1] Supportive information only

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference
						[redacted]	
Mode of Action	General 5.4.1	Glutaraldehyde	[redacted]	Chemical uptake study Cell desorption study Metabolic process effect study	[redacted]	[redacted]	BPD ID A5.4.1_01[1] Supportive information only
Mode of Action	General 5.4.1	Glutaraldehyde	[redacted]	Cell wall cross-linking study	[redacted]	[redacted]	BPD ID A5.4.1_02[1] Supportive information only
Development of resistance	General 5.7.1	Glutaraldehyde	[redacted]	Organisms exposed to 2[redacted] Glutaraldehyde for given time durations. Survivors enumerated.	[redacted] aqueous, alkaline solution	[redacted]	BPD ID A5.7.1_01[1] Supportive information only

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference
Development of resistance	General 5.7.1	Glutaraldehyde		Study to determine the effect of washing, flushing and chemically disinfecting flexible endoscopes	% aqueous, solution contact time		BPD ID A5.7.1_02[1] Supportive information only
Development of resistance	General 5.7.1	Glutaraldehyde		Bacterial counts following both washing and washing and disinfecting processes	% aqueous, solution, contact time		BPD ID A5.7.1_03[1] Supportive information only
Development	General	Glutaraldehyde		Organisms isolated	Organisms exposed to		BPD ID A5.7.1_04[1]

[1] This study was previously submitted in support of Product Types 2, 3, 4 & 6. This data has therefore not been re-submitted but is cross referenced to the Part C dossier, where it can be found in Document IVA.

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference
of resistance	5.7.1		[redacted]	from hatcheries and exposed to levels of glutaraldehyde that were above, below and similar to the manufacturers recommended levels. Survivors were identified and enumerated	[redacted]% glutaraldehyde solution. Contact time was [redacted]s. Manufacturers recommendation was [redacted]	[redacted]	Supportive information only

Section A5 **Annex Point IIA,V.**	**Effectiveness against target organisms and intended uses** **PT 11 Preservatives for liquid-cooling and processing systems**	
Subsection (Annex Point)		**Official use only**
5.1 Function (IIA5.1)	Active substance conferring preservation of liquid cooling and processing systems. In general, glutaraldehyde is able to control the organisms responsible for slime, biofilms and biocorrosion conditions found in PT 11.	
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)	Gram +ve Bacteria, Gram –ve Bacteria, Anaerobic bacteria, Bacterial Spores, fungi and algae. See general section 5.2.1	x
5.2.2 Products, organisms or objects to be protected (IIA5.2)	Liquid cooling and processing systems are employed in a wide range of industries. The most common are cooling towers which use water as their cooling medium by circulating it through various temperature cycles. Similarly, many of the processes involving heat transfer also employ water as the cooling medium with the objective of maintaining good heat exchange properties. PT11: Recirculating cooling systems. Cooling towers. Water circuits in heat transfer systems including pasteurisers, retorts and evaporative condensers, humidifying systems. Industrial scrubbing systems and air washers. Reverse osmosis membranes, industrial waste water. Process water, stored non-potable water, service water and auxiliary systems. Hydrotesting of oil and gas pipelines – preservation of the water and protection of the internal pipe surfaces against microbially induced corrosion. Use in once through cooling systems is not expected. NB: Air conditioning has been covered under PT 2.5 as part of the phase 3 submission.	
5.3 Effects on target organisms, and likely concentration at which the active substance will be used		x
5.3.1 Effects on target organisms (IIA5.3)	Glutaraldehyde will control the growth of microorganisms by killing actively growing cells. Where cells are not actively growing (e.g. spores) they will be killed provided that there is exposure to sufficient concentration for a suitable time period.	

5.3.2 Likely concentrations at which the A.S. will be used (IIA5.3)	PT 11 Dose rates rely upon the relationship between the biocide concentration and frequency of addition for microbial control. Glutaraldehyde is normally dosed at or above the recorded MIC for the particular type of contaminant such as bacteria, fungi, algae and spores. See Reference: BPD ID A5.3.1_01[1] Apply either as an intermittent or shock dose will depend on the level of microbial contamination within the system but should not exclude manual cleaning if necessary. Heavily fouled systems can be shock treated by using the highest recommended dose rate. Under these conditions, blowdown (discharge to effluent) should be discontinued for up to 24 hours. **Cooling tower water**: Ref:BPD ID A5.3.2_01 Recirculating cooling towers but not for once through systems. Shock dose: [redacted] **Air washers, industrial scrubbing systems:** Ref:BPD ID A5.3.2_01 Use only in industrial air washer systems, which have mist-eliminating components. Badly fouled systems can be shock treated by using the highest recommended dose rate but this should not exclude manual cleaning if necessary. Shock dose: [redacted] **Water circuits in heat transfer systems**: Ref:BPD ID A5.3.2_01 & BPD ID A5.3.2_02 For water circuits present in evaporative condensers, dairy sweetener systems, hydrostatic sterilizers and retorts, pasteurisers and warmers. Glutaraldehyde should be added to the water circuit at the coolest part of the process. For example, pasteurizer water circuits have a temperature gradient between 25 C to 60 C; hence the biocide is added at 25C. Shock dose: [redacted] **Stored, service and auxiliary water:** BPD ID A5.3.2_03 For water present in systems such as fire water reserves, spray paint booths and emergency cooling water systems. Badly fouled systems can be shock treated by using the highest recommended dose rate but this should not exclude manual cleaning if necessary. Use Glutaraldehyde [redacted]. **Reverse osmosis membranes:** BPD ID A5.3.2_04 Reverse osmosis membranes are used to clean water whether for industrial process applications or to convert brackish water, to clean up wastewater or to recover salts from industrial processes. The water contains nutrients which act as a food source for microbes to proliferate and eventually biofoul the membrane. Use only where approved for compatibility by the membrane	x x x x

[1] This study was previously submitted in support of Product Types 2, 3, 4 & 6. This data has therefore not been re-submitted but is cross referenced to the Part C dossier, where it can be found in Document IVA

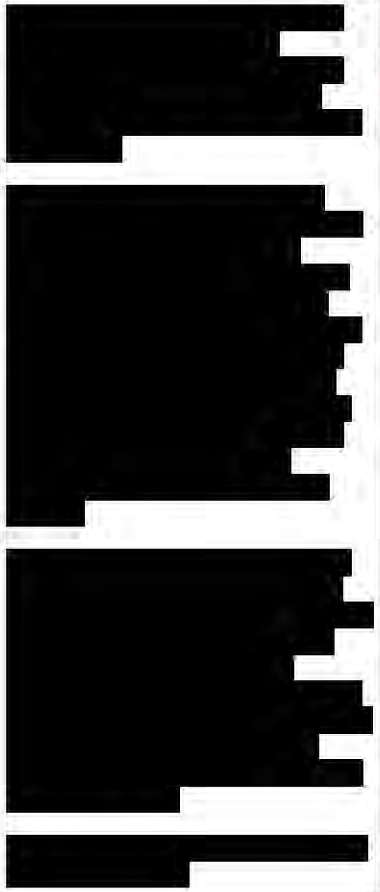
	manufacturer. Glutaraldehyde can also be added to in-line recirculating systems of installed out of service reverse osmosis equipment. Ensure organic and inorganic deposits are removed and flush the system through with clean water before returning to service. Soaking: [redacted] **Waste water clean up**: BPD ID A5.3.2_05 To clean water present in aerobic and anaerobic, belt pressed, digested and undigested sludges and holding tanks. Glutaraldehyde is added to the initial excess decanted water and after post treatment before discharging to the environment after a holding period of 1 or 2 days. Glutaraldehyde is not used to treat the waste water plant and hence does not impact on the microbes used for waste water treatment. The likely concentration is between [redacted] NB: For the disinfection of air-conditioning systems (through incorporation in the cooling water), in particular the control of [redacted] See References: BPD ID A5.3.1_14(1). BPD ID A5.3.1_15(1) **Hydrotesting applications** : Ref:BPD ID A5.3.2_01 Glutaraldehyde is added directly to the water used in the hydrotesting process. It is used once, at the initial charging of the system. It is used predominantly to control the growth of sulphate reducing bacteria and is used at or above the MIC for such organisms (see Ref:BPD ID A5.3.2_01) and [redacted]	
5.4	**Mode of action (including time delay) (IIA5.4)**	
5.4.1	**Mode of action**	See general section A5.4.1.
5.4.2	**Time delay**	Glutaraldehyde will be used for contact times [redacted] This will differ depending on the application and further detail can be found in the relevant sub-section of the Product Type. In hydrotesting applications, Glutaraldehyde should remain in the pipe for a period of [redacted]
5.5	**Field of use envisaged (IIA5.5)**	PT 11
5.6	**User (IIA5.6)**	
	Industrial	Industrial users such as the service companies either apply the product as supplied or manufacture a dilution or combine with another a.s.
	Professional	Professional users can apply Glutaraldehyde.
	General public	The active substance, Glutaraldehyde, is not used directly by the general public.
5.7	**Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies (IIA5.7)**	

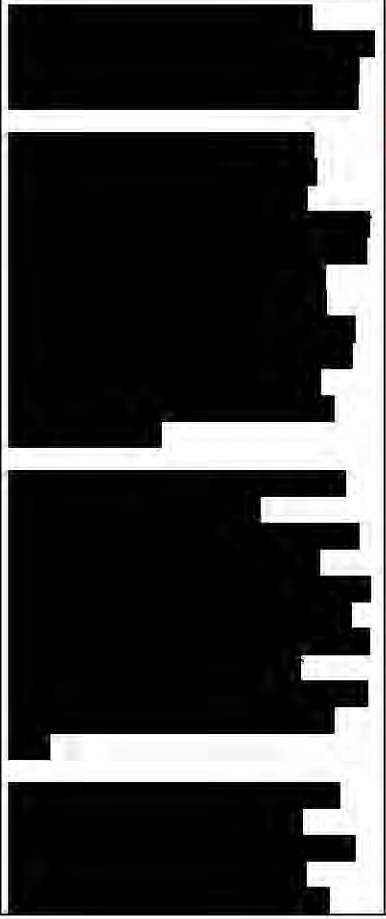
5.7.1 **Development of resistance**	See general section.	
5.7.2 **Management strategies**	To prevent development of resistant bacteria it is common to dose products or systems with more than one biocide at once.	
5.8 **Likely tonnage to be placed on the market per year (IIA5.8)**	Please see confidential Doc V	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
Date	**EVALUATION BY RAPPORTEUR MEMBER STATE** November 2012	
Materials and methods	This evaluation covers PT 11 both from the general part of IIIA for PT 11 and 12 and the specific part of IIIA for PT 11. Two acceptable key studies with study summaries on efficacy (A5.3.2_04, A5.3.2_05) were provided by the applicant. In addition one key study (A5.2.1_14) evaluated in connection with PTs 2, 3, 4 and 6 was referred. Several studies with supportive information were included in the document. No evidence based on key studies was provided on algicidal effect of glutaraldehyde. Only study providing information on efficacy against biofilms was a supportive study A5.3.2_01 where the results were based on a visual observation. 5.2.1 Organisms to be controlled No evidence based on key studies was provided on algicidal effect of glutaraldehyde. Only study providing information on efficacy against biofilms was a supportive study A5.3.2_01 where the results were based on a visual observation (also point 5.2.2). Reference A5.3.1_01 in the summary table is not giving any information on algae. 5.3 Summary table The full bibliographic data (author, year, title, source) of the references should be listed in the end of the table. The information on algistatic/algicidal function (Euglena is a protist, not an algae) should be removed from the table because the data is not supported by the given reference. 5.3.2 Likely concentrations The given likely concentrations were not supported by acceptable key studies in case of cooling towers, air washers and industrial scrubbing systems, water circuits in heat transfer systems, and stored, service and auxiliary water. The references given are supportive information. Algae and spores were not covered by the given reference (A5.3.1_01). The reference A5.3.2_02 is a technical discussion document. 5.4.2 Time delay The given reference (supportive information) is not giving [redacted] 5.7.1 Development of resistance Resistance has been observed also in other species than [redacted] esistance is discussed in more detail in connection with PT2. In air-conditioning systems glutaraldehyde was effective at [redacted]	

	[redacted]
Conclusion	Efficacy in ROM membranes and water treatment plants was supported by reliable key studies. For other uses (cooling towers, air washers, scrubbing systems, water treatment plants, hydrotesting applications) only supportive information was available. However, similar microbes might cause problems in all these applications. The missing information on efficacy (also against biofilms) should be provided at the product authorization stage. Claim on algae should be removed if not substantiated by data.
Remarks	Instead of ppm, SI (mg/l) units should be used.
	COMMENTS FROM ...
Date	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

(1) This study was previously submitted in support of Product Types 2, 3, 4 & 6. This data has therefore not been re-submitted but is cross referenced to the Part C dossier, where it can be found in Document IVA.

Section 5.3: Summary table of experimental data on the effectiveness of the active substance against target organisms at different fields of use envisaged, where applicable

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference
Cooling Water and chiller loop	PT 11	Glutaraldehyde	Field trials (x3) Various: bacteria, fungi, algae, and sulphate reducing bacteria (SRB)	Field Trials (x3) Before the trials were started, a baseline for microbial and non microbial conditions was established prior to treatment with Glutaraldehdye using the following methods. Heterotrophic Plate Count SM 9215B Fungus and Yeast Count SM 9610A pH value SM 4500H Sulfate Reducing Bacteria API Method Algae (Microscopic Count) SM 10200E Total Organic Carbon (TOC) EPA 9060 Chemical Oxygen Demand EPA 410.4 Specific Conductivity EPA 120.1 Aldehydes & Ketones EPA 8315	Field trials (x3) Tower volume(s) between 75 tons to 200 tons of water. pH between 8.5 to 9. Scale and corrosion inhibitors employed. Field trial conducted for 6 weeks Temp range between 70C to 75C. Chiller loop temp 55 C.		BPD ID A5.3.2_01Supportive information only ([redacted]

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference
Heat transfer systems	PT11	Glutaraldehyde	Various: bacteria, fungi, algae, and sulphate reducing bacteria (SRB)		All types of heat transfer systems.		BPD ID A5.3.2_02 [redacted] Supportive information only

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference
						[redacted]	
Stored and auxiliary water	PT11	Glutaraldehyde	[redacted]	The test vehicle chosen was water of standard hardness dosed with [redacted] active ingredient (Glutaraldehyde) and stored in polypropylene containers. Samples were stored in open (uncovered) & closed (covered) conditions at 28±2°C. The open system samples were stored in a Gallenkamp temperature controlled incubator, which was lit by 7 x 30 Watt daylight fluorescent tubes to represent natural daylight conditions. Closed system samples were covered and stored in a dark standard laboratory incubator. Surviving organisms were evaluated by total viable counts (TVC).	Sample variants were inoculated and checked for test organism recovery at 1, 7, 14 and 30-days. Each sample was inoculated with 1% (v/v)of either the mixed aerobic bacterial inocula or mixed sulphate reducing bacteria inoculum to give an in-situ concentration of approximately 1.0×10^5 cfu ml^{-1}. After [redacted] incubation, the number of surviving aerobic organisms were determined by the plate count method using 0.1% Peptone water + 0.85% Salt diluent and Tryptone Soya Agar. The plates were incubated at 28±2°C for at least 3 days. Whilst, the number of surviving anaerobic organisms were determined by the spread plate method using 2% Histidine inTryptone Soya Broth as a diluent/ inactivator, ¼ Ringer diluents and Iron Sulphite Agar (ISA). The ISA plates were incubated anaerobically at 28±2°C for at least 7-days.	[redacted]	BPD ID A5.3.2_03 [redacted] Supportive information only

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference
Reverse osmosis	PT11	Glutaraldehyde	[redacted]	A pump system was set up from a 50 litre reservoir containing 1/50 dilution TSB and an *in-situ* inoculum of approximately 1.0 x 10^5 cfu/ml . The flow rate through the RO system was set to 400 ml/min or 24 l/hr. The used RO membranes were cleaned either in-line cleaning or by soaking the membrane in a solution of Glutaraldehyde. Total viable counts of the surviving organisms on the membrane and in the water circuit were determined [redacted].	A 24 hr, 2nd passage [redacted] culture in TSB was prepared and added to the water circuit. In-line cleaning: The RO system was then disconnected from the reservoir and a cleaning solution pumped around the RO system. Samples of the RO membrane were taken at 3 and 24 hrs after cleaning. Surviving organisms on the membranes were resuspended by "stomaching" with an inactivator and enumerated by Total Viable Count. Soaking: 6 frames were soaked in a beaker containing 500 ml of inoculated distilled water and connected to the pump system and reservoir for 5 days. The frames were then removed and soaked separately in different concentrations of [redacted] using two frames per concentration. The surviving organisms from the membranes were resuspended by "stomaching" with an	[redacted]	BPD ID A5.3.2_04 Key study [redacted]

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference
					inactivator and enumerated by Total Viable Count.		
Waste Water	PT11	Glutaraldehyde	[redacted]	Two simulated waste water systems (A & B) were prepared by suspending shredded waste paper in sterile distilled water at a concentration of 1% (w/v). These were allowed to stand for 7 days. Waste water system A was inoculated with [redacted] Waste water system B was transferred to an anaerobic cabinet and inoculated with [redacted] The surviving organisms were determined in both the pellet and supernatant by Total Viable Count (TVC).	Waste water system A was inoculated with a 24 hr, 2nd passage Tryptone Soya Broth (TSB) culture of [redacted] to give an in-situ concentration of between 1.0×10^6 to 5.0×10^6 cfu/ml. This was allowed to stand for 1 hr, then thoroughly mixed, divided into three aliquots of 300 ml and labelled A1, A2 and A3. The waste water system B was transferred to an anaerobic cabinet and inoculated with a suspension of a 14 day, 2nd passage mixed culture of Sulphate Reducing Bacteria (SRB's) in Postgate's Anaerobic Medium to give an *in-situ* concentration of approximately 5.0×10^4 cfu/ml. This was allowed to stand for 1 hr, then thoroughly mixed, divided into three aliquots of 300 ml and labelled B1, B2 and B3. The aliquots were then dosed with [redacted] to give *in-situ* concentrations of: [redacted]	[redacted]	BPD ID A5.3.2_05 Key study [redacted]

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference
					[redacted] The systems were allowed to stand for a further 4 hrs before being pressed and the supernatant and pellet separated.The plates were then incubated aerobically at 30±2°C for at least 3 days and 14 days for aerobic and anaerobic bacteria, respectively.		

Section A5 Annex Point IIA,V.	Effectiveness against target organisms and intended uses PT 12 Slimicides	
Subsection (Annex Point)		**Official use only**
5.1 Function (IIA5.1)	Products used for the prevention or control of slime growth on materials, equipment and structures, used in industrial processes, e.g. on wood and paper pulp, injection and formation water in oil and gas production. In general, glutaraldehyde is able to control the organisms responsible for slime, biofilms and biocorrosion conditions found in PT 12.	
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)	Gram +ve and Gram –ve bacteria, anaerobic bacteria, bacterial spores, fungi and algae. See general section 5.2.1.	x
5.2.2 Products, organisms or objects to be protected (IIA5.2)	PT 12.1: Paper manufacture as a process additive for continuous paper production as well as for pulp, paper broke, slurries and starches, including de-inking. Preservation aspects for pulp, paper broke, slurries and starches was covered under Part C submission. PT12.2: For application in injection and water in oil and gas production.	
5.3 Effects on target organisms, and likely concentration of the active substance (IIA5.3)		
5.3.1 Effects on target organisms (IIA5.3)	Glutaraldehyde will control the growth of microorganisms by killing actively growing cells. Where cells are not actively growing (e.g. spores) they will be killed provided that there is exposure to sufficient concentration for a suitable time period. Glutaraldehyde will reduce the numbers and inhibit the metabolic activity of slime forming bacteria, especially [redacted] See general section 5.3.1	
5.3.2 Likely concentrations at which the A.S. will be used (IIA5.3)	PT 12.1 Paper mill slimicide: BPD ID A5.3.2_06 & BPD ID A5.3.2_07 Glutaraldehyde is added into the white water circuit by automatic metered pumps either intermittently or as a shock dose. Intermittent, refers to the biocide being applied at the lower end of the recommended dosing regime for a limited time over a certain period and repeating regularly to maintain microbial control. Whereas, shock dose requires dosing the biocide at the upper end of the dosing range to achieve microbial slime control over a short time period. However, continuous dosing is not likely due to economic reasons. The point of biocide addition is into the white water recirculating loop directly related to the initial paper forming process at the wet end of the paper mill, where slime build up is prevalent. Depending on accessibility, Glutaraldehyde can also be added via the head box or machine chest. Preferably the dosing occurs directly into the white process water such that operators have no direct contact with the biocide and only come into contact with the product upon changing and filling the dosing containers. For heavily fouled paper making machines, where both organic and inorganic deposits may be present then the maximum dose of Glutaraldehyde may not be sufficient and therefore manual cleaning is advised initially followed by biocide application at the higher end of the dosing regime. Microbial analysis should be performed during	x

Section A5 Annex Point IIA,V.	Effectiveness against target organisms and intended uses PT 12 Slimicides	
	cleaning to ensure that the microbial population is under control, once this is achieved then the biocide can be dosed intermittently. Apply either as an intermittent or shock dose will depend on the level of microbial contamination within the system but should not exclude manual cleaning if necessary. **Shock dose:** [redacted] **Intermittent dose:** [redacted] **Calculation of GA/tonne paper:** The dosage of glutaraldehyde applied that is calculated in grams/tonne paper is given below. The point of addition is the white water loop, head box or machine chest. It is assumed that the volume of water in the short loop is 2000 litre and that the average production of paper is 30 tonnes/hour. The calculated amount of GA/tonne paper is set out below for shock and intermittent dosing. These are reasonable worst case calculations, as they are based on the highest recommended dose for shock and intermittent dosing. **Shock dosing:** [redacted] **Intermittent dosing:** [redacted]	

Section A5 **Annex Point IIA,V.**	**Effectiveness against target organisms and intended uses** **PT 12 Slimicides**	
	Papermill de-inking process : Glutaraldehyde is added to control bacteria ([redacted].) and the catalase enzymes released, which interfere with the deinking process using hydrogen peroxide. The effect is both microbiological and chemical. The chemical effect is shown in BPD ID 5.3.2_08.	x
	Glutaraldehyde dosage amount [redacted] PT 12.2 Mineral Oil Injection Water Glutaraldehyde is added into the injection water stream at a concentration of between [redacted]. The same dosing concentration and periods are also applied preceding and following every shut down. [redacted] [redacted] See Reference: BPD ID A5.3.2_10	x
5.4 Mode of action (including time delay) (IIA5.4)		
5.4.1 Mode of action	See Doc IIIA 5 General Section 5.4.1	
5.4.2 Time delay	Glutaraldehyde will be used [redacted] This will differ depending on the application and further detail can be found in the relevant sub-section of the Product Type.	
5.5 Field of use envisaged (IIA5.5)	PT 12	
5.6 User(IIA5.6)		
Industrial	The active substance, Glutaraldehyde, is used by industrial users	
Professional	The A.S. is applied by professional users.	
General public	No	
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	See general section. See General Section A5.7.1.	
5.7.2 Management strategies	See general section. See General Section A5.7.2.	
5.8 Likely tonnage to be	See confidential document V	

Section A5 **Annex Point IIA,V.**	**Effectiveness against target organisms and intended uses** **PT 12 Slimicides**	
placed on the market per year (IIA5.8)		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	November 2012	
Materials and methods	One key study with study summary (A5.3.2_06) on efficacy specific for PT12 was provided by the applicant. Several studies with supportive information were included in the document. No evidence based on key studies was provided on algicidal effect of glutaraldehyde, neither effect on biofilms. 5.2.1 Organisms to be controlled No efficacy studies on algae, therefore the claim must be removed. 5.3 Summary table The full bibliographic data (author, year, title, source) of the references should be listed in the end of the table. 5.3.2 Likely concentrations Only the paper mill application is covered by an acceptable key study. References for paper mill de-inking process and oil production are supportive information only. (In oil production the reference A5.3.2_09 a higher [redacted]	
Conclusion	Efficacy as paper mill slimicide was supported by a reliable key studies. For other other uses (oil field) only supportive information was available. However, similar microbes might cause problems in all presented applications. The missing information on efficacy (also against biofilms) should be provided at the product authorization stage. Claim on algae should be removed unless substantiated by data.	
Remarks	Instead of ppm, SI (mg/l) units should be used.	
	COMMENTS FROM ...	
Date		
Results and discussion		
Conclusion		
Reliability		
Acceptability		
Remarks		