Competent Authority Report

DOCUMENT III-A

Study Summaries Active Substance

Addendum to Section 7

Rapporteur Member State: Italy

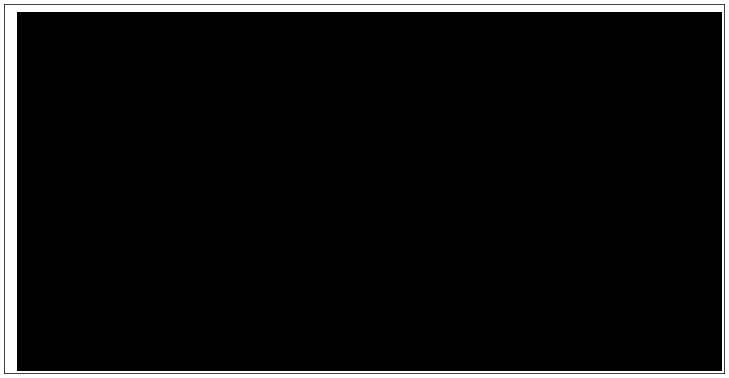
April 2021

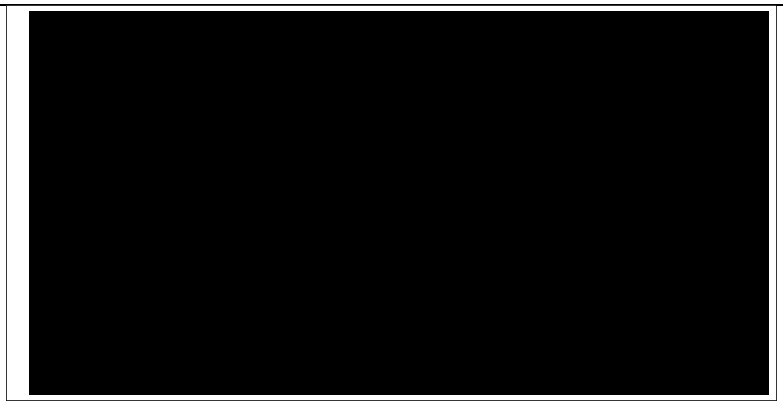
Section A7.2.2.1 **BPD Annex Point IIIA, VII. 4, XII. 1.1, XII.1.4**		**Aerobic degradation and metabolism in soil**	
		1 REFERENCE	**Official use only**
1.1	**Reference**	[redacted] [N-methyl-14C]Bardap 26 Aerobic Degradation and Metabolism in four Soils at 20 °C in the Dark, [redacted] [redacted] Report Amendment 1, [N-methyl-14C]Bardap 26 Aerobic Degradation and Metabolism in four Soils at 20 °C in the Dark, [redacted] [redacted] Bardap 26 – Kinetic Modelling and Evaluation of Data from Laboratory Aerobic Soil Degradation Studies for Persistence Endpoints, [redacted] [redacted] Bardap 26 – Summary of Soil and Aquatic System Degradation Data in a Regulatory Context. [redacted]	
1.2	**Data protection**	Yes	
1.2.1	Data owner	Lonza Cologne GmbH	
1.2.2	Criteria for data protection	Article 60 of Regulation 528/2012, on data protection periods for data submitted for the purposes of Directive 98/8/EC or Regulation 528/2012.	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	OECD 307; Aerobic and Anaerobic transformation in soil systems	
2.2	**GLP**	Yes	
2.3	**Deviations**	No	X
		3 MATERIALS AND METHODS	
3.1	**Test material**	Common name: [N-methyl-14C]Bardap 26 Chemical name: N,N –Didecyl – N- (^{14}C) methyl- N-(oxyethyl) ammonium propionate	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Purity	[redacted]	
3.1.3	Further relevant properties	[redacted]	
3.1.4	Position of radiolabel	[redacted]	
3.1.5	Method of analysis (of the	[redacted]	

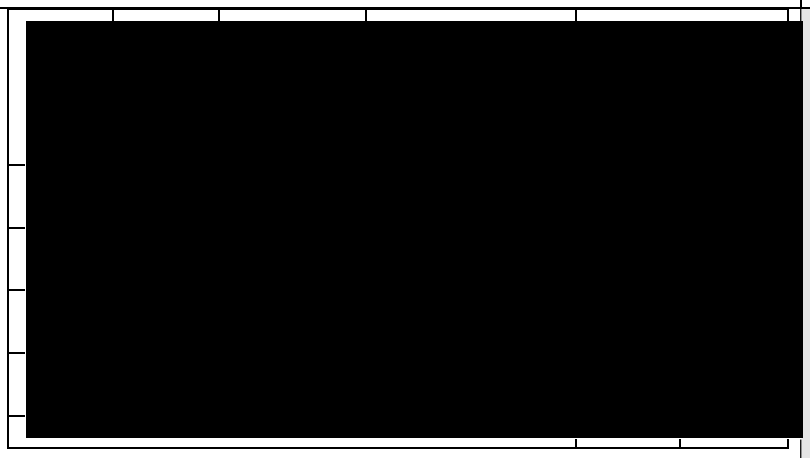
Section A7.2.2.1 **BPD Annex Point IIIA, VII. 4, XII. 1.1, XII.1.4**		**Aerobic degradation and metabolism in soil**	
	radiolabelled test item)	[redacted]	
3.2	**Analysis of test item and degradation products in study**	-	
3.2.1	Method of analysis for test item	[redacted]	

Section A7.2.2.1 **BPD Annex Point IIIA, VII. 4, XII. 1.1, XII.1.4**		**Aerobic degradation and metabolism in soil**	
3.2.2	Method of analysis for degradation products	[redacted]	
3.3	**Soil types**	See table A7.2.1-2.	
3.4	**Testing procedure**	-	
3.4.1	Test system	[redacted]	
3.4.2	Test conditions	[redacted]	
3.5	**Test performance**	-	
3.5.1	Preliminary test	n/a	
3.5.2	Dose rates	[redacted]	

Section A7.2.2.1 **BPD Annex Point IIIA, VII. 4, XII. 1.1, XII.1.4**	**Aerobic degradation and metabolism in soil**	
	[redacted]	
3.5.3 Limit of detection	[redacted]	
	4 RESULTS	
4.1 Preliminary test	n/a	
4.2 Extractable residues	[redacted]	

Section A7.2.2.1 **BPD Annex Point IIIA, VII. 4, XII. 1.1, XII.1.4**	**Aerobic degradation and metabolism in soil**	
4.3 Distribution of degradation products in the soil extracts	[redacted]   	

Section A7.2.2.1 **BPD Annex Point IIIA, VII. 4, XII. 1.1, XII.1.4**	**Aerobic degradation and metabolism in soil**	
	[redacted] 	
4.4 Mass balance (recovery of AR)	[redacted]	
4.5 Degradation rate	[redacted]  [redacted]	

Section A7.2.2.1 **BPD Annex Point IIIA, VII. 4, XII. 1.1, XII.1.4**	**Aerobic degradation and metabolism in soil**	
		
4.6 Degradation product(s)	[redacted]	

Section A7.2.2.1 **BPD Annex Point IIIA, VII. 4, XII. 1.1, XII.1.4**	**Aerobic degradation and metabolism in soil**	
	[redacted] *) Secondary amine [redacted]	

Section A7.2.2.1 **BPD Annex Point IIIA, VII. 4, XII. 1.1, XII.1.4**	**Aerobic degradation and metabolism in soil**	
	[redacted] 	
	5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	[redacted]	

Section A7.2.2.1 **BPD Annex Point IIIA, VII. 4, XII. 1.1, XII.1.4**	**Aerobic degradation and metabolism in soil**	
	[redacted]	

Section A7.2.2.1 **BPD Annex Point IIIA, VII. 4, XII. 1.1, XII.1.4**	**Aerobic degradation and metabolism in soil**	
	[redacted]	

Section A7.2.2.1 **BPD Annex Point IIIA, VII. 4, XII. 1.1, XII.1.4**	**Aerobic degradation and metabolism in soil**	
	[redacted]	
5.2 Results and discussion	[redacted]	
5.2.1 Degradation products (% of AR.)	[redacted]	
5.3 Conclusion	[N-methyl-14C]Bardap 26 degraded under aerobic laboratory conditions, with a typical half-live of 14.6, 10.8, 16.2 and 28.2 days in soil extracts for the soils Lufa 2.1, Lufa 2.2, Lufa 2.3 and Lufa 2.4, respectively. Metabolite M1a reached up to 29.4% and 12.7% AR in the soils Lufa 2.1 and Lufa 2.2, respectively. Metabolites H6 and H10 were observed at higher than 5% AR but less than 10% AR during the study. H6 was identified but it was not possible to identify H10. Up to 12 minor transformation products occurred during the incubation	

Section A7.2.2.1 **BPD Annex Point IIIA, VII. 4, XII. 1.1, XII.1.4**	**Aerobic degradation and metabolism in soil**	
	[redacted]	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	[redacted]	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*October 2019*	
Materials and Methods	*Adopt applicant's version*	
Results and discussion	*Adopt applicant's version*	
Conclusion	Adopt applicant's version. The WG agreed with the DT50 value calculated by applicant (geometric mean of the 4 soils investigated): 31 days at 12˚C.	
Reliability	*The reliability indicator is appropriate.*	
Acceptability	acceptable	
Remarks	X [redacted]	
	COMMENTS FROM ...	
Date	*Give date of comments submitted*	
Materials and Methods	*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*	
Results and discussion	*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		

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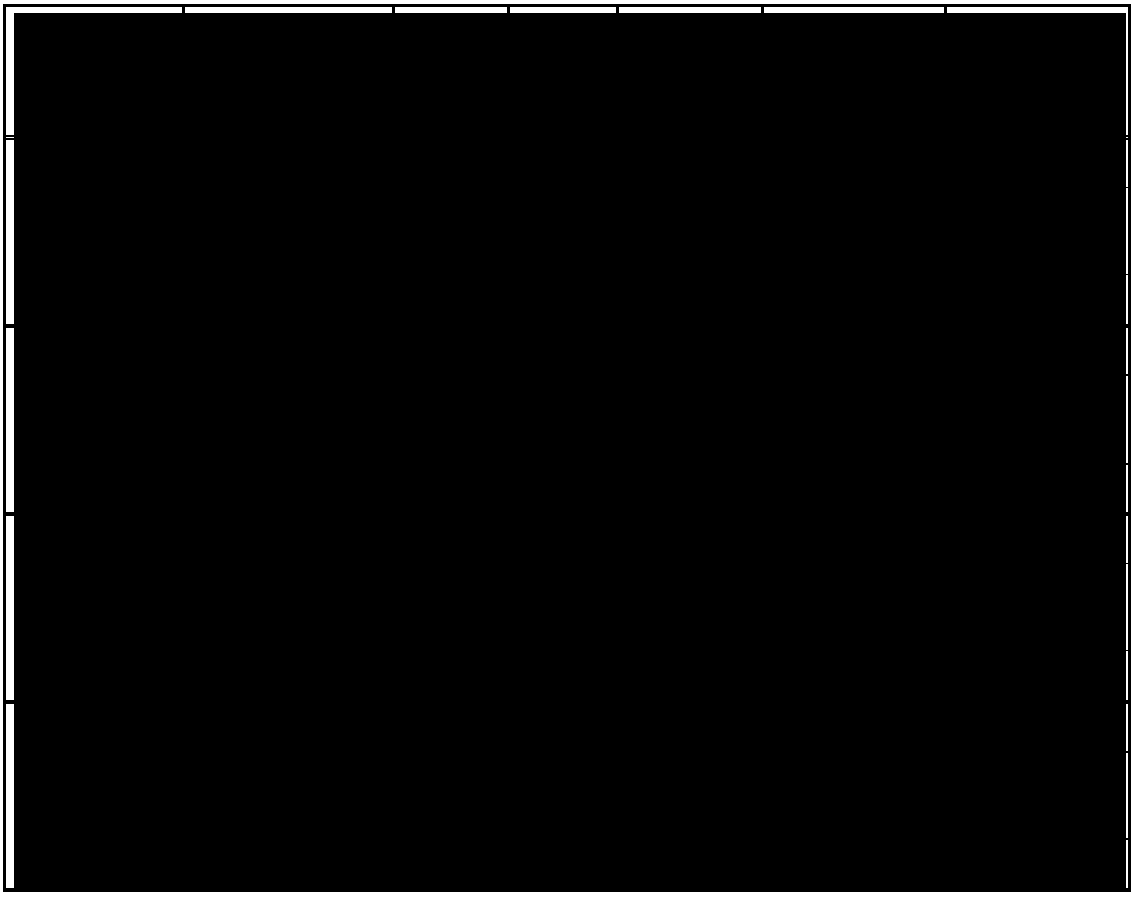

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Table A7.2.1-13: Characterisation of the extractable radioactivity in % of the applied radioactivity (AR) of [N-methyl-^{14}C]Bardap 26 in the Lufa 2.4 soil system

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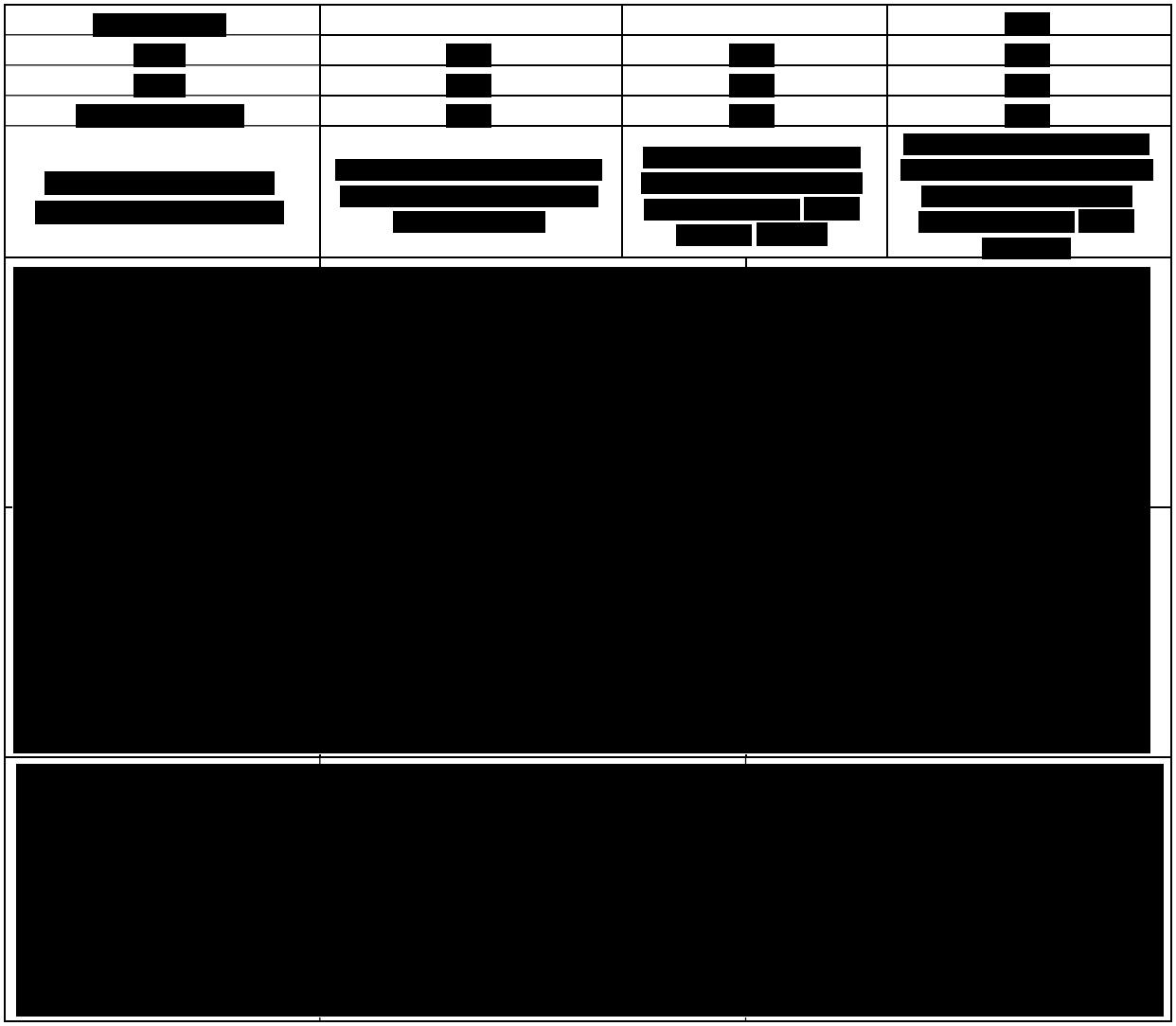

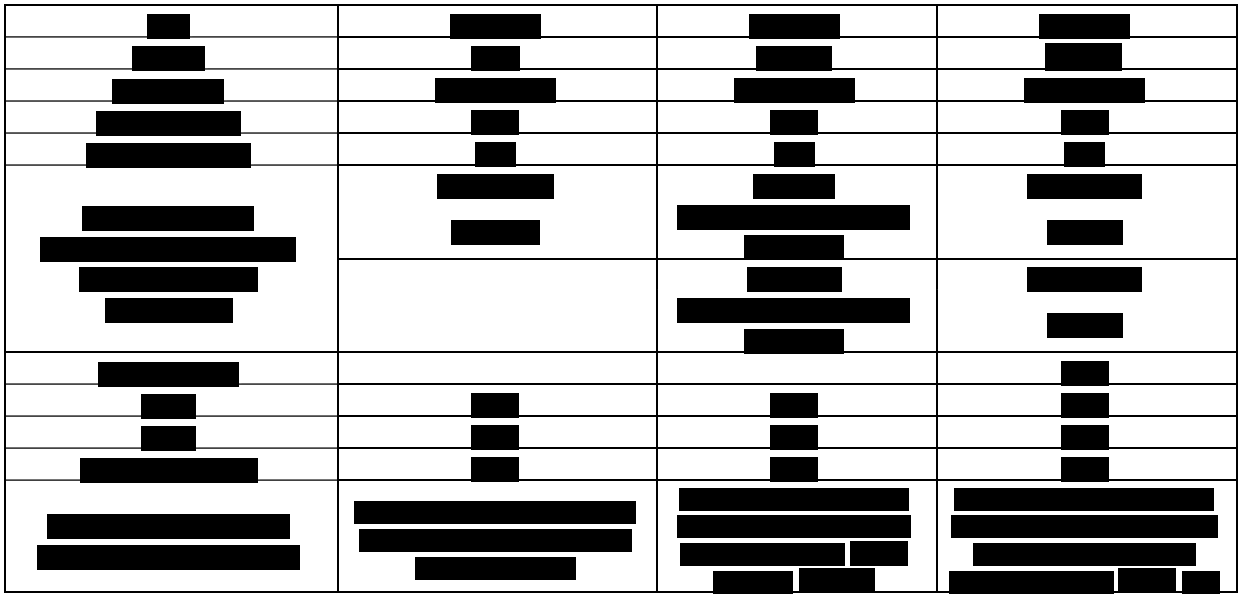

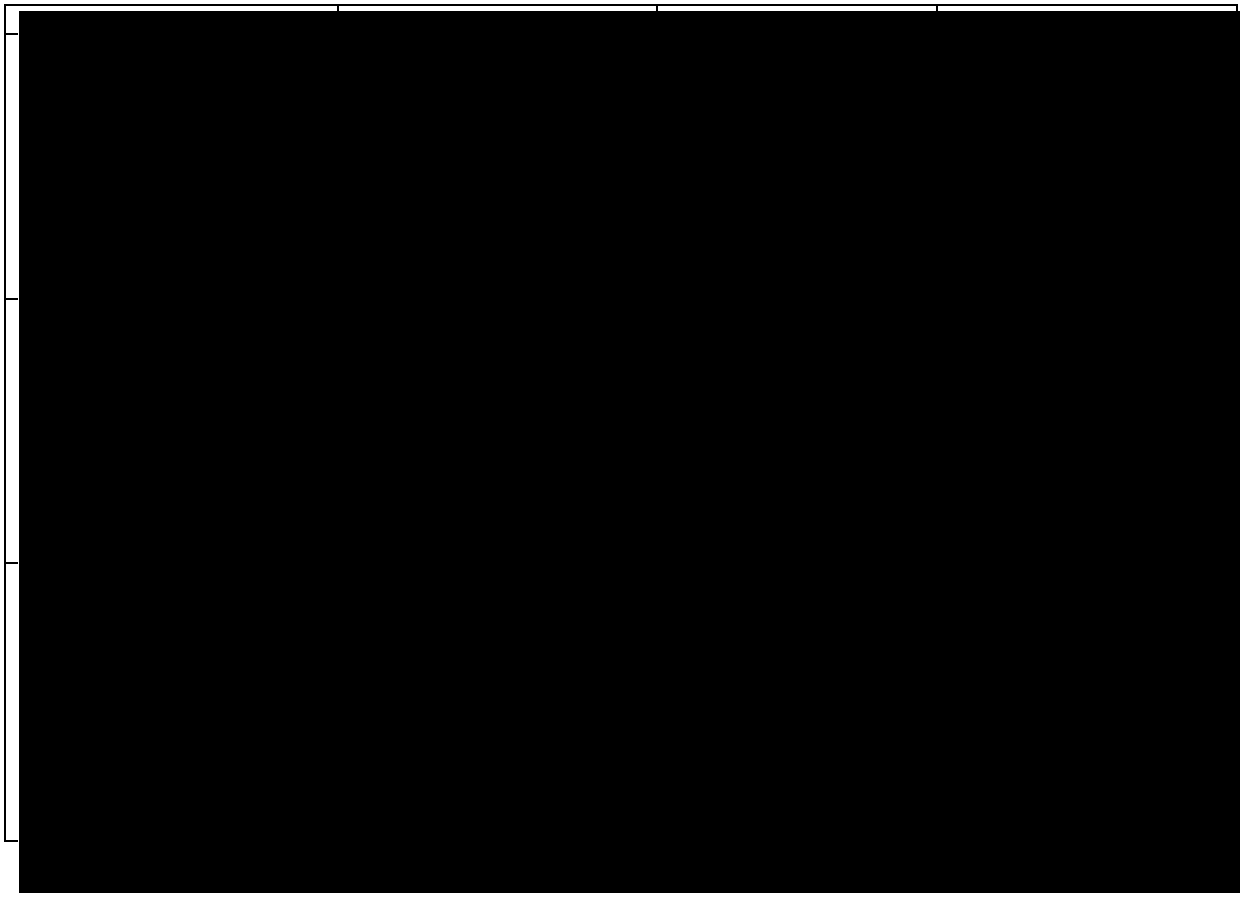

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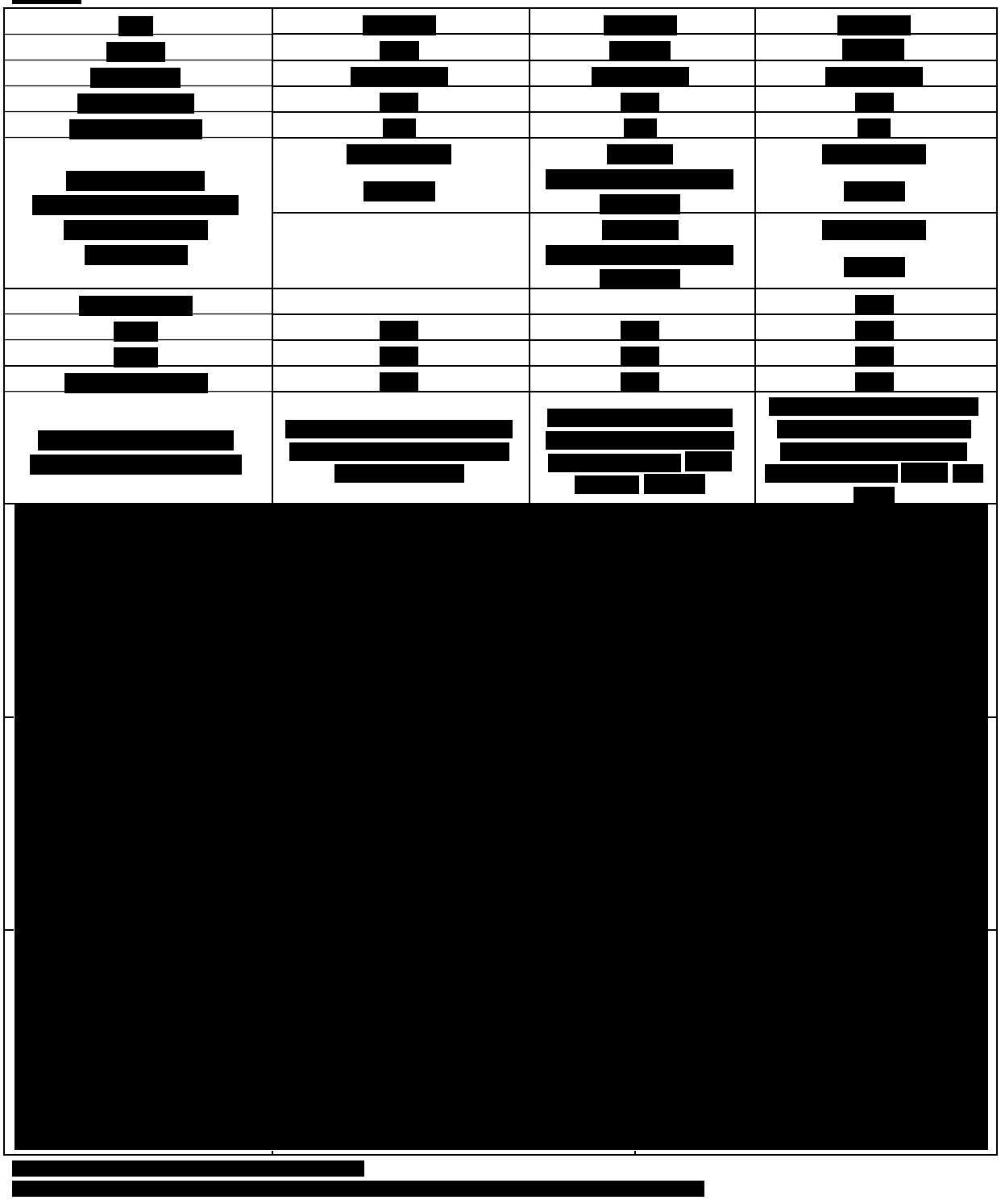

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[redacted]

Conclusion by WG: the DT50 value (geometric mean of the 4 soils investigated) is 31 days at 12˚C.

[redacted]

Section A7.1.2.2.2 **BPD Annex Point IIIA, XII. 2.1**		**Aerobic Degradation and Metabolism in two Water/Sediment Systems**	
Section A7.1.2.2.2 **BPD Annex Point IIIA, XII. 2.1**		**Aerobic Degradation and Metabolism in two Water/Sediment Systems**	
		6 REFERENCE	**Official use only**
6.1	**Reference**	[redacted] [N-methyl-14C] Bardap 26 Aerobic Degradation and Metabolism in two Water/Sediment Systems, [redacted] Report Amendment 1, [N-methyl-14C] Bardap 26 Aerobic Degradation and Metabolism in two Water/Sediment Systems, [redacted] Bardap 26 – Kinetic Modelling Evaluation of Data from a Water Sediment Study for Persistence Endpoints at Level PI, [redacted] (2019c). Bardap 26 – Summary of Soil and Aquatic System Degradation Data in a Regulatory Context. [redacted].	
6.2	**Data protection**	Yes	
6.2.1	Data owner	Lonza Cologne GmbH	
6.2.2	Criteria for data protection	Article 60 of Regulation 528/2012, on data protection periods for data submitted for the purposes of Directive 98/8/EC or Regulation 528/2012.	
		7 GUIDELINES AND QUALITY ASSURANCE	
7.1	**Guideline study**	OECD 308; Aerobic and Anaerobic Transformation in Aquatic Sediment Systems	
7.2	**GLP**	Yes	
7.3	**Deviations**	No	
		8 MATERIALS AND METHODS	
8.1	**Test material**	Common name: [N-methyl-14C]Bardap 26 Chemical name: N,N –Didecyl – N- (^{14}C) methyl- N-(oxyethyl) ammonium propionate	
8.1.1	Lot/Batch number	[redacted]	
8.1.2	Purity	[redacted]	
8.1.3	Further relevant properties	[redacted]	

Section A7.1.2.2.2 **BPD Annex Point IIIA, XII. 2.1**	**Aerobic Degradation and Metabolism in two Water/Sediment Systems**	
Section A7.1.2.2.2 **BPD Annex Point IIIA, XII. 2.1**	**Aerobic Degradation and Metabolism in two Water/Sediment Systems**	
8.1.4 Position of radiolabel	[redacted]	
8.1.5 Method of analysis (of the radiolabelled test item)	[redacted]	
8.2 Analysis of test item and degradation products in study	-	
8.2.1 Method of analysis for test item	[redacted]	

Section A7.1.2.2.2 **BPD Annex Point IIIA, XII. 2.1**	**Aerobic Degradation and Metabolism in two Water/Sediment Systems**	
Section A7.1.2.2.2 **BPD Annex Point IIIA, XII. 2.1**	**Aerobic Degradation and Metabolism in two Water/Sediment Systems**	
	[redacted]	
8.2.2 Method of analysis for degradation products	[redacted]	
8.3 Testing procedure	-	
8.3.1 Test system	[redacted]	
8.3.2 Test conditions	[redacted]	

Section A7.1.2.2.2 **BPD Annex Point IIIA, XII. 2.1**	**Aerobic Degradation and Metabolism in two Water/Sediment Systems**	
Section A7.1.2.2.2 **BPD Annex Point IIIA, XII. 2.1**	**Aerobic Degradation and Metabolism in two Water/Sediment Systems**	
	[redacted]	

Section A7.1.2.2.2 **BPD Annex Point IIIA, XII. 2.1**	**Aerobic Degradation and Metabolism in two Water/Sediment Systems**	
Section A7.1.2.2.2 **BPD Annex Point IIIA, XII. 2.1**	**Aerobic Degradation and Metabolism in two Water/Sediment Systems**	
	[redacted]	
8.4 **Test performance**	-	
8.4.1 Preliminary test	n/a	
8.4.2 Dose rates	[redacted]	

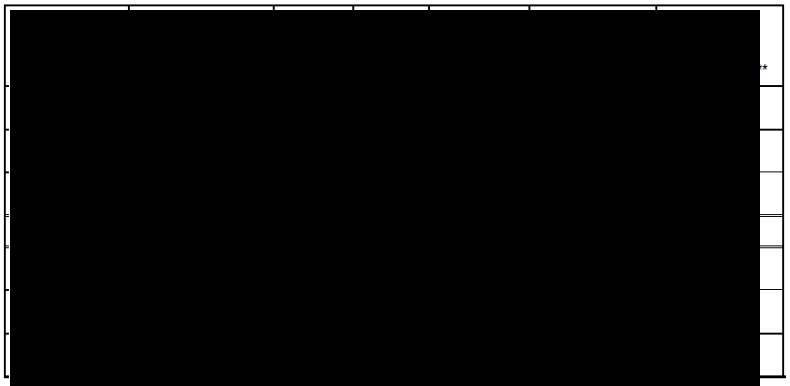
Section A7.1.2.2.2 **BPD Annex Point IIIA, XII. 2.1**	**Aerobic Degradation and Metabolism in two Water/Sediment Systems**	
Section A7.1.2.2.2 **BPD Annex Point IIIA, XII. 2.1**	**Aerobic Degradation and Metabolism in two Water/Sediment Systems**	
	[redacted]	
8.4.3 Limit of detection	[redacted]	
	9 RESULTS	
9.1 Preliminary test	n/a	
9.2 Distribution of radioactivity in water-sediment systems	[redacted]	

Section A7.1.2.2.2 **BPD Annex Point IIIA, XII. 2.1**	**Aerobic Degradation and Metabolism in two Water/Sediment Systems**	
Section A7.1.2.2.2 **BPD Annex Point IIIA, XII. 2.1**	**Aerobic Degradation and Metabolism in two Water/Sediment Systems**	
		

Section A7.1.2.2.2 **BPD Annex Point IIIA, XII. 2.1**	**Aerobic Degradation and Metabolism in two Water/Sediment Systems**	
Section A7.1.2.2.2 **BPD Annex Point IIIA, XII. 2.1**	**Aerobic Degradation and Metabolism in two Water/Sediment Systems**	
	[redacted]	
9.3 Characterisation of radioactivity in water-sediment systems	[redacted]	

Section A7.1.2.2.2 **BPD Annex Point IIIA, XII. 2.1**	**Aerobic Degradation and Metabolism in two Water/Sediment Systems**	
Section A7.1.2.2.2 **BPD Annex Point IIIA, XII. 2.1**	**Aerobic Degradation and Metabolism in two Water/Sediment Systems**	
	[redacted]  [redacted]	

Section A7.1.2.2.2 **BPD Annex Point IIIA, XII. 2.1**	**Aerobic Degradation and Metabolism in two Water/Sediment Systems**	
Section A7.1.2.2.2 **BPD Annex Point IIIA, XII. 2.1**	**Aerobic Degradation and Metabolism in two Water/Sediment Systems**	
	[redacted]	
9.4 Mass balance (recovery of AR)	[redacted]	

Section A7.1.2.2.2 **BPD Annex Point IIIA, XII. 2.1**	**Aerobic Degradation and Metabolism in two Water/Sediment Systems**	
Section A7.1.2.2.2 **BPD Annex Point IIIA, XII. 2.1**	**Aerobic Degradation and Metabolism in two Water/Sediment Systems**	
9.5 Degradation rate	[redacted]  [redacted]  [redacted]	

Section A7.1.2.2.2 **BPD Annex Point IIIA, XII. 2.1**	**Aerobic Degradation and Metabolism in two Water/Sediment Systems**	
Section A7.1.2.2.2 **BPD Annex Point IIIA, XII. 2.1**	**Aerobic Degradation and Metabolism in two Water/Sediment Systems**	
	[redacted]	
9.6 Degradation product(s)	[redacted]	

Section A7.1.2.2.2 **BPD Annex Point IIIA, XII. 2.1**	**Aerobic Degradation and Metabolism in two Water/Sediment Systems**	
Section A7.1.2.2.2 **BPD Annex Point IIIA, XII. 2.1**	**Aerobic Degradation and Metabolism in two Water/Sediment Systems**	
	on the molecular structure. See table A7.1.2.2.2-15 for details of the metabolite %AR in the water phase. The following metabolic pathway is proposed by the results of the study: [redacted]	
	10 APPLICANT'S SUMMARY AND CONCLUSION	
10.1 Materials and methods	[redacted]	

Section A7.1.2.2.2 **BPD Annex Point IIIA, XII. 2.1**	**Aerobic Degradation and Metabolism in two Water/Sediment Systems**	
Section A7.1.2.2.2 **BPD Annex Point IIIA, XII. 2.1**	**Aerobic Degradation and Metabolism in two Water/Sediment Systems**	
	[redacted]	

Section A7.1.2.2.2 **BPD Annex Point IIIA, XII. 2.1**	**Aerobic Degradation and Metabolism in two Water/Sediment Systems**	
Section A7.1.2.2.2 **BPD Annex Point IIIA, XII. 2.1**	**Aerobic Degradation and Metabolism in two Water/Sediment Systems**	
	[redacted]	

Section A7.1.2.2.2 **BPD Annex Point IIIA, XII. 2.1**	**Aerobic Degradation and Metabolism in two Water/Sediment Systems**	
Section A7.1.2.2.2 **BPD Annex Point IIIA, XII. 2.1**	**Aerobic Degradation and Metabolism in two Water/Sediment Systems**	
	[redacted]	
10.2 Results and discussion	[redacted]	

Section A7.1.2.2.2 **BPD Annex Point IIIA, XII. 2.1**	**Aerobic Degradation and Metabolism in two Water/Sediment Systems**	
Section A7.1.2.2.2 **BPD Annex Point IIIA, XII. 2.1**	**Aerobic Degradation and Metabolism in two Water/Sediment Systems**	
	[redacted]	
10.2.1 Degradation products (% of AR.)	[redacted]	

Section A7.1.2.2.2 **BPD Annex Point IIIA, XII. 2.1**	**Aerobic Degradation and Metabolism in two Water/Sediment Systems**	
Section A7.1.2.2.2 **BPD Annex Point IIIA, XII. 2.1**	**Aerobic Degradation and Metabolism in two Water/Sediment Systems**	
	[redacted]	
10.3 Conclusion	Bardap 26 was degraded in both systems under aerobic laboratory conditions, with typical half-lives of 4.4 (1WS Pfalz) and 1.2 days (2 WS Weißach) in the water phase, 25.9 (1WS Pfalz) and 25.3 days (2WS Weißach) in the sediment extract and 45.9 (1WS Pfalz) and 24.6 days (2WS Weißach) in the total system. The mean recoveries for the higher sampling times (from 61 days on) were sometimes below 90 % of the applied radioactivity. The low recoveries result out of CO_2 lost in the samples and has no effect on the outcome of this study. In both systems one major transformation product evolved during the study. M1 reached maximum values of 43 % AR (1WS water phase), 0.4 % AR (1WS sediment extract), 46.7 % AR (2WS water phase) and 2.2 % AR (2WS sediment extract). The identification of M1 via mass spectrometry revealed four major metabolites within the M1 signal. Three could be identified as M1a, M1b and M1c. One metabolite could not be identified but can be characterized as more polar than M1a, M1b, and M1c. It is proposed that M1d is a structure with shorter C-chains, an oxidation product of the N-oxyethyl moiety, or both.	
10.3.1 Reliability	[redacted]	
10.3.2 Deficiencies	[redacted]	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*20/12/ 2018*	
Materials and Methods	Adopt applicant's version	
Results and discussion	Adopt applicant's version	
Conclusion	Adopt applicant's version	
Reliability	The reliability indicator is appropriate	
Acceptability	*acceptable*	
Remarks		
	COMMENTS FROM ...	

Section A7.1.2.2.2 **BPD Annex Point IIIA, XII. 2.1**	**Aerobic Degradation and Metabolism in two Water/Sediment Systems**	
Section A7.1.2.2.2 **BPD Annex Point IIIA, XII. 2.1**	**Aerobic Degradation and Metabolism in two Water/Sediment Systems**	
Date	*Give date of comments submitted*	
Materials and Methods	*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*	
Results and discussion	*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		

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* Replicate not used for evaluation/kinetic calculations, total recovery too low

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Table A7.1.2.2.2-19: Parameters characterising the physico-chemical state of the Weißach water/sediment system at individual samplings

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Section 7.4.3.4 Annex Point IIIA XIII 2.4 — Effects on reproduction and growth rate with an invertebrate species

			Official use only
		11 REFERENCE	
11.1	**Reference**	[redacted] 2016, Bardap 26: Toxicity to the Water Flea Daphnia magna Straus under Laboratory Conditions (Reproduction Test), [redacted] [redacted] 2017, Report Amendment 1: Bardap 26: Toxicity to the Water Flea Daphnia magna Straus under Laboratory Conditions (Reproduction Test), [redacted]	
11.2	**Data protection**	Yes	
11.2.1	Data owner	Lonza AG	
11.2.2	Companies with letter of access	None	
11.2.3	Criteria for data protection	Article 60 of Regulation 528/2012, on data protection periods for data submitted for the purposes of Directive 98/8/EC or Regulation 528/2012.	
		12 GUIDELINES AND QUALITY ASSURANCE	
12.1	**Guideline study**	OECD 211	
12.2	**GLP**	Yes	
12.3	**Deviations**	No	
		13 METHOD	
13.1	**Test material**	Bardap 26	X
13.1.1	Lot/Batch number	[redacted]	
13.1.2	Specification	[redacted]	
13.1.3	Purity	[redacted]	
13.1.4	Composition of Product	[redacted]	
13.1.5	Further relevant properties	[redacted]	
13.1.6	Method of analysis	[redacted]	
13.2	**Preparation of TS solution for poorly soluble or volatile test substances**	[redacted]	
13.3	**Reference substance**	[redacted]	

Section 7.4.3.4 Effects on reproduction and growth rate with an invertebrate species
Annex Point IIIA XIII 2.4

[redacted]

13.3.1 Method of analysis for reference substance [redacted]

13.4 Testing procedure

13.4.1 Dilution water [redacted]

13.4.2 Test organisms [redacted]

13.4.3 Handling of offspring [redacted]

13.4.4 Test system [redacted]

13.4.5 Test conditions [redacted]

13.4.6 Duration of the test [redacted]

13.4.7 Test parameter [redacted]

13.4.8 Examination / Sampling [redacted]

13.4.9 Monitoring of TS concentration [redacted]

13.4.10 Statistics [redacted]

14 RESULTS

14.1 Range finding test [redacted]

14.1.1 Concentrations [redacted]

Section 7.4.3.4 Effects on reproduction and growth rate with an invertebrate species
Annex Point IIIA XIII 2.4

14.1.2 Number/ percentage of animals showing adverse effects

[redacted]

14.1.3 Nature of adverse effects

[redacted]

14.2 Results test substance

[redacted]

14.2.1 Initial concentrations of test substance

[redacted]

14.2.2 Actual concentrations of test substance

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Section 7.4.3.4 Effects on reproduction and growth rate with an invertebrate species

Annex Point IIIA XIII 2.4

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14.2.3 Effect data

[redacted]

Section 7.4.3.4 Effects on reproduction and growth rate with an invertebrate species
Annex Point IIIA XIII 2.4

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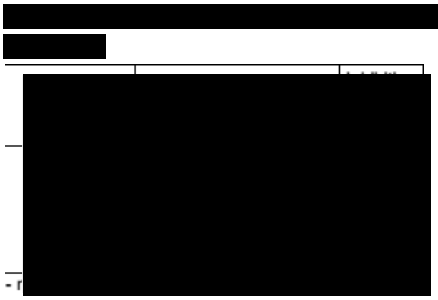
14.2.4 Concentration / response curve

[redacted]

Section 7.4.3.4 Effects on reproduction and growth rate with an invertebrate species
Annex Point IIIA XIII 2.4

Plot of mortality of adult daphnids for every day of test:

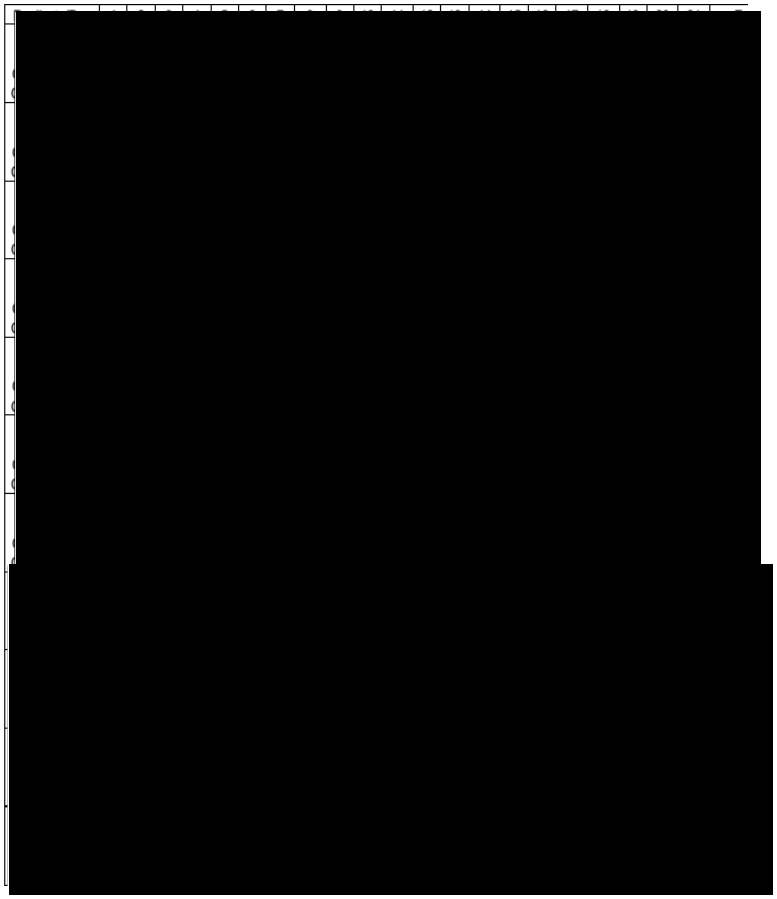
14.2.5 Other effects



Section 7.4.3.4 Annex Point IIIA XIII 2.4 — Effects on reproduction and growth rate with an invertebrate species

14.3 Results of controls

[redacted]



14.4 Test with reference substance Not performed

14.4.1 Concentrations Not applicable

14.4.2 Results Not applicable

15 APPLICANT'S SUMMARY AND CONCLUSION

15.1 Materials and methods

[redacted]

15.2 Results and discussion

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Section 7.4.3.4 Effects on reproduction and growth rate with an invertebrate species
Annex Point IIIA XIII 2.4

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15.2.1	NOEC	Mortality: 185 µg/L (actual) Reproductive output: 219 µg/L (actual) Body length: 256 µg/L (actual)	
15.2.2	LOEC	Mortality: 219 µg/L (actual) Reproductive output: 256 µg/L (actual) Body length: 303 µg/L (actual)	
15.2.3	EC_{50} (EC_x)	Mortality: LC_{50} = 233 µg/L (actual), LC_{10} = 206 µg/L (actual) Reproductive output: EC_{50} = 263 µg/L (actual), EC_{10} = 256 µg/L (actual) Body length: Not calculable.	
15.3	**Conclusion**	The validity criteria are comfortably fulfilled for both mortality and reproductive output parameters in the test. There is a general upward trend in effect vs dose indicating that Bardap 26 is producing a dose-response effect on the test organism for both reproductive effects and mortality.	
15.3.1	Reliability	[redacted]	X
15.3.2	Deficiencies	[redacted]	

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*20/12/2018*
Materials and Methods	*Adopt Applicant's version*
Results and discussion	*Adopt applicant's version*
Conclusion	*Adopt applicant's version*
Reliability	[redacted]
Acceptability	Acceptable..

Section 7.4.3.4 Effects on reproduction and growth rate with an invertebrate species
Annex Point IIIA XIII 2.4

Remarks	[redacted]
	COMMENTS FROM ... *(specify)*
Date	*Give date of comments submitted*
Materials and Methods	*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*
Results and discussion	*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	

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