Competent Authority Report

DOCUMENT III-A

Study Summaries Active Substance

Didecyldimethylammonium chloride
(DDAC, CAS no.7173-51-5)

Product types 3-4
(Veterinary hygiene; Food and feed area)

eCA: Italy

February 2021

Section A7.2.1	*Biodegradation in soil*	For official use only
	1 REFERENCE	
1.1 Reference	[methyl-14C]Didecyldimethylammonium chloride Aerobic Transformation in Soil Author [redacted] [redacted] [redacted] [redacted]	
1.2 Data protection	yes	
1.2.1 Data owner	Sponsors DDAC Issue Steering Committee (ISC) clo The Household & Consumer Products Association (HCPA) 1667 K Street NW Suite 300 20006 Washington DC United States of America Representing: LONZA Inc, with offices at 90 Boroline Road Allendale New Jersey 07401, United States; STEPAN COMPANY, whose registered office is at 22 W. Frontage Road, Northfield, IL, 60093, United States; MASON CHEMICAL COMPANY, with its registered office located at 723 B West Alonquin Road, Arlington Heights, IL 60005, United States AND European Quat Consortium (EQC) pIa Akzo Nobel Chemicals nv Velperweg 76 P.O. Box 9300 6800 SB Arnhem The Netherlands Representing: AKZO NOBEL SURFACE CHEMISTRY AB; trading under the trade name Nouryon, with its registered office at Stenunge Allé 3, SE-444 85 Stenungsund, Sweden; THOR ESPECIALIDADES SA, with its registered office at Polígon Industrial el Pla, Avinguda de la Industria 1, 08297, Castellgalí, Barcelona, Spain,	

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1.2.2	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]*	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	OECD Guideline 307 for Testing of Chemicals (April 2002)	
2.2	**GLP**	yes	
2.3	**Deviations**	Deviations from the guideline: None Deviation from GLP The 14C-labelled test item was not retained due to its radioactivity and small sample amount.	
		3 MATERIALS AND METHODS	
3.1	**Test material**	[redacted]	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	[redacted]	
3.1.3	Purity	[redacted]	
3.1.4	Further relevant properties	[redacted]	
3.1.5	TS inhibitory to microorganisms	[redacted]	
3.1.6	Specific chemical analysis	[redacted]	
3.2	**Reference substance**	According to the guideline no reference item is recommended for this test.	
3.2.1	Initial concentration of reference substance	na	

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3.3 Testing procedure	Application [redacted] **Test vessels** [redacted] **Replicates** Transformation rate: [redacted] Metabolite Identification: [redacted]	
3.3.1 Inoculum / test species	na	
3.3.2 Test system	[redacted]	
3.3.3 Test conditions	**Incubation** [redacted] **Soil moisture content** [redacted]	

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3.3.4	Method of preparation of test solution	[redacted]	
3.3.5	Initial TS concentration	[redacted]	
3.3.6	Duration of test	Soil 2.1: 120 days Soil 2.2: 120 days Soil 2.3: 127 days Soil 2.4: 120 days	
3.3.7	Analytical parameter	**Extraction of the Soils** [redacted] **Method of Accelerated Solvent Extraction** [redacted] **Analytical Evaluation by LSC** [redacted] **Humus Fraction** [redacted] **Analytical Evaluation by LC – FSA (radio-HPLC)** [redacted]	

3.3.8 Sampling

[redacted]

[redacted]

[redacted]

Sampling Times

Soil	Number of Samplings	Sampling Times
2.1	8	0, 2, 7, 14, 22, 56, 85, 120 days
2.2	9	0, 1, 3, 7, 14, 24, 49, 85, 120 days
2.3	8	0, 3, 7, 13, 29, 56, 79, 127 days
2.4	8	0, 2, 7, 21, 30, 55, 91, 120 days

Test item and transformation products

[redacted]

14CO2

[redacted]

Volatile organic transformation products

[redacted]

NER

[redacted]

Soil moisture

[redacted]

Biomass activity

[redacted]

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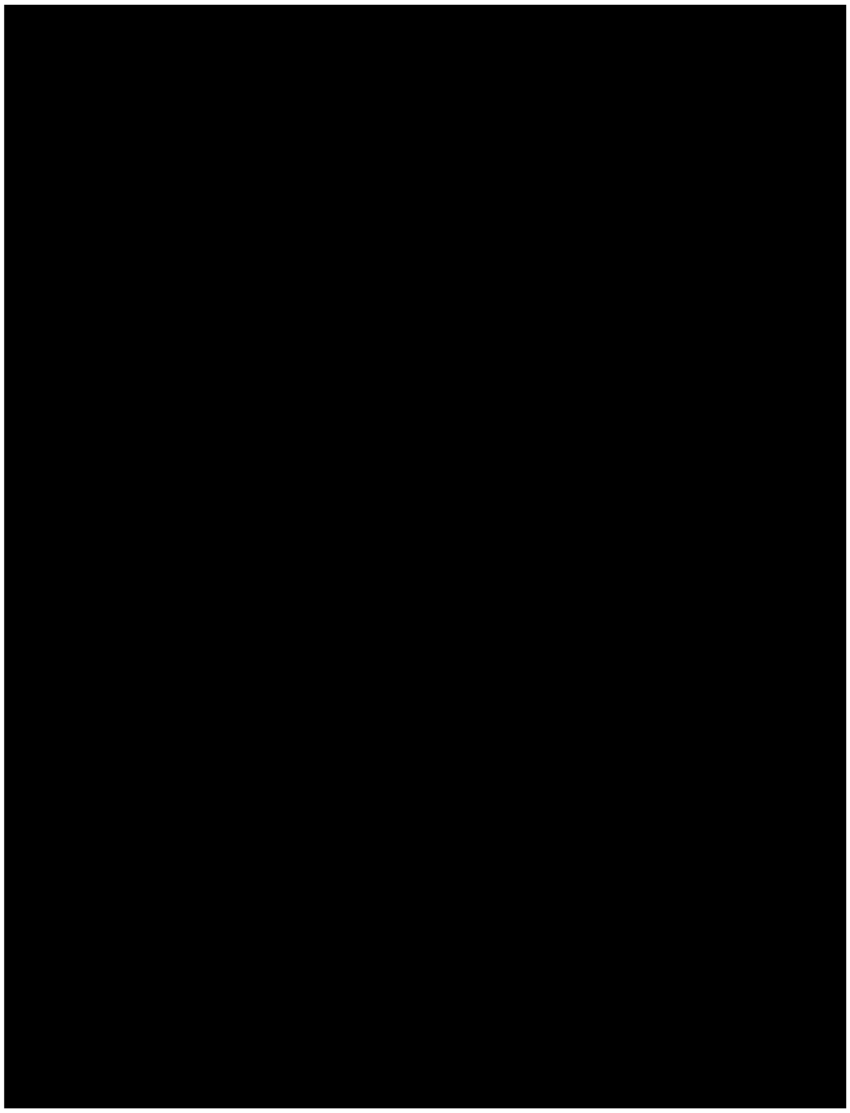
3.3.9	Intermediates/ degradation products	**Sampling for Metabolite Identification and Evaluation of Transformation Pathway** [redacted] **Analytical Evaluation by LC-HRMS (Metabolite Identification)** [redacted]	
3.3.10	Nitrate/nitrite measurement	none	
3.3.11	Controls	Control soil samples were not treated with the test item and were incubated under the same aerobic conditions as the treated soil samples. These samples were used for biomass measurements at test start, during and at the end of the study.	
3.3.12	Statistics	[redacted]	
		4 RESULTS AND DISCUSSION	

Section A7.2.1	*Biodegradation in soil*	For official use only
4.1 Degradation of test substance	[redacted]	

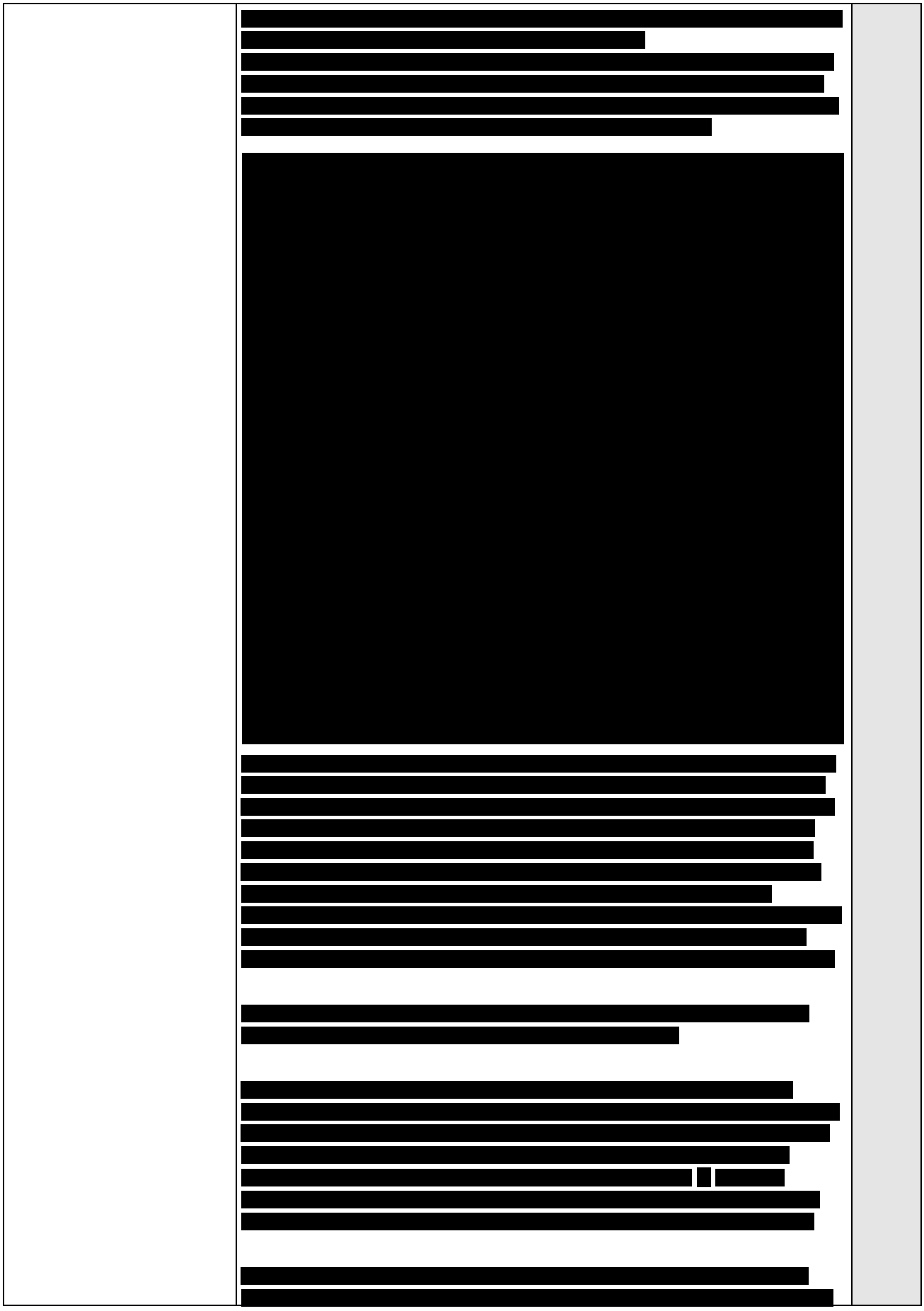
4.1.1 Graph	 	

Section A7.2.1	*Biodegradation in soil*	For official use only
	[redacted]	

Section A7.2.1	*Biodegradation in soil*	For official use only
4.1.2 Degradation	[redacted]	

Section A7.2.1		*Biodegradation in soil*	For official use only
4.1.3	Other observations	**Microbial Biomass** [redacted] **Mass Balance** [redacted] **Characterization of Non-Extractable Residues (NER)** [redacted]	
4.1.4	Degradation of TS in abiotic control	na	
4.1.5	Degradation of reference substance	na	

4.1.6	Intermediates/ degradation products	**Formation of Metabolites** [redacted] **Evaluation of Transformation Pathway** [redacted]



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	[redacted]d and bioavailability decreased, resulting in a less rapid biodegradation.	
	5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	[redacted]	

5.2 Results and discussion	[redacted]	

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	[redacted]	
5.3 Conclusion	The test item [redacted] was rapidly degraded in all four soils. The dominant transformation/dissipation process of [redacted] was mineralization. Evaluation of the transformation pathway indicated, that not only are the [redacted] rapidly cleaved, but also that whole molecule is rapidly degraded. The calculated DT50 values with the Single-First-Order Model (SFO) for the dissipation of [redacted] were 10.3 – 17.7 days, the DT90 values were 34.3 – 58.7 days. The calculated DT50 values with the First-Order Multi-Compartment Model (FOMC) for the dissipation of [redacted] were 7.7 – 13.3 days, the DT90 values were 91.1 – 219.0 days.	X
5.3.1 Reliability	*1*	
5.3.2 Deficiencies		
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	

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Date		
Materials and Methods		
Results and discussion		
Conclusion		
Reliability		
Acceptability		
Remarks		
	COMMENTS FROM ...	
Date		
Materials and Methods		
Results and discussion		
Conclusion		
Reliability		
Acceptability		
Remarks		

Add tables if needed

Soil Parameters

Parameter	LUFA-soil 2.1 Batch-No. F2.1 2917	LUFA-soil 2.2 Batch-No. F2.2 2617	LUFA-soil 2.3 Batch-No. F2.3 3017	LUFA-soil 2.4 Batch-No. F2.4 2617
Sampling depth*	ca. 20 cm	ca. 20 cm	ca. 20 cm	ca. 20 cm
pH-value*	4.9 ± 0.3	5.6 ± 0.4	5.8 ± 0.6	7.4 ± 0.1
Maximum water holding capacity* [g/100 g DW]	32.5 ± 1.5	45.8 ± 1.9	45.8 ± 1.9	44.6 ± 2.2
Particle size distribution#*				
Sand:				
0.63 - 2.0 mm	2.4 ± 0.4	0.7 ± 0.2	2.8 ± 0.4	1.7 ± 0.2
0.2 - 0.63 mm	53.6 ± 1.7	40.2 ± 1.7	29.8 ± 1.0	5.9 ± 0.5
0.063 - 0.2 mm	28.8 ± 1.3	34.8 ± 3.0	24.6 ± 1.0	19.7 ± 1.0
Silt:				
0.02 - 0.063 mm	6.8 ± 1.1	7.5 ± 1.6	18,5 ± 1.1	23.0 ± 1.1
0.006 - 0.02 mm	3.5 ± 10.3	5.2 ± 0.8	11,4 ± 0,7	15.2 ± 1.0
0.002 - 0.006 mm	1.6 ± 0.7	3.0 ± 1.2	5,3 ± 0.7	7.9 ± 0.4
Clay:				
< 0.002 mm	3.3 ± 0.0.9	8.6 ± 1.2	7,6 ± 0,4	26.6 ± 0.6
Organic carbon content [%][1]	0.92	1.72	0.62	1.85
Microbial biomass [%] of total organic carbon[2)]	3.36	2.74	5.11	3.14
Cation exchange capacity* [meq/100 g]*	4.2 ± 0.6	9.8 ± 0.5	7.5 ± 0.8	26.5 ± 15.5
Weight per Volume (g/1000)* mL)	1420 ± 41	1201 ± 41	1307 ± 41	1251 ± 39
Soil texture*	silty sand [redacted]	loamy sand [redacted]	silty sand [redacted]	clayey loam [redacted]
Sampling date	2017-07-21	2017-06-29	2017-07-21	2017-06-27

*) data provided by LUFA SPEYER [redacted]

[redacted]

2) determined at the respective application day of the respective soil

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]