

## MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE **RENEWAL OF 1-Methylcyclopropene** (confidential)

Rapporteur Member State	Month and year	Active Substance <sup>2</sup> (Name)	Notifier	Applicant
The Netherlands (took over the responsibility as RMS from UK)	August 2020	<b>1-Methylcyclopropene</b>	[REDACTED] [REDACTED]	[REDACTED]

### **RMS note and overall conclusion (Ctgb, The Netherlands)**

4 September 2020

**Conclusion on the data matching request by [REDACTED] for the dossier of the active substance 1-methylcyclopropene (1-mcp).**

RMS (the Netherlands) has assessed the proposals and statements, waivers and matching reasoning of the applicant.

Category 4 extension was not applied for.

#### **RMS conclusion.**

All necessary studies are matched\* except for 5 vertebrate studies:

Mammalian Toxicology: KCA 5.1.1./01, KCA 5.3.2/01, KCA 5.3.2/02, KCA 5.6.1/01.

Ecotoxicology: KCA 8.1.1.1, KCA 8.1.2.2 (Study 8.1.2.2. is the same as study 5.3.2/01)

The non-matched studies are vertebrate studies and duplicates are therefore not permitted (article 62 of (EU) 1107/2009). The applicant provided RMS Ctgb-NL with sufficient evidence that the applicant is active in negotiations with the data owner of these studies. However, these negotiations have not yet led to a final agreement on data access between the parties involved. As data-access is a national issue, the RMS decided to declare the data matching list complete, except for the 5 vertebrate studies mentioned above. MS should individually judge a letter of access for these data or based on the evidence of commitment from the applicant decide to invoke access through article 62.4 for mandatory sharing of vertebrate data.

\* **The RMS for the active substance did not consider whether data protection applies to all studies for which data protection has been claimed.** It is the responsibility of MSs to ensure that data protection standards as laid down in Regulation (EC) No 1107/2009 are respected.

**The RMS did not check whether valid Letters of Access were submitted.** It is the responsibility of MSs to ensure that appropriate Letters of Access, valid for the respective MSs are available.

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The conclusion is stated in the table below, for each aspect.  
Details can be found in the data matching tables for each aspect.

Aspect	Is current dossier acceptable for matching?	Final Conclusion
Identity, Physical and Chemical properties	No remarks	All studies are matched.
analytical method	No remarks	All studies are matched
Mammalian toxicology	All studies are matched, except for four vertebrate studies. The applicant must gain access to these four <i>in vivo</i> studies as these were submitted either based on the data requirements and/or for derivation of reference values which are needed for risk assessment purposes. Please address.  Reply applicant: Regarding the four <i>in vivo</i> studies: Negotiations have been initiated with Agrofresh. A letter of access will be submitted as soon as available.	All studies are matched, except for 4 vertebrate studies; KCA 5.1.1./01, KCA 5.3.2/01, KCA 5.3.2/02, KCA 5.6.1/01. An agreement between [REDACTED] and the data owner is pending.
Residues	During the renewal of 1-methylpropene, data protection was claimed for one study only. The applicant [REDACTED] [REDACTED] I claims that this study does not need to be matched. The RMS agrees with the applicant.	All studies are matched/waived.
Environmental Fate and Behaviour	No remarks	All studies are matched.
Ecotoxicology	Ctgb considers that data access needs to be shown for two vertebrate studies in the Ecotox list: one on quail and one on rats (the latter is also used in the mammalian toxicology section).	All studies are matched, except for 2 vertebrate studies; KCA 8.1.1.1, KCA 8.1.2.2). (Study 8.1.2.2. is the same as study 5.3.2/01). An

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	Thus, the applicant must show access to two vertebrate studies (KCA 8.1.1.1, KCA 8.1.2.2).	agreement between [REDACTED] and the data owner is pending.
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Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
<b>A.1. IDENTITY</b>											
KCA 1.11/01 KCA 4.1.1	[REDACTED]	2010	GLP characterization of 5 representative matches of 1-methylcyclopropene (1-MCP) Manufacturing Use Product – HAIP. Study No. AF-10-044 AF-P-10-05 GLP, Unpublished		[REDACTED]	2019	Analysis of 5-batches of 1-MCP Technical Material to Determine the Content of Active Ingredient and specified impurities , in Compliance with Good Laboratory Practice.	The matching study was submitted.			CTGB 23-07-2019:  <b>Acceptable</b> This study does not have to be matched as it is considered a confidential study, included in Volume 4 of the notifier. Study on the identity of the active substance should be

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The Netherlands (took over the responsibility as RMS from UK)	August 2020	1-Methylcyclopropene	[REDACTED] [REDACTED]	[REDACTED]

							Study Number: DNA4900				evaluated within the equivalence application of the manufacturing source of the applicant.
KCA 1.11/04	[REDACTED]	2015a	1-MCP:Five-Batch Analysis ..... ..... ..... ..... Huntingdon Life Science, IMB0095 AGR 5224 GLP Not Published CONFIDENTIAL		[REDACTED]	2019	Analysis of 5-batches of 1-MCP Technical Material to Determine the Content of Active Ingredient and specified impurities , in Compliance with Good Laboratory Practice.  Study Number: DNA4900	The matching study was submitted .			CTGB 23-07-2019:  <b>Acceptable</b> This study does not have to be matched as it is considered a confidential study, included in Volume 4 of the notifier. Study on the identity of the active substance should be evaluated within the equivalence application of the manufacturing source of the applicant.
KCA, 4.1.1/06	[REDACTED]	2010	GLP Validation of the ..... Method ..... ..... ..... ..... ..... ..... in Manufacturing Use Product – HAIP (1-Methylcyclopropene)		[REDACTED]	2019	Validation of the method of analysis used for the determination of Specified Solvents in 1-MCP Technical Material, in Compliance with Good Laboratory Practice.  Study Number: DNA4901	The matching studies was submitted.			CTGB 23-07-2019:  <b>Acceptable</b> This study does not have to be matched as it is considered a confidential study, included in Volume 4 of the notifier. Study on the identity of the active substance should be evaluated within the equivalence application of

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[REDACTED]	[REDACTED]	Report No.: AF-10-047 AF-P-10-08 [REDACTED] [REDACTED], [REDACTED] Unpublished	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	the manufacturing source of the applicant.
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**A.2. PHYSICAL AND CHEMICAL PROPERTIES**

KCA 2.1/04	Kühne, M.	2010a	Manufacturing Use Product – HAIP: Determination of the physico-chemical-property “Melting / Freezing Temperature” Report No.: C69811 AF-09-085 [REDACTED] [REDACTED] Unpublished	N	[REDACTED]	[REDACTED]	No required.  The study was done on MUP-HAIP-intermediate material.  (4.5% 1-methylcyclopropene complexed with alpha-cyclodextrin in Manufacturing Use Product High Active Ingredient Powder (MUP-HAIP))	[REDACTED]	CTGB 23-07-2019:  <b>Acceptable</b> The waiver is not found to be acceptable, as no reasoning is provided why it is considered acceptable in view of the applicant to not address this study with an matching study for the determination of the melting point. However, the applicant refers to open (not protected) data from the DAR (2005), also evaluated in the RAR (2018) and found to be acceptable for renewal. Therefore, no further data
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										is required and for data matching reference is made to the study below.	
					[REDACTED]	2002a	Determination of the melting point/melting range of 1-MCP. Report No.: 823566 AF-01-155 [REDACTED] [REDACTED] [REDACTED] [REDACTED] Unpublished	The old unprotected study is still valid.			CTGB 23-07-2019:  <b>Acceptable</b> a) GLP compliant: Y b) Guideline compliant: Y EC A.1 methodology used for the melting point (decomposition point). c) Equivalent endpoint: Y It is stated that <i>"The melting point could not be empirically determined due to the extreme hazards associated with pure 1-methylcyclopropene. This is considered acceptable. This data has been previously considered under the first approval, and outlines that the melting point of 1-MCP is &lt; -100°C based upon literature data. The study also reported the melting point, tested according to EEC Method A.1, of the product, SmartFresh,</i>

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										<p>which was determined to decompose &gt;240°C. This data was reported because the active substance technical material was manufactured as SmartFresh when originally considered for the previous approval of 1-MCP. ". Therefore the results indicates the product decomposes at &gt; 240°C, with an melting point &lt;-100°C for the active substance taken from literature. These values are equal to the results found in the study by [REDACTED] (2010).</p> <p>Remark: It is unclear in which form the active substance is manufactured by the applicant [REDACTED].</p>
KCA 2.2/04	[REDACTED]	2010b	Expert Statement: N Manufacturing Use Product – HAIP: Calculation of Vapour Pressure.					No required.  The study was done on MUP-HAIP-intermediate material.		<p>CTGB 24-07-2019:  <b>Acceptable</b> Agree with the applicant, as the study/expert statement is not performed</p>

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The Netherlands (took over the responsibility as RMS from UK)	August 2020	1-Methylcyclopropene	[REDACTED] [REDACTED]	[REDACTED]

			Report No.: C69787 AF-09-112 [REDACTED] [REDACTED] [REDACTED], Unpublished				(4.5% 1-methylcyclopropene complexed with alpha-cyclodextrin in Manufacturing Use Product High Active Ingredient Powder (MUP-HAIP))  The study cannot be protected due to is not conducted under GLP regime			under GLP it cannot have data protection. Therefore this study/statement does not have to be matched.
KCA 2.3/03	[REDACTED]	2010c	Manufacturing Use Product – HAIP: Determination of the Physico-Chemical Property “Appearance (Color, Physical State and Odor)” Report No.: C69800 AF-09-084 [REDACTED] [REDACTED] [REDACTED], unpublished	N			No required.  The study was done on MUP-HAIP-intermediate material.  (4.5% 1-methylcyclopropene complexed with alpha-cyclodextrin in Manufacturing Use Product High Active Ingredient Powder (MUP-HAIP))			CTGB 24-07-2019:  <b>Acceptable</b> The waiver is not found to be acceptable, as no reasoning is provided why it is considered acceptable in view of the applicant to not address this study with an matching study for the determination of the appearance. However, the applicant refers to open (not protected) data from the DAR (2005), also evaluated in the RAR



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The Netherlands (took over the responsibility as RMS from UK)	August 2020	1-Methylcyclopropene	[REDACTED] [REDACTED]	[REDACTED]

										(2018) and found to be acceptable for renewal. Therefore, no further data is required and for data matching reference is made to the study below.
					[REDACTED], [REDACTED]	2002f	Determination of colour and physical state of 1-MCP. Report No.: 823623 AF-01-157 [REDACTED] [REDACTED] [REDACTED] [REDACTED] Unpublished		The old unprotected study is still valid.	CTGB 24-07-2019:  <b>Acceptable</b> a) GLP compliant: Y b) Guideline compliant: n.a. EPA Test Methods used for the appearance. c) Equivalent endpoint: Y It is stated that " <i>Physical State: Gas, Colour: Colourless, Odor: Sharp, light sweetish smell. 1-methylcyclopropene was generated from the formulation.</i> ". As the study by [REDACTED] (2010c), refers to the intermediate product (MUP-HAIP) and this study to the pure active substance, no equivalence can be shown. However, the study has been found acceptable in the DAR

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The Netherlands (took over the responsibility as RMS from UK)	August 2020	1-Methylcyclopropene	[REDACTED] [REDACTED]	[REDACTED]

										(2005) for the active substance and therefore this is considered sufficient in light of this application. Therefore this study has been matched.  Remark: It is unclear in which form the active substance is manufactured by the applicant [REDACTED]. However the applicant has provided a study by [REDACTED]. [REDACTED] (2012) below on their VP product.
					[REDACTED]	2012	CHR/RW/MCP Determination of physicochemical properties of the initial preparation [REDACTED] GLP, Unpublished  VP formulation of 1-MCP was tested in submitted study.	The matching study was submitted.		CTGB 24-07-2019:  <b>Acceptable</b> a) GLP compliant: Y b) Guideline compliant: n.a. Visual c) Equivalent endpoint: Y White h small crystalline powder of slight characteristic odour.
KCA 2.4/06	[REDACTED]	2010d	Manufacturing Product –	Use N HAIP:				No required.		CTGB 24-07-2019:  <b>Acceptable</b>

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The Netherlands (took over the responsibility as RMS from UK)	August 2020	1-Methylcyclopropene	[REDACTED] [REDACTED]	[REDACTED]

			Determination of the IR Spectrum. Report No.: C88564 AF-10-036 [REDACTED] [REDACTED] [REDACTED] Unpublished							The study was done on MUP-HAIP-intermediate material.  (4.5% 1-methylcyclopropene complexed with alpha-cyclodextrin in Manufacturing Use Product High Active Ingredient Powder (MUP-HAIP)			The waiver is not found to be acceptable, as no reasoning is provided why it is considered acceptable in view of the applicant to not address this study with an matching study for the determination of the IR-spectra. However, the applicant refers to open (not protected) data from the DAR (2005), also evaluated in the RAR (2018) and found to be acceptable for renewal. Therefore, no further data is required and for data matching reference is made to the study below.
					[REDACTED]	2002i	Determination of the IR spectrum of 1-MCP. Report No.: 823656 AF-01-161 RCC Ltd, [REDACTED] [REDACTED] [REDACTED] Unpublished			The old unprotected study is still valid.			CTGB 24-07-2019:  <b>Acceptable</b> a) GLP compliant: N Spectra were obtained in a specialist laboratory that did not have GLP status. The study was accepted under the first approval of the active substance and therefore found to be

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										<p>acceptable for data matching.</p> <p>b) Guideline compliant: n.a.</p> <p>IR-spectrometry</p> <p>c) Equivalent endpoint: Y</p> <p>It is stated that “1-methylcyclopropene was generated from the formulation. The peak assignments identified in the IR spectrum support the proposed structure of the active substance.”. As the study by [REDACTED] (2010d), refers to the intermediate product (MUP-HAIP) and this study to the pure active substance, no equivalence can be shown. However, the study has been found acceptable in the DAR (2005) for the active substance and therefore this is considered sufficient in light of this application. Therefore this study has been matched.</p>
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										Remark: It is unclear in which form the active substance is manufactured by the applicant [REDACTED].
KCA 2.4/07	[REDACTED]	2017	GLP Determination of Mass Spectrum of 1-chloromethylpropene (1-CMP) and 3-chloromethylpropene (3-CMP) Report No. AF-16-046 Protocol No. AF-P-16-021 AgroFresh, Inc. Collegeville, PA 19426 USA GLP, Unpublished	N	[REDACTED]	2019	Validation of The Method of analysis used for determination of specified solvents in 1-MCP Technical Material, in Compliance with Good Laboratory Practice.  Study Number: DNA4901	The analysis of mentioned standards were analysed by GC-MS in 5-Batch analysis.		CTGB 24-07-2019:  <b>Acceptable</b> a) GLP compliant: Y b) Guideline compliant: n.a. Mass-spectrometry c) Equivalent endpoint: Y Identity of the two relevant impurities 1-CMP and 3-CMP was confirmed with mass-spectrometry. Therefore the study has been matched.
KCA 2.4/08	[REDACTED]	2017a	1-CMP: Determination of Spectral Characteristics (UV/Vis, ITR, and NMR). Report No. AP-17-007 EAG Study No. 84745 Analytical Bio-Chemistry Laboratories, Inc. Columbia, Missouri, 65201, USA GLP, Unpublished	N	[REDACTED]	2019	Analysis of 1-CMP and 3-CMP ( Reference Standards) to Determine the Spectral Characteristic, in Compliance with Good Laboratory Practice Study number: DNA5338 DNA Laboratory GLP, Unpublished	The study is not required.  The NMR spectrum of relevant impurities are commercially available on Sigma-Aldrich webpage.  4.09.2019 [REDACTED] comment:		CTGB 24-07-2019:  <b>Acceptable (also applicable to KCA 2.4/09)</b> The waiver is not found to be acceptable, as no sufficiently substantiated reasoning is provided why it is considered acceptable in view of the applicant to not address this study with an matching study for the

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The Netherlands (took over the responsibility as RMS from UK)	August 2020	1-Methylcyclopropene	[REDACTED] [REDACTED]	[REDACTED]

										<p>determination of the spectra (UV, IR and <sup>1</sup>H-NMR/<sup>13</sup>C-NMR) for the relevant impurity 1-CMP, as required according to Reg. (EU) 283/2013.</p> <p>Remark: Missing is also a matching study for KCA 2.4/09, Whiting, S. (2017b), 3-CMP: Determination of Spectral Characteristics (UV/Vis, IR, NMR). Report No. AP-17-001 EAG Study No. 84746</p> <p>[REDACTED] [REDACTED] [REDACTED]</p> <p>GLP, Unpublished, Included in the reference table of the renewal.</p> <p>CTGB 02-10-2019:</p> <p><b>Pending.</b> The study plan provides an outline of an adequate test battery: determination of spectral characteristics by</p>
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										<p>UV/VIS, FTIR, NMR, and MS for both 1-CMP and 3-CMP. Potentially, the study report that is to be generated (finalized nov 2019) can be used for matching of both currently unaddressed Annex Points 2.4/08 and 2.4/09. At present however, based on the study plan, no matching can be demonstrated.</p> <p>CTGB 07-01-2019: DNA5338 a) GLP compliant: Y b) Guideline compliant: n.a. UV/VIS (OECD 101) FTIR NMR MS c) Equivalent endpoint: Y Identity of the two relevant impurities 1-CMP and 3-CMP was confirmed with UV/VIS, FTIR, NMR and MS. Therefore the study has been matched.</p>
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KCA 2.5/02	[REDACTED]	2010a	<p>Manufacturing Use Product – HAIP: Determination of the water solubility. Report No.: C74210 AF-09-106 [REDACTED] [REDACTED] [REDACTED] Unpublished</p>	N				<p>No required.</p> <p>The study was done on MUP-HAIP-intermediate material.</p> <p>(4.5% 1-methylcyclopropene complexed with alpha-cyclodextrin in Manufacturing Use Product High Active Ingredient Powder (MUP-HAIP)</p> <p>According to RAR comment:</p> <p>“Data on additional physical, chemical and technical properties of MUP-HAIP have also been submitted. As data on these properties are not required for the renewal of approval of the active substance,</p>		<p>CTGB 24-07-2019:</p> <p><b>Acceptable</b> The waiver is found to be acceptable. Nevertheless, the applicant refers to open (not protected) data from the DAR (2005), also evaluated in the RAR (2018) and found to be acceptable for renewal. Therefore, no further data is required and for data matching reference is made to the study below.</p> <p>Remark: It is unclear in which form the active substance is manufactured by the applicant [REDACTED].</p>
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							nor for establishing the CLP classification of MUP-HAIP, they have been provided separately for information purposes only.”			
					[REDACTED]	2002I	Determination of the water solubility of 1-MCP. Report No.: 830801 AF-01-191 [REDACTED] [REDACTED] [REDACTED] [REDACTED], Unpublished	The old unprotected study is still valid.		CTGB 24-07-2019:  <b>Acceptable</b> a) GLP compliant: Y b) Guideline compliant: N Preferred is EC A.6. In house method (GC) is used, however this has been found acceptable and as stated in the comment “Solubility was determined using acceptable in-house method. The analytical method has been considered in B.5.1.2.7 of the RAR.” c) Equivalent endpoint: Y As the study by [REDACTED], [REDACTED] (2010a), refers to the intermediate product (MUP-HAIP) and this study to the pure active

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The Netherlands (took over the responsibility as RMS from UK)	August 2020	1-Methylcyclopropene	[REDACTED] [REDACTED]	[REDACTED]

										substance, no equivalence can be shown. However, the study has been found acceptable in the DAR (2005) for the active substance and therefore this is considered sufficient in light of this application. Therefore this study has been matched.	
KCA 2.6/02	[REDACTED]	2010b	Manufacturing Use Product – HAIP: Determination of the solubility in organic solvents. Report No.: C74254 AF-09-104 [REDACTED] [REDACTED] [REDACTED] Unpublished	N						<p>No required.</p> <p>The study was done on MUP-HAIP-intermediate material.</p> <p>(4.5% 1-methylcyclopropene complexed with alpha-cyclodextrin in Manufacturing Use Product High Active Ingredient Powder (MUP-HAIP)</p> <p>Please see comment from KCA 2.5/02.</p>	<p>CTGB 24-07-2019:</p> <p><b>Acceptable</b> The waiver is found to be acceptable. Nevertheless, the applicant refers to open (not protected) data from the DAR (2005), also evaluated in the RAR (2018) and found to be acceptable for renewal. Therefore, no further data is required and for data matching reference is made to the study below.</p> <p>Remark: It is unclear in which form the active substance is manufactured by the applicant [REDACTED].</p>

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				[REDACTED]	2002m	Determination of the solubility of 1-MCP in organic solvents Report No.: 830812 AF-01-189 [REDACTED] [REDACTED] [REDACTED], Unpublished	The old unprotected study is still valid.			CTGB 24-07-2019: <b>Acceptable</b> a) GLP compliant: Y b) Guideline compliant: n.a. In house shake flask method (GC) is used, however this has been found acceptable and as stated in the comment “Solubility was determined using same in-house method as for water solubility. The analytical method has been considered in B.5.1.2.7 of the RAR.” c) Equivalent endpoint: Y As the study by [REDACTED] (2010b), refers to the intermediate product (MUP-HAIP) and this study to the pure active substance, no equivalence can be shown. However, the study has been found acceptable in the DAR (2005) for the active substance and therefore this is considered
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**MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF 1-Methylcyclopropene (confidential)**

Rapporteur Member State	Month and year	Active Substance <sup>2</sup> (Name)	Notifier	Applicant
The Netherlands (took over the responsibility as RMS from UK)	August 2020	1-Methylcyclopropene	[REDACTED] [REDACTED]	[REDACTED]

											sufficient in light of this application. Therefore this study has been matched.
KCA 2.7/02	[REDACTED]	2010c	Manufacturing Use Product – HAIP: Determination of the partition coefficient (n-octanol / water). Report No.: C74232 AF-09-105 [REDACTED] [REDACTED] [REDACTED] Unpublished	N				No required.  The study was done on MUP-HAIP-intermediate material.  (4.5% 1-methylcyclopropene complexed with alpha-cyclodextrin in Manufacturing Use Product High Active Ingredient Powder (MUP-HAIP) Please see comment from KCA 2.5/02.			CTGB 24-07-2019:  <b>Acceptable</b> The waiver is found to be acceptable. Nevertheless, the applicant refers to open (not protected) data from the DAR (2005), also evaluated in the RAR (2018) and found to be acceptable for renewal. Therefore, no further data is required and for data matching reference is made to the study below.  Remark: It is unclear in which form the active substance is manufactured by the applicant [REDACTED]
					[REDACTED]	2001e	Determination of the partition coefficient (n-octanol/water) of 1-MCP formulation. Report No.: 794125 APR-01-014 RCC Ltd,	The old unprotected study is valid.			CTGB 24-07-2019:  <b>Acceptable</b> a) GLP compliant: Y b) Guideline compliant: Y EC A.8 methodology (HPLC)

**MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF 1-Methylcyclopropene (confidential)**

Rapporteur Member State	Month and year	Active Substance <sup>2</sup> (Name)	Notifier	Applicant
The Netherlands (took over the responsibility as RMS from UK)	August 2020	1-Methylcyclopropene	[REDACTED] [REDACTED]	[REDACTED]

							[REDACTED] [REDACTED] [REDACTED] [REDACTED] Unpublished				c) Equivalent endpoint: Y As the study by [REDACTED] (2010c), refers to the intermediate product (MUP-HAIP) and this study to the pure active substance, no equivalence can be shown. However, the study has been found acceptable in the DAR (2005) for the active substance and therefore this is considered sufficient in light of this application. Therefore this study has been matched.
KCA 2.8/01	[REDACTED]	2010e	Manufacturing Use Product – HAIP: Determination of the dissociation constant in water. Report No.: C74221 AF-09-103 [REDACTED] [REDACTED] [REDACTED] [REDACTED] Unpublished	N				No required. 1-MCP in as unsaturated aliphatic hydrocarbon and it does not contains functional groups capable of dissociation.  The study was done on MUP-HAIP-intermediate material.			CTGB 24-07-2019:  <b>Acceptable</b> The waiver is found to be acceptable. Furthermore, this has also been concluded in the DAR (2005). Therefore, no further data is required for data matching.

**MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF 1-Methylcyclopropene (confidential)**

Rapporteur Member State	Month and year	Active Substance <sup>2</sup> (Name)	Notifier	Applicant
The Netherlands (took over the responsibility as RMS from UK)	August 2020	1-Methylcyclopropene	[REDACTED] [REDACTED]	[REDACTED]

								(4.5% 1-methylcyclopropene complexed with alpha-cyclodextrin in Manufacturing Use Product High Active Ingredient Powder (MUP-HAIP) Please see comment from KCA 2.5/02.			
KCA 2.9/02	[REDACTED]	2010f	Manufacturing Use Product – HAIP: determination of the physico-chemical property “flammability”. Report No.: C74243 AF-10-023 [REDACTED] [REDACTED] [REDACTED] [REDACTED] Unpublished	N				No required.  The study was done on MUP-HAIP-intermediate material.  (4.5% 1-methylcyclopropene complexed with alpha-cyclodextrin in Manufacturing Use Product High Active Ingredient Powder (MUP-HAIP)  Additionally, the flash point is only relevant to substances with a			CTGB 24-07-2019:  <b>Acceptable</b> The waiver is found to be acceptable. Nevertheless, the applicant refers to open (not protected) data from the DAR (2005), also evaluated in the RAR (2018) and found to be acceptable for renewal and a new study provided by the applicant. Therefore, no further data is required and for data matching reference is made to the studies below.  Remark:

**MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF 1-Methylcyclopropene (confidential)**

Rapporteur Member State	Month and year	Active Substance <sup>2</sup> (Name)	Notifier	Applicant
The Netherlands (took over the responsibility as RMS from UK)	August 2020	1-Methylcyclopropene	[REDACTED] [REDACTED]	[REDACTED]

							melting point below 40 oC. MUP-HAIP is a solid $\geq 40$ oC; the flash point is therefore not relevant.			It is unclear in which form the active substance is manufactured by the applicant [REDACTED]. However the applicant has provided a study by [REDACTED] (2012) below on their VP-product.
				[REDACTED]	2012	CHR/RW/MCP Determination of relative self-ignition temperature, flammability and oxidizing properties.  VP formulation of 1-MCP was tested in submitted study.	The matching study was submitted.			CTGB 24-07-2019:  <b>Acceptable</b> a) GLP compliant: Y b) Guideline compliant: Y EC A.10 (flammability for solids) has been used, as tested on the VP-product (solid). c) Equivalent endpoint: Y Test item (VP-product) is not highly flammable.
				[REDACTED]	2000	Process safety test results and interpretation for methylcyclopropene. Report No.: R/2685A/0800/PE RO2685AR 00RC-1033 [REDACTED], [REDACTED]	The old unprotected study is still valid.			CTGB 24-07-2019:  <b>Acceptable</b> a) GLP compliant: [REDACTED] [REDACTED] was concluded in the DAR (2005) and RAR (2018) that the study was not conducted to GLP but was carried out by a specialist laboratory. As

**MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF 1-Methylcyclopropene (confidential)**

Rapporteur Member State	Month and year	Active Substance <sup>2</sup> (Name)	Notifier	Applicant
The Netherlands (took over the responsibility as RMS from UK)	<b>August 2020</b>	<b>1-Methylcyclopropene</b>	[Redacted]	[Redacted]

							[Redacted], [Redacted] Unpublished			<p>this was considered acceptable, this has also been found acceptable for data matching.</p> <p>b) Guideline compliant: N The preferred methodology is EC A.11, however measured with ASTM Method E681, 1985. As this was considered acceptable in the DAR (2005) and RAR (2018), it is considered acceptable for data matching.</p> <p>c) Equivalent endpoint: Y As the study by [Redacted] (2010f), refers to the intermediate product (MUP-HAIP) and this study to the pure active substance, no equivalence can be shown. However, the study has been found acceptable in the DAR (2005) for the active substance and therefore this is considered sufficient in light of this application. Therefore this study has been matched.</p>
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**MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF 1-Methylcyclopropene (confidential)**

Rapporteur Member State	Month and year	Active Substance <sup>2</sup> (Name)	Notifier	Applicant
The Netherlands (took over the responsibility as RMS from UK)	August 2020	1-Methylcyclopropene	[REDACTED] [REDACTED]	[REDACTED]

KCA 2.9/03	[REDACTED]	2010g	Manufacturing Use Product – HAIP: determination of the physico-chemical property “relative self-ignition temperature”. Report No.: C69743 AF-09-077 [REDACTED] [REDACTED] [REDACTED] Unpublished	N				No required.  The study was done on MUP-HAIP-intermediate material.  (4.5% 1-methylcyclopropene complexed with alpha-cyclodextrin in Manufacturing Use Product High Active Ingredient Powder (MUP-HAIP)			CTGB 24-07-2019:  <b>Acceptable</b> The waiver is not found to be acceptable, as no reasoning is provided why it is considered acceptable in view of the applicant to not address this study with an matching study for the determination of the self-heating. However, the applicant refers to a new study below. It should be mentioned that the original study by [REDACTED] (2000) evaluated in the DAR (2005), on the active substance, is also found to be acceptable in the RAR (2018), although the applicant did not make reference to this study. The conclusion above KCA 2.9/02 is also applicable to this study and as such the study has been matched.  Remark:
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**MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF 1-Methylcyclopropene (confidential)**

Rapporteur Member State	Month and year	Active Substance <sup>2</sup> (Name)	Notifier	Applicant
The Netherlands (took over the responsibility as RMS from UK)	August 2020	1-Methylcyclopropene	[REDACTED] [REDACTED]	[REDACTED]

										It is unclear in which form the active substance is manufactured by the applicant [REDACTED]. However the applicant has provided a study by [REDACTED] (2012) below on their VP-product.
					[REDACTED]	2012	CHR/RW/MCP Determination of relative self-ignition temperature, flammability and oxidizing properties.  VP formulation of 1-MCP was tested in submitted study.	The matching study was submitted.		CTGB 24-07-2019:  <b>Acceptable</b> a) GLP compliant: Y b) Guideline compliant: Y EC A.16 (self-heating for solids) has been used, as tested on the VP-product (solid). c) Equivalent endpoint: Y Test item (VP-product) is not self-heating.
KCA 2.11/01	[REDACTED] [REDACTED] [REDACTED]	2010	Manufacturing Use Product –HAIP: determination of explosive properties. Report No.: 3061/0001 AF-09-111 [REDACTED] [REDACTED] [REDACTED] Unpublished	N				No required.  The study was done on MUP-HAIP-intermediate material.  (4.5% 1-methylcyclopropene complexed with alpha-cyclodextrin in		CTGB 24-07-2019:  <b>Acceptable</b> The waiver is not found to be acceptable, as no reasoning is provided why it is considered acceptable in view of the applicant to not address this study with an matching study for the determination of the

**MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF 1-Methylcyclopropene (confidential)**

Rapporteur Member State	Month and year	Active Substance <sup>2</sup> (Name)	Notifier	Applicant
The Netherlands (took over the responsibility as RMS from UK)	August 2020	1-Methylcyclopropene	[REDACTED] [REDACTED]	[REDACTED]

								Manufacturing Use Product High Active Ingredient Powder (MUP-HAIP)			<p>explosive properties. However, the applicant refers to a new study below. It should be mentioned that in the DAR (2005), no evaluation has been made on the explosive properties of the active substance, as stated “<i>Explosivity classification does not apply to gases as the overriding classification is flammability. All flammable gases if contained and given an ignition source will form explosive mixtures with air.</i>”. However, as no evaluation was mentioned by the RMS in the RAR (2018), a final conclusion on the explosive properties of the active substance seem to be lacking, therefore no further data is required for data matching and as such the data has been matched.</p> <p>Remark:</p>
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**MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF 1-Methylcyclopropene (confidential)**

Rapporteur Member State	Month and year	Active Substance <sup>2</sup> (Name)	Notifier	Applicant
The Netherlands (took over the responsibility as RMS from UK)	August 2020	1-Methylcyclopropene	[REDACTED] [REDACTED]	[REDACTED]

										It is unclear in which form the active substance is manufactured by the applicant [REDACTED]. However the applicant has provided a study by [REDACTED] (2012) below on their VP-product.
					[REDACTED]	2012	CHR/RW/MCP Determination of explosive properties Study code: BW-02/13  VP formulation of 1-MCP was tested in submitted study.	The matching study was submitted.		CTGB 24-07-2019:  <b>Acceptable</b> a) GLP compliant: Y b) Guideline compliant: Y EC A.14 (explosive properties for solids) has been used, as tested on the VP-product (solid). c) Equivalent endpoint: Y Test item (VP-product) does not have explosive properties.
KCA 2.13/02	[REDACTED]	2010h	Manufacturing Use Product – HAIP: determination of the oxidizing properties Report No.: C69765 AF-09-110 [REDACTED] [REDACTED]	N				No required.  The study was done on MUP-HAIP-intermediate material.  (4.5% 1-methylcyclopropene		CTGB 24-07-2019:  <b>Acceptable</b> The waiver is not found to be acceptable, as no reasoning is provided why it is considered acceptable in view of the applicant to not address this study with

**MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF 1-Methylcyclopropene (confidential)**

Rapporteur Member State	Month and year	Active Substance <sup>2</sup> (Name)	Notifier	Applicant
The Netherlands (took over the responsibility as RMS from UK)	August 2020	1-Methylcyclopropene	[REDACTED] [REDACTED]	[REDACTED]

								<p>complexed with alpha-cyclodextrin in Manufacturing Use Product High Active Ingredient Powder (MUP-HAIP)</p>		<p>an matching study for the determination of the oxidising properties. However, the applicant refers to a new study below. It should be mentioned that the original study by [REDACTED] (2000) evaluated in the DAR (2005), on the active substance, is also found to be acceptable in the RAR (2018), although the applicant did not make reference to this study. The conclusion is also applicable to this study and as such the study has been matched.</p> <p>Remark: It is unclear in which form the active substance is manufactured by the applicant [REDACTED]. However the applicant has provided a study by [REDACTED] (2012) below on their VP-product.</p>
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**MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF 1-Methylcyclopropene (confidential)**

Rapporteur Member State	Month and year	Active Substance <sup>2</sup> (Name)	Notifier	Applicant
The Netherlands (took over the responsibility as RMS from UK)	August 2020	1-Methylcyclopropene	[REDACTED] [REDACTED]	[REDACTED]

						2012	CHR/RW/MCP Determination of relative self-ignition temperature, flammability and oxidizing properties.  VP formulation of 1-MCP was tested in submitted study.	The matching study was submitted.			CTGB 24-07-2019:  <b>Acceptable</b> a) GLP compliant: Y b) Guideline compliant: Y EC A.147(oxidising properties for solids) has been used, as tested on the VP-product (solid). c) Equivalent endpoint: Y Test item (VP-product) does not have oxidising properties.
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**A.5. METHODS OF ANALYSIS**

KCA 4.1.1/05	[REDACTED]	2007	GLP Validation of the GC/FID Method for the Determination of 1-MCP in SmartFresh™ and Formulations using cis-2-Butene as a Calibration / Internal Standard [REDACTED], [REDACTED] [REDACTED] Report No. AF-06-078 AF-P-06-13 GLP, Unpublished	N				The study is not required.  The active content was determined using CIPAC method 767/VP/M3. This method has been validated for vapour releasing products. As such validation data are not required.  RMS comment from RAR:			CTGB 24-07-2019:  <b>Acceptable</b> The waiver is found to be acceptable, as the determination of the content of the active substance 1-MCP in the vapour releasing product is an CIPAC method 767/VP/M, no further validation data is required, therefore the applicant can refer to this open data
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**MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF 1-Methylcyclopropene (confidential)**

Rapporteur Member State	Month and year	Active Substance <sup>2</sup> (Name)	Notifier	Applicant
The Netherlands (took over the responsibility as RMS from UK)	August 2020	1-Methylcyclopropene	[REDACTED] [REDACTED]	[REDACTED]

								<i>The method outlined in the study (method 'AF-06-076') is a CIPAC method (767/VP/M/3) intended for determination of 1-MCP content in vapour releasing products. As the method is a CIPAC method further validation data is not required.</i>		(method) and as such the study has been matched.
KCA 4.1.1(b)/01	Verona, D.	2009	1-Methylcyclopropene Impurities – GC Method. Report No.: CIPAC/4667/m [REDACTED] [REDACTED] [REDACTED] Not GLP, Unpublished	N				The study is not required.  CHR/RW/MCP contains 2 relevant impurities 1-CMP and 3-CMP. CIPAC method 767 is available and used for determination 1-CMP and 3-CMP in CHR/RW/MCP.		CTGB 24-07-2019:  <b>Acceptable</b> The waiver is found to be acceptable, as the determination of the content of the relevant impurities 1-CMP and 3-CMP in the vapour releasing product is an CIPAC method 767/VP/M/4 (information sheet number 282), no further validation data is required, therefore the applicant can refer to this

**MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF 1-Methylcyclopropene (confidential)**

Rapporteur Member State	Month and year	Active Substance <sup>2</sup> (Name)	Notifier	Applicant
The Netherlands (took over the responsibility as RMS from UK)	August 2020	1-Methylcyclopropene	[REDACTED] [REDACTED]	[REDACTED]

								The method details are consistent with those of CIPAC Method '767/VP/M/4'. As the method is a CIPAC method further validation data is not required.			open data (method) and as such the study has been matched.
CA 4.1.1/01	[REDACTED]	2014d	Method Validation [REDACTED] Study nr. IMB0063 [REDACTED] Study nr. AGR 4958 GLP, Not published	N				Please see point KCA 4.1.1(b) /01 and KCA 4.1.1/05			CTGB 24-07-2019:  <b>Acceptable</b> Point covered under KCA 4.1.1/05 and KCA 4.1.1(b)/01.
KCA 4.1.2	-	2011	A 14-day oral (dietary) palatability and range-finding toxicity study of manufacturing use product - haip (1-methylcyclopropene) in sprague dawley rats Report No.: '08RC-149' GLP, unpublished	Y				If the original study is required, the validation will be repurchased.			CTGB 24-07-2019:  <b>Acceptable</b> Point covered under KCA 4.1.1/05 and KCA 4.1.1(b)/01. CTGB 24-07-2019:  Data matching for pre-registration methods is very (practically) difficult to determine and therefore not considered required, as
KCA 4.1.2	-	2012	A 90-day (dietary) toxicity study of manufacturing use product-haip (1-	Y				If the original study is required, the			



**MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF 1-Methylcyclopropene (confidential)**

Rapporteur Member State	Month and year	Active Substance <sup>2</sup> (Name)	Notifier	Applicant
The Netherlands (took over the responsibility as RMS from UK)	August 2020	1-Methylcyclopropene	[REDACTED] [REDACTED]	[REDACTED]

			methylcyclopropene) in rats Report No.: 08RC-150 DR-0380-8911-010 20120517165324 51133-27-1 GLP, unpublished					validation will be repurchased.			only the studies (in which these methods are used to determine the end-point(s)) should be matched. The analytical methods, used in these studies, should however be validated according to SANCO/3029/99 rev. 4 and GLP compliant. Therefore if the study is matched and the method is validated and GLP compliant it is considered that the pre-registration method is matched.
KCA 4.1.2(c)/ 03	[REDACTED]	2009	Development and Validation of a GC-FID Method for the Determination of 1-MCP Concentration in Diet Admix Formulations, [REDACTED] Report No.: WIL-91054. 08RC-040, GLP, Unpublished	N				The following studies were submitted by the applicant and include validation data for methods of analysis used in support of vertebrate toxicological studies.  The study is not required as the original study is not required.			Reference is made to the studies in the sections for which these analytical pre-registration methods are used (Residues, Toxicology, Fate and behaviour, Eco-toxicology, Physical and Chemical properties and Efficacy).
KCA 4.1.2(f)/ 01	[REDACTED]	2015	Manufacturing Use Product – High Active Ingredient Powder (MUP-HAIP) containing the active ingredient 1-methylcyclopropene (1-MCP) : A 7-day renewal toxicity test with	N	[REDACTED],	2013	1-Methylcyclopropene: Validation of an Analytical Procedure for use in Ecotoxicology Studies ([REDACTED]) Study Number 3200160 GLP, unpublished	The matching study was submitted.  Determination of concentrations of 1-MCP in air, was quantified by GC using FID			

**MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF 1-Methylcyclopropene (confidential)**

Rapporteur Member State	Month and year	Active Substance <sup>2</sup> (Name)	Notifier	Applicant
The Netherlands (took over the responsibility as RMS from UK)	August 2020	1-Methylcyclopropene	[REDACTED] [REDACTED]	[REDACTED]

			duckweed (lemna gibba G3).					detection, based on methodology validated at [REDACTED] according to study number 3200160.			
KCA 4.1.2	[REDACTED]	2010a	Manufacturing use product - HAIP: determination of the water solubility Report No.: C74210 AF-09-106 [REDACTED] [REDACTED] [REDACTED] GLP, unpublished	N				The following studies were submitted by the applicant and include validation data for methods of analysis used in support of physical-chemical studies.  The study is not required as the original study is not required.			
KCA 4.2 (a)/03	[REDACTED]	2004	14C-1-METHYLCYCLOPROPENE (1-MCP) AVOCADO RESIDUE STUDY Report No.: AF-03-056 AF-P-03-02 [REDACTED] [REDACTED]	N				The study is not required. FruitSmart is not registered in avocado.			

**MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF 1-Methylcyclopropene (confidential)**

Rapporteur Member State	Month and year	Active Substance <sup>2</sup> (Name)	Notifier	Applicant
The Netherlands (took over the responsibility as RMS from UK)	August 2020	1-Methylcyclopropene	[REDACTED] [REDACTED]	[REDACTED]

			USA GLP, unpublished Doc. No.: 611-002								
KCA 4.2(c) /02	[REDACTED]	2011	GLP Validation of GC/MS confirmatory method for the determination of 1-methylcyclopropene (1-MCP) in air using isobutylene as an external standard. Report No.: AF-11-143 AF-P-11-29 [REDACTED] [REDACTED], [REDACTED], [REDACTED], Unpublished	N	[REDACTED],	2013	1-Methylcyclopropene: Validation of an Analytical Method for the Determination of Residues in Air [REDACTED] [REDACTED] Study Number 3200155 GLP, unpublished	The matching study was submitted.			CTGB 24-07-2019:  <b>Acceptable</b> a) GLP compliant: Y b) Guideline compliant: N Although it is not stated to which guidance document the analytical method has been validated, it is considered acceptable as the study by [REDACTED] (2011) to be matched is not (fully) acceptable. c) Equivalent endpoint: N The analytical method determines the content 1-MCP in air with an LOQ of 0.31 mg/m <sup>3</sup> , which is not sufficient low enough for the target AOEL of 0.03 mg/m <sup>3</sup> . However, this is considered acceptable as the study by [REDACTED] (2011) to be matched is not (fully) acceptable.  Remark: The primary method in study by [REDACTED] (2002)

**MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF 1-Methylcyclopropene (confidential)**

Rapporteur Member State	Month and year	Active Substance <sup>2</sup> (Name)	Notifier	Applicant
The Netherlands (took over the responsibility as RMS from UK)	August 2020	1-Methylcyclopropene	[REDACTED] [REDACTED]	[REDACTED]

										evaluated in the DAR (2005) and RAR (2018) is found to be acceptable, see below. Therefore the it can be concluded that the availability of an monitoring/enforcement method for 1-MCP in air is addressed and considered sufficient.
					[REDACTED]	2002	Validation of the analytical method for determining 1-methylcyclopropene in air. Report No.: 1507.00 TD2002-005 [REDACTED] [REDACTED] [REDACTED] Unpublished	Old unprotected study is valid.		CTGB 24-07-2019:  <b>Acceptable</b> a) GLP compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y It was concluded in the RAR (2018) that “ <i>The method was previously considered and accepted for the first approval of 1-MCP, and is considered to be valid and acceptable for the renewal of approval.</i> ”. Therefore, the study has been matched.  Remark: It should be mentioned that the study by [REDACTED] (2011), was intended to be

**MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF 1-Methylcyclopropene (confidential)**

Rapporteur Member State	Month and year	Active Substance <sup>2</sup> (Name)	Notifier	Applicant
The Netherlands (took over the responsibility as RMS from UK)	August 2020	1-Methylcyclopropene	[REDACTED] [REDACTED]	[REDACTED]

											used as confirmatory method for the original method (in study by [REDACTED], [REDACTED] (2002). However, a data gap was set for the LOQ, being too high for the AOEL in the study by Guo, I. (2011). Therefore the study does not have to be matched as it is considered not (fully) acceptable.
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**A.6. TOXICOLOGY AND METABOLISM DATA**

								Reason for equivalence / justification for non-provision	Cat 4 data? Y/N	Submission deadline	RMS conclusion
KCA 5.1.1/01	-	2011	TOXICOKINETICS AND METABOLISM OF 14C-1-MCP (1-METHYLCYCLOPROPENE) IN RAT Report No.: 06RC-157 RPT02083 07000 DR-0428-9070-002 20110408165448	Y				Yes, the study is necessary. After confirmation by RMS the study will repurchased from original owner.  Nevertheless, the inhalation study was submitted during the inclusion on Annex I .	N		Matching required, applicant has to demonstrate access to this vertebrate study.

**MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF 1-Methylcyclopropene (confidential)**

Rapporteur Member State	Month and year	Active Substance <sup>2</sup> (Name)	Notifier	Applicant
The Netherlands (took over the responsibility as RMS from UK)	August 2020	1-Methylcyclopropene	[REDACTED] [REDACTED]	[REDACTED]

							As the 1-MCP is a gas, the inhalation is the best route of administration in relation to expected human use or exposure. According to OECD 417:  Other routes of administration, such as dermal and inhalation, (see paragraphs 74-78) may be applicable for certain chemicals, considering their physico-chemical properties and the expected human use or exposure.			
KCA 5.2.1/01		2009a	1-MCP: MANUFACTURING USE PRODUCT: ACUTE ORAL TOXICITY STUDY (UP- AND-DOWN PROCEDURE) IN RATS	Y			Not required.  According to RMS comment from RAR: MUO-HAIP was used	N		Agreed with the argumentation provided; no matching required.

**MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF 1-Methylcyclopropene (confidential)**

Rapporteur Member State	Month and year	Active Substance <sup>2</sup> (Name)	Notifier	Applicant
The Netherlands (took over the responsibility as RMS from UK)	August 2020	1-Methylcyclopropene	[REDACTED] [REDACTED]	[REDACTED]

		(AMENDED FINAL REPORT) Report No.: G6799 G6799-AOR					<p>due to the difficulties of testing 1-MCP, a gas at room temperature. These studies have been submitted for the renewal of 1-MCP in order to support an future developments of <b>new higher concentration formulations</b>.</p> <p>Chemiro's representative formulation AppleSmart ( FruitSmart ) is containing 3.3% of 1-MCP.</p> <p>[REDACTED] has access to mentioned study:</p> <p>2001,</p>			
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**MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF 1-Methylcyclopropene (confidential)**

Rapporteur Member State	Month and year	Active Substance <sup>2</sup> (Name)	Notifier	Applicant
The Netherlands (took over the responsibility as RMS from UK)	August 2020	1-Methylcyclopropene	[REDACTED] [REDACTED]	[REDACTED]

								1-Methylcyclopropene Alpha-Cyclodextrin Complex (3,3% a.i.) Acute Oral Toxicity Study in Male and Female Rats , Lab Project Number: OOP- 100-00R-199 GLP, unpublished			
				2001b	-	1- METHYLCYCLOPROPENE ALPHA-CYCLODEXTRIN COMPLEX (3.3% A.I.) - ACUTE ORAL TOXICITY STUDY IN MALE AND FEMALE RATS Report No.: OOR-199 OOP-199 GLP, unpublished	The old unprotected study is still valid.			Agreed as alternative study. The study not included in RAR, but is available for the applicant at product level.	
KCA 5.2.2/01		2009b	1-MCP: MANUFACTURING USE PRODUCT: ACUTE DERMAL TOXICITY STUDY IN RATS (AMENDED FINAL REPORT) Report No.: G6800 G6800-ADR		Y		Not required.  According to RMS comment from RAR: MUP-HAIP was used due to the difficulties of testing 1-MCP, a gas at room temperature. These studies have			Agreed with the argumentation provided; no matching required.	



**MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF 1-Methylcyclopropene (confidential)**

Rapporteur Member State	Month and year	Active Substance <sup>2</sup> (Name)	Notifier	Applicant
The Netherlands (took over the responsibility as RMS from UK)	August 2020	1-Methylcyclopropene	[REDACTED] [REDACTED]	[REDACTED]

								<p>been submitted for the renewal of 1-MCP in order to support an future developments of new higher concentration formulations.</p> <p>Chemirol's representative formulation AppleSmart ( FruitSmart ) is containing 3.3% of 1-MCP.</p> <p>PUH Chemirol has access to mentioned study: 2001, 1-Methylcyclopropene Alpha-Cyclodextrin Complex (3,3% a.i.) Acute Dermal Toxicity Study in Male and Female Rats , Lab</p>			
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**MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF 1-Methylcyclopropene (confidential)**

Rapporteur Member State	Month and year	Active Substance <sup>2</sup> (Name)	Notifier	Applicant
The Netherlands (took over the responsibility as RMS from UK)	August 2020	1-Methylcyclopropene	[REDACTED] [REDACTED]	[REDACTED]

								Project Number: OOP-200-00R-200 GLP, unpublished			
					2000a	-	1-METHYLCYCLOPROPENE ALPHA-CYCLODEXTRIN COMPLEX (3.3% A.I.) - ACUTE DERMAL TOXICITY STUDY IN MALE AND FEMALE RATS Report No.: OOR-200 OOP-200 GLP, unpublished	The old unprotected study is still valid.			Agreed as alternative study. The study not included in RAR, but is available for the applicant at product level.
KCA 5.2.3/02		2010a	MANUFACTURING USE Y PRODUCT - HAIP (1-METHYLCYCLOPROPENE): ACUTE INHALATION TOXICITY STUDY IN RATS Report No.: 30311 100137					Not required.  According to RMS comment from RAR: MUP-HAIP was used due to the difficulties of testing 1-MCP, a gas at room temperature. These studies have been submitted for the renewal of 1-MCP in order to support an future developments of new higher			Agreed with the argumentation provided; no matching required.

**MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF 1-Methylcyclopropene (confidential)**

Rapporteur Member State	Month and year	Active Substance <sup>2</sup> (Name)	Notifier	Applicant
The Netherlands (took over the responsibility as RMS from UK)	August 2020	1-Methylcyclopropene	[REDACTED] [REDACTED]	[REDACTED]

								concentration formulations. [REDACTED] representative formulation AppleSmart ( FruitSmart ) is containing 3.3% of 1-MCP. [REDACTED] has access to mentioned study:  <i>2001, 1-Methylcyclopropene Alpha-Cyclodextrin Complex (3,3% a.i.) Acute Inhalation Toxicity Study in Rats , Lab Project Number: OOP-180-00R-180 GLP, unpublished</i>			
				2001	-	1-METHYLCYCLOPROPENE - ACUTE INHALATION TOXICITY STUDY IN RATS	The old unprotected study is still valid.				Agreed as alternative study. The study not included in RAR, but is

**MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF 1-Methylcyclopropene (confidential)**

Rapporteur Member State	Month and year	Active Substance <sup>2</sup> (Name)	Notifier	Applicant
The Netherlands (took over the responsibility as RMS from UK)	August 2020	1-Methylcyclopropene	[REDACTED] [REDACTED]	[REDACTED]

					Report No.: OOR-180A OOP-180 GLP, unpublished				available for the applicant at product level.
KCA 5.2.4/01		2010b	MANUFACTURING USE Y PRODUCT - HAIP (1- METHYLCYCLOPROPENE): PRIMARY SKIN IRRITATION STUDY IN RABBITS (REVISED REPORT) Report No.: 090596 28876 DR-0380- 8911-008 20100212091355 51133- 27-2				Not required.  According to RMS comment from RAR: MUP-HAIP was used due to the difficulties of testing 1-MCP, a gas at room temperature. These studies have been submitted for the renewal of 1-MCP in order to support an future developments of new higher concentration formulations.  [REDACTED] representative formulation AppleSmart ( FruitSmart ) is containing 3.3% of 1- MCP..		Agreed with the argumentation provided; no matching required.

**MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF 1-Methylcyclopropene (confidential)**

Rapporteur Member State	Month and year	Active Substance <sup>2</sup> (Name)	Notifier	Applicant
The Netherlands (took over the responsibility as RMS from UK)	August 2020	1-Methylcyclopropene	[REDACTED] [REDACTED]	[REDACTED]

								[REDACTED] has access to mentioned study:  2001, 1-Methylcyclopropene Alpha-Cyclodextrin Complex (3,3% a.i.) Skin Irritation Study in Rabbits, Lab Project Number: 00P-201-00R-201 GLP, unpublished			
				2001	-	1-Methylcyclopropene Alpha-Cyclodextrin Complex (3,3% a.i.) Skin Irritation Study in Rabbits, Lab Project Number: 00P-201-00R-201 GLP, unpublished	The old unprotected study is still valid				Agreed as alternative study. The study not included in RAR, but is available for the applicant at product level.
KCA 5.2.5/01		2010c	MANUFACTURING USE Y PRODUCT - HAIP (1- METHYLCYCLOPROPENE): PRIMARY EYE IRRITATION STUDY IN RABBITS (REVISED REPORT) Report				Not required.  According to RMS comment from RAR: MUP-HAIP was used				Agreed with the argumentation provided; no matching required.

**MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF 1-Methylcyclopropene (confidential)**

Rapporteur Member State	Month and year	Active Substance <sup>2</sup> (Name)	Notifier	Applicant
The Netherlands (took over the responsibility as RMS from UK)	August 2020	1-Methylcyclopropene	[REDACTED] [REDACTED]	[REDACTED]

		No.: 090597 28875 DR-0380-8911-009 20100212091355 51133-27-2			due to the difficulties of testing 1-MCP, a gas at room temperature. These studies have been submitted for the renewal of 1-MCP in order to support an future developments of new higher concentration formulations.  [REDACTED] representative formulation AppleSmart ( FruitSmart ) is containing 3.3% of 1-MCP.  [REDACTED] has access to mentioned study:  2001,			
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**MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF 1-Methylcyclopropene (confidential)**

Rapporteur Member State	Month and year	Active Substance <sup>2</sup> (Name)	Notifier	Applicant
The Netherlands (took over the responsibility as RMS from UK)	August 2020	1-Methylcyclopropene	[REDACTED] [REDACTED]	[REDACTED]

								1-Methylcyclopropene Alpha-Cyclodextrin Complex (3,3% a.i.) Eye Irritation Study in Rabbits, Lab Project Number: 00P-202-00R- 202 GLP, unpublished			
				2001	-	1-Methylcyclopropene Alpha-Cyclodextrin Complex (3,3% a.i.) Eye Irritation Study in Rabbits, Lab Project Number: 00P-202-00R- 202 GLP, unpublished	The old unprotected study is still valid				Agreed as alternative study. The study not included in RAR, but is available for the applicant at product level.
KCA 5.2.6/01		2010	MANUFACTURING USE Y PRODUCT - HAIP (1- METHYLCYCLOPROPENE): LOCAL LYMPH NODE ASSAY IN CBA/J MICE Report No.: 091146				Not required.  According to RMS comment from RAR: MUP-HAIP was used due to the difficulties of testing 1-MCP, a gas at room temperature. These studies have been submitted for the renewal of 1-MCP				Agreed with the argumentation provided; no matching required.

**MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF 1-Methylcyclopropene (confidential)**

Rapporteur Member State	Month and year	Active Substance <sup>2</sup> (Name)	Notifier	Applicant
The Netherlands (took over the responsibility as RMS from UK)	August 2020	1-Methylcyclopropene	[REDACTED] [REDACTED]	[REDACTED]

								<p>in order to support an future developments of new higher concentration formulations.</p> <p>[REDACTED] representative formulation AppleSmart ( FruitSmart ) is containing 3.3% of 1-MCP.</p> <p>[REDACTED] has access to mentioned study:</p> <p>2001, 1-Methylcyclopropene Alpha-Cyclodextrin Complex (3,3% a.i.) Dermal Sensitization Study in Guinea Pigs Maximization Test, Lab Project Number: 00P-203-00R-203</p>			
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**MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF 1-Methylcyclopropene (confidential)**

Rapporteur Member State	Month and year	Active Substance <sup>2</sup> (Name)	Notifier	Applicant
The Netherlands (took over the responsibility as RMS from UK)	August 2020	1-Methylcyclopropene	[REDACTED] [REDACTED]	[REDACTED]

								GLP, unpublished			
					2001	-	1-Methylcyclopropene Alpha-Cyclodextrin Complex (3,3% a.i.) Dermal Sensitization Study in Guinea Pigs Maximization Test, Lab Project Number: OOP- 203-00R-203 GLP, unpublished	The old unprotected study is still valid.			Agreed as alternative study. The study not included in RAR, but is available for the applicant at product level.
KCA 5.3.1/01		2011	A 14-DAY ORAL (DIETARY) Y PALATABILITY AND RANGE-FINDING TOXICITY STUDY OF MANUFACTURING USE PRODUCT - HAIP (1- METHYLCYCLOPROPENE) IN SPRAGUE DAWLEY RATS Report No.: WIL- 91072 08RC-149					The study is not required.  [REDACTED] representative formulation AppelSmart ( FriutSmart ) containing 3.3% of 1- MCP.  The old unprotected 2-week inhalation toxicity study in female rats study is still valid ( 2001a, Lab			No matching required as study is a range-finding study which is not critical to derive an endpoint.

**MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF 1-Methylcyclopropene (confidential)**

Rapporteur Member State	Month and year	Active Substance <sup>2</sup> (Name)	Notifier	Applicant
The Netherlands (took over the responsibility as RMS from UK)	August 2020	1-Methylcyclopropene	[REDACTED] [REDACTED]	[REDACTED]

							Projektc Number: OOP-183B, OOP/183A).  The study is not required due to exposure via oral route is very limited. The 1-MCP product users are exposed only for inhalation of 1-MCP.			
				2001a	-	1-METHYLCYCLOPROPENE TWO-WEEK INHALATION RANGE-FINDING STUDY IN FEMALE RATS Report No.: 00R-183A OOP-183A GLP, unpublished	The old unprotected study is still valid.			Study is out of data protection, no matching required.
KCA 5.3.1/02		2016a	A 28-DAY ORAL (DIETARY) TOXICITY STUDY OF MANUFACTURING USE PRODUCT - HAIP (1-METHYLCYCLOPROPENE) IN BEAGLE DOGS Report No.: -229504				The study is not required.  [REDACTED] representative formulation AppelSmart (			No matching required as study does not provide additional information above the 90-day study in Beagle dogs (refer to KCA 5.3.2/02).

**MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF 1-Methylcyclopropene (confidential)**

Rapporteur Member State	Month and year	Active Substance <sup>2</sup> (Name)	Notifier	Applicant
The Netherlands (took over the responsibility as RMS from UK)	August 2020	1-Methylcyclopropene	[REDACTED] [REDACTED]	[REDACTED]

		AF-15-028					<p>FriutSmart ) containing 3.3% of 1-MCP.</p> <p>The old unprotected 3-week inhalation toxicity study in male rats study is still valid ( 2001d).</p> <p>The study is not required due to exposure via oral route is very limited. The 1-MCP product users are exposed only for inhalation of 1-MCP.</p>		
				2001a	-	1-METHYLCYCLOPROPENE 3-WEEK INHALATION RANGE-FINDING STUDY IN FEMALE RATS Report No.: OOR-183A OOP-183A GLP, unpublished	The old unprotected study is still valid.		Study is out of data protection, no matching required.

**MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF 1-Methylcyclopropene (confidential)**

Rapporteur Member State	Month and year	Active Substance <sup>2</sup> (Name)	Notifier	Applicant
The Netherlands (took over the responsibility as RMS from UK)	August 2020	1-Methylcyclopropene	[REDACTED] [REDACTED]	[REDACTED]

KCA 5.3.2/01		2012	A 90-DAY (DIETARY) TOXICITY STUDY OF MANUFACTURING USE PRODUCT-HAIP (1-METHYLCYCLOPROPENE) IN RATS Report No.: WIL-91073 08RC-150 DR-0380-8911-010 20120517165324 51133-27-1				<p>The study is not required.</p> <p>[REDACTED] representative formulation AppleSmart ( FruitSmart ) is containing 3.3% of 1-MCP.</p> <p>The old unprotected 90 day inhalation toxicity study in rats ( 2001c, Lab Project Number: 00P-183-00R-183) is still valid.</p> <p>The study is not required due to exposure via oral route is very limited. The 1-MCP product users are exposure only for inhalation of 1-MCP.</p>		<p>Matching required; the study is submitted in order to determine the toxicity by the oral route at subchronic exposure which is relevant for the risk assessment for the worker (contact with treated fruits).</p> <p><b>The applicant has to demonstrate access to this vertebrate study.</b></p>
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**MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF 1-Methylcyclopropene (confidential)**

Rapporteur Member State	Month and year	Active Substance <sup>2</sup> (Name)	Notifier	Applicant
The Netherlands (took over the responsibility as RMS from UK)	August 2020	1-Methylcyclopropene	[REDACTED] [REDACTED]	[REDACTED]

					2001c	-	1-METHYLCYCLOPROPENE: THREE-MONTH INHALATION (WHOLE-BODY) TOXICITY STUDY IN RATS Report No.: 00R-183 00P-183 GLP, unpublished	The old unprotected study is still valid.			Study is out of data protection, no matching required.
KCA 5.3.2/02		2016b	A 90-DAY ORAL (DIETARY) TOXICITY STUDY OF MANUFACTURING USE PRODUCT - HAIP (1-METHYLCYCLOPROPENE) IN BEAGLE DOGS Report No.: -229505 AF-15-030	Y				Yes, the study is necessary.			Matching required; the study is relevant as reference values have been derived based on this study, which is relevant for the risk assessment for the worker (contact with treated fruits).  <b>The applicant has to demonstrate access to this vertebrate study.</b>
KCA 5.6.1/01		2016	MANUFACTURING USE PRODUCT - HAIP (1-METHYLCYCLOPROPENE): A DIETARY TWO GENERATION REPRODUCTIVE TOXICITY	Y				<b>The study is not required.</b> The study is not required due to exposure via oral			Matching required; the study is relevant as reference values have been derived based on this study, which is

**MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF 1-Methylcyclopropene (confidential)**

Rapporteur Member State	Month and year	Active Substance <sup>2</sup> (Name)	Notifier	Applicant
The Netherlands (took over the responsibility as RMS from UK)	August 2020	1-Methylcyclopropene	[REDACTED] [REDACTED]	[REDACTED]

		STUDY IN CRL:CD(SD) RATS Report No.: -229501 AF-15-030				<p>route is very limited. The 1-MCP product users are exposure only for occasionally inhalation of 1-MCP.</p> <p>The old unprotected developmental toxicity study in Sprague Dawley rats via whole-body inhalation with 1-MCP gas was submitted during Annex I inclusion.</p> <p>Due to the Chemirol's representative formulation AppleSmart ( FruitSmart ) is containing 3.3% of 1-MCP can not be comparable to study on MUP-HAIP (4.5.4%</p>		<p>relevant for the risk assessment for the worker (contact with treated fruits).</p> <p><b>The applicant has to demonstrate access to this vertebrate study.</b></p>
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**MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF 1-Methylcyclopropene (confidential)**

Rapporteur Member State	Month and year	Active Substance <sup>2</sup> (Name)	Notifier	Applicant
The Netherlands (took over the responsibility as RMS from UK)	August 2020	1-Methylcyclopropene	[REDACTED] [REDACTED]	[REDACTED]

								<p>1-MCP complex with <math>\alpha</math>-cyclodextrin).</p> <p>In [REDACTED] opinion the two generation study is not required, since there is minimal or potential for long-term exposure over significant portion of the human lifespan. With respect to worker exposure the use patterns are such that it is unlikely that any individual would be exposed continuously to the active substance . Any exposure would be sporadic in nature and/or accidental. Similarly, with respect to consumer exposure, dietary intake would be at most <math>\leq 0.2 \mu\text{g}/\text{kg}</math></p>			
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**MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF 1-Methylcyclopropene (confidential)**

Rapporteur Member State	Month and year	Active Substance <sup>2</sup> (Name)	Notifier	Applicant
The Netherlands (took over the responsibility as RMS from UK)	August 2020	1-Methylcyclopropene	[REDACTED] [REDACTED]	[REDACTED]

								bw/day using worst case assumption and significant margins of safety are demonstrated using conservative calculations and the available toxicological information.			
					2001	-	1-METHYLCYCLOPROPENE: INHALATION (WHOLE-BODY) DEVELOPMENTAL TOXICITY STUDY IN RATS Report No.: 00R-181 00P-181 GLP, unpublished	The old unprotected study is still valid.			Study is out of data protection, no matching required.
<b>A.7. RESIDUE DATA</b>											
KCA 6.2.1/01	Verona, D.	2004	14C-1-METHYLCYCLOPROPENE (1-MCP) AVOCADO RESIDUE STUDY Report No.: AF-03-056 AF-P-03-02 [REDACTED] [REDACTED] [REDACTED] [REDACTED]	N				The FruitFresh is not cover use in avocado. The study is not required.			RMS, 30 July 2019: Acceptable.



**MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF 1-Methylcyclopropene (confidential)**

Rapporteur Member State	Month and year	Active Substance <sup>2</sup> (Name)	Notifier	Applicant
The Netherlands (took over the responsibility as RMS from UK)	August 2020	1-Methylcyclopropene	[REDACTED] [REDACTED]	[REDACTED]

			GLP, unpublished Doc. No.: 611-002								
<b>A.8. ENVIRONMENTAL FATE AND BEHAVIOUR</b>											
KCA 7.3.1/01	[REDACTED]	2014	Estimation of the atmospheric residence time of 1-Methylcyclopropene using the Atkinson method. PP278-00044-2014/01. Non GLP. Not published	N				The study can not be protected, due to mentioned study was not conducted under GLP regime.	-	-	Acceptable a) N b) Y c) n.r.  <i>This study is used in the environmental fate assessment and is not protected, because it is non-GLP. Study considered matched.</i>
KCA 7.3.1/01	[REDACTED] L.	2014	1-MCP: Physico-Chemical Properties. [REDACTED] n [REDACTED], Project IMB0064. Non GLP. Not published	N				The study can not be protected, due to mentioned study was not conducted under GLP regime.	-	-	Acceptable a) N b) Y c) n.r.  <i>This study is used in the environmental fate assessment and is not protected, because it is non-GLP. Study considered matched.</i>
<b>A.9. ECOTOXICOLOGY DATA</b>											

**MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF 1-Methylcyclopropene (confidential)**

<b>Rapporteur Member State</b>	<b>Month and year</b>	<b>Active Substance<sup>2</sup> (Name)</b>	<b>Notifier</b>	<b>Applicant</b>
The Netherlands (took over the responsibility as RMS from UK)	<b>August 2020</b>	<b>1-Methylcyclopropene</b>	████████████████████ ████████████████████	████████████████████

Please note: In ████████ opinion only studies which are claimed for data protection should be considered in data matching list. However, at the request of the RMS, for clarification below please find all studies, protected and unprotected included in the list of studies relied upon with Applicant comment

**MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF 1-Methylcyclopropene (confidential)**

Rapporteur Member State	Month and year	Active Substance <sup>2</sup> (Name)	Notifier	Applicant
The Netherlands (took over the responsibility as RMS from UK)	August 2020	1-Methylcyclopropene	[REDACTED] [REDACTED]	[REDACTED]

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	

**MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF 1-Methylcyclopropene (confidential)**

Rapporteur Member State	Month and year	Active Substance <sup>2</sup> (Name)	Notifier	Applicant
The Netherlands (took over the responsibility as RMS from UK)	August 2020	1-Methylcyclopropene	[REDACTED] [REDACTED]	[REDACTED]

KCA 8.1.1.1		2006	<p>AN ACUTE ORAL TOXICITY STUDY WITH THE NORTHERN BOBWHITE Report No.: 129-185 05RC-071</p> <p>GLP, unpublished</p>	Y			<p>The endpoint was set up in EFSA LoEP</p> <p>Not required. The supplementary study.</p> <p>RMS comment from RAR to B.9.1.1 points:</p> <p>It was agreed during the original EU review of 1-MCP to extrapolate from the endpoints generated with mammals. Additionally the applicant AgroFresh has provided an acute toxicity study with the Northern Bobwhite (Colinus virginianus).</p>		<p>The applicant argues that the study is supplementary only and needs no matching. However, it is included in the List of Studies Relied Upon (with data protection claimed) and the LoEP (EFSA 2018). Thus, it appears that it was used to base the decision on. <b>The applicant has to demonstrate access to this vertebrate study.</b></p> <p>Update 10/12/2019: The applicant did not provide additional argumentation to that already present. Therefore, the conclusion above remains valid: the applicant needs to demonstrate access.</p>
KCA 8.1.2.1 See 5.2.1/01)		2009a	1-MCP: MANUFACTURING USE PRODUCT: ACUTE ORAL TOXICITY STUDY (UP-ANDDOWN PROCEDURE) IN RATS (AMENDED FINAL	Y			<p>Please, see comment from point KCA 8.1.1.1. and comment from point KCA 5.2.1/01</p>		<p>Argumentation from RMS at 5.2.1/01 copied here: Agreed with the argumentation provided; no matching required.</p>



**MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF 1-Methylcyclopropene (confidential)**

Rapporteur Member State	Month and year	Active Substance <sup>2</sup> (Name)	Notifier	Applicant
The Netherlands (took over the responsibility as RMS from UK)	August 2020	1-Methylcyclopropene	[REDACTED] [REDACTED]	[REDACTED]

KCA 8.1.2.1		2001	1-METHYLCYCLOPROPENE - ACUTE INHALATION TOXICITY STUDY IN RATS Report No.: 00R-180A 00P-180 ..... ..... GLP, unpublished	Y				Not required.  Part I  According to “list if studies relied upon” the study was not claimed for data protection, due to above reason to the study shall not be required presentation of matching study.  Part II  Additionally, according to RMS comment from RAR: MUP-HAIP was used due to the difficulties of testing 1-MCP, a gas at room temperature. These studies have been submitted for the renewal of 1-MCP in order to support an future developments of new higher concentration formulations.			Study not data protected so data matching not required. Acceptable.
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**MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF 1-Methylcyclopropene (confidential)**

Rapporteur Member State	Month and year	Active Substance <sup>2</sup> (Name)	Notifier	Applicant
The Netherlands (took over the responsibility as RMS from UK)	August 2020	1-Methylcyclopropene	[REDACTED] [REDACTED]	[REDACTED]

								<p>[REDACTED] representative formulation AppleSmart ( FruitSmart ) is containing 3.3% of 1- MCP. [REDACTED] has access to mentioned study:</p> <p>2001, 1- Methylcyclopropene Alpha-Cyclodextrin Complex (3,3% a.i.) Acute Inhalation Toxicity Study in Rats , Lab Project Number: 00P-180-00R-180 GLP, unpublished</p> <p>Mentioned study was evaluated in the original DAR ( 2005) and was acceptable.</p>			
KCA 8.1.2.1		2010a	MANUFACTURING USE PRODUCT - HAIP (1-METHYLCYCLOPROPENE): ACUTE INHALATION TOXICITY STUDY IN	Y				Please, see PART II of comment from KCA 8.1.2.1. and comment from KCA 5.2.3/02			Argumentation from RMS at 5.2.1/01 copied here: Agreed with the argumentation provided; no matching required.

**MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF 1-Methylcyclopropene (confidential)**

Rapporteur Member State	Month and year	Active Substance <sup>2</sup> (Name)	Notifier	Applicant
The Netherlands (took over the responsibility as RMS from UK)	August 2020	1-Methylcyclopropene	████████████████████ ████████████████████	████████████████████

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
			RATS Report No.: 30311 100137 ..... ..... GLP, unpublished								
KCA 8.1.2.2		2001c	1 - METHYLCYCLOPROPENE: THREE -MONTH INHALATION (WHOLE -BODY) TOXICITY STUDY IN RATS Report No.: 00R -183 00P -183 ..... ..... ..... GLP, unpublished	Y				Please see PART II comment from KCA 8.1.2.1.			Study not data protected so data matching not required. Acceptable.







**MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF 1-Methylcyclopropene (confidential)**

Rapporteur Member State	Month and year	Active Substance <sup>2</sup> (Name)	Notifier	Applicant
The Netherlands (took over the responsibility as RMS from UK)	August 2020	1-Methylcyclopropene	[REDACTED]	[REDACTED]

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 8.2.1		2001a	1 -Methylcyclopropene: A 96 -hour static -renewal acute toxicity test with the rainbow trout (Oncorhynchus mykiss) ..... "....." ER Ref No: 4.8 US Ref No: 01RC-0001 GLP, Unpublished	Y				Study on rainbow trout, 2001a was already evaluated in DAR for first inclusion, thus it is not protected anymore.  According to "list if studies relied upon" the study was not claimed for data protection, due to above reason to the study shall not be required presentation of matching study			Study not data protected so data matching not required. Acceptable.

**MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF 1-Methylcyclopropene (confidential)**

Rapporteur Member State	Month and year	Active Substance <sup>2</sup> (Name)	Notifier	Applicant
The Netherlands (took over the responsibility as RMS from UK)	August 2020	1-Methylcyclopropene	[REDACTED] [REDACTED]	[REDACTED]

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 8.2.4.1	[REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]	2001b	1 -Methylcyclopropene: A 48 -hour static acute immobilization test with the cladoceran (Daphnia magna) [REDACTED] I [REDACTED] Project No. 129A -184A ER Ref No: 4.9 US Ref No: 01RC-0002 GLP, Unpublished	N				Study by [REDACTED] [REDACTED] [REDACTED] was already evaluated in DAR from first inclusion, thus it is not protected.  According to "list if studies relied upon" the study was not claimed for data protection, due to above reason to the study shall not be required presentation of matching study			Study not data protected so data matching not required. Acceptable.

**MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF 1-Methylcyclopropene (confidential)**

Rapporteur Member State	Month and year	Active Substance <sup>2</sup> (Name)	Notifier	Applicant
The Netherlands (took over the responsibility as RMS from UK)	August 2020	1-Methylcyclopropene	[REDACTED] [REDACTED]	[REDACTED]

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 8.2.4.1	[REDACTED]	2014	1 -MCP: Acute Toxicity to Daphnia magna [REDACTED] AGR 4906 [REDACTED] Study nr. IMB0053 GLP Unpublished	N	[REDACTED]	2013	1-MCP: acute toxicity to Daphnia magna Code: 3200158 [REDACTED] [REDACTED] [REDACTED] GLP Unpublished	According to “list if studies relied upon” the study was not claimed for data protection, due to above reason to the study shall not be required presentation of matching study  However, [REDACTED] has done the equivalent study for product registration, so if required, could be provided.			Study not data protected so data matching not required. Acceptable.

**MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF 1-Methylcyclopropene (confidential)**

Rapporteur Member State	Month and year	Active Substance <sup>2</sup> (Name)	Notifier	Applicant
The Netherlands (took over the responsibility as RMS from UK)	August 2020	1-Methylcyclopropene	[REDACTED] [REDACTED]	[REDACTED]

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 8.2.6.1	[REDACTED] [REDACTED] [REDACTED], [REDACTED]	2001c	1-Methylcyclopropene: A 96-hour toxicity test with the freshwater alga (Selenastrum capricornutum) [REDACTED] No. 129A-185 ER Ref No: 4.10 US Ref No: 01RC-0003 GLP, Unpublished	N				Study by [REDACTED] [REDACTED] was evaluated in DAR from first inclusion, thus it is not protected.  According to "list if studies relied upon" the study was not claimed for data protection, due to above reason to the study shall not be required presentation of matching study			Study not data protected so data matching not required. Acceptable.

**MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF 1-Methylcyclopropene (confidential)**

Rapporteur Member State	Month and year	Active Substance <sup>2</sup> (Name)	Notifier	Applicant
The Netherlands (took over the responsibility as RMS from UK)	August 2020	1-Methylcyclopropene	[REDACTED] [REDACTED]	[REDACTED]

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 8.2.7	[REDACTED]	2015	MANUFACTURING USE PRODUCT HIGH ACTIVE INGREDIENT POWDER (MUP-HAIP) CONTAINING THE ACTIVE INGREDIENT 1-METHYLCYCLOPROPENE (1-MCP): A 7-DAY STATIC RENEWAL TOXICITY TEST WITH DUCKWEED (LEMNA GIBBA G3) Report No.: 103P-125 AF-P-14-024 [REDACTED], [REDACTED], unpublished	N	[REDACTED]	2015	7 Day Growth Inhibition Test with Duckweed, Lemna gibba. Study Number: 3201069 Study Director: [REDACTED] Test Facility: [REDACTED] [REDACTED] GLP, unprotected	The equivalent study is submitted.			Acceptable. a) Y b) Y c) Y

**MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF 1-Methylcyclopropene (confidential)**

Rapporteur Member State	Month and year	Active Substance <sup>2</sup> (Name)	Notifier	Applicant
The Netherlands (took over the responsibility as RMS from UK)	August 2020	1-Methylcyclopropene	[REDACTED] [REDACTED]	[REDACTED]

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 8.3.1.1	[REDACTED] [REDACTED] [REDACTED]	2001	1-Methylcyclopropene alpha-cyclodextrin complex (3.3% a.i.): An acute toxicity study with the honey bee. [REDACTED] No. 129-178 ER Ref No: 4.11 US Ref No: 01RC-0097 GLP, Unpublished	N				Study by [REDACTED] was already evaluated in DAR from first inclusion, thus it is not protected.  According to "list if studies relied upon" the study was not claimed for data protection, due to above reason to the study shall not be required presentation of matching study			Study not data protected so data matching not required. Acceptable.



**MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF 1-Methylcyclopropene (confidential)**

Rapporteur Member State	Month and year	Active Substance <sup>2</sup> (Name)	Notifier	Applicant
The Netherlands (took over the responsibility as RMS from UK)	August 2020	1-Methylcyclopropene	[REDACTED] [REDACTED]	[REDACTED]

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 8.3.1.1	[REDACTED]	2013	An acute toxicity study to determine the effects of 1-METHYLCYCLOPROPENE (1-MCP) on the honey bees <i>Apis mellifera</i> L. (Hymenoptera: Apidae) according to OECD No. 214 (1998) modified for inhalation route of exposure Janssen PMP, AGR 4914 Syntech study number: 168SRFR13C3 GLP Unpublished	N	[REDACTED]	2013	CHR/RW/MCP – acute toxicity for honeybees [REDACTED] [REDACTED] [REDACTED] Study code: 3200161 GLP Unpublished CHR/RW/MCP – acute contact toxicity to honeybees [REDACTED] [REDACTED] [REDACTED] Study code: 3200161 GLP Unpublished	According to “list if studies relied upon” the study was not claimed for data protection, due to above reason to the study shall not be required presentation of matching study  However, the equivalent studies were done for product registration, so if required, could be provided.			Study not data protected so data matching not required. Acceptable.

**MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF 1-Methylcyclopropene (confidential)**

Rapporteur Member State	Month and year	Active Substance <sup>2</sup> (Name)	Notifier	Applicant
The Netherlands (took over the responsibility as RMS from UK)	August 2020	1-Methylcyclopropene	[REDACTED] [REDACTED]	[REDACTED]

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 8.3.2.1	[REDACTED]	2002 a	1-Methylcyclopropene: Toxicity test with the parasitic wasp, <i>Aphidius rhopalosiphii</i> (Hymenoptera: Braconidae). [REDACTED] Report No. 1007-078-270. ER Ref No: 8.9 US Ref No: 01RC-0283 GLP, Unpublished					Study by [REDACTED] was already evaluated in DAR from first inclusion, thus it is not protected.  According to "list if studies relied upon" the study was not claimed for data protection, due to above reason to the study shall not be required presentation of matching study			Study not data protected so data matching not required. Acceptable.

**MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF 1-Methylcyclopropene (confidential)**

Rapporteur Member State	Month and year	Active Substance <sup>2</sup> (Name)	Notifier	Applicant
The Netherlands (took over the responsibility as RMS from UK)	August 2020	1-Methylcyclopropene	[REDACTED] [REDACTED]	[REDACTED]

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 8.3.2.1	[REDACTED]	2013	A laboratory study to determine the effects of 1-METHYLCYCLOPROPENE (1 -MCP) on the non-target arthropod <i>Aphidius rhopalosiphi</i> (Hymenoptera: Braconidae); according to [REDACTED] modified for inhalation route of exposure. [REDACTED] AGR 4912 [REDACTED] number: 168SRFR13C1 GLP Unpublished	N	[REDACTED]	2013	1-MCP– acute toxicity to <i>Aphidius rhopalosiphi</i> laboratory study [REDACTED] [REDACTED] Kod badania 3200163 GLP Unpublished	According to “list if studies relied upon” the study was not claimed for data protection, due to above reason to the study shall not be required presentation of matching study  However, the equivalent studies were done for product registration, so if required, could be provided.			Study not data protected so data matching not required. Acceptable.

**MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF 1-Methylcyclopropene (confidential)**

Rapporteur Member State	Month and year	Active Substance <sup>2</sup> (Name)	Notifier	Applicant
The Netherlands (took over the responsibility as RMS from UK)	August 2020	1-Methylcyclopropene	[REDACTED] [REDACTED]	[REDACTED]

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 8.3.2.2	[REDACTED]	2002 b	1 -Methylcyclopropene: Laboratory toxicity test with the predatory mite, Typhlodromus pyri [REDACTED] Acari: [REDACTED] Phytoseiidae), [REDACTED] Report No. 1007 -078 - 268. ER Ref No: 8.10 US Ref No: 01RC-0282 GLP, Unpublished					Study by [REDACTED] was already evaluated in DAR from first inclusion, thus it is not protected.  According to "list if studies relied upon" the study was not claimed for data protection, due to above reason to the study shall not be required presentation of matching study			Study not data protected so data matching not required. Acceptable.

**MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF 1-Methylcyclopropene (confidential)**

Rapporteur Member State	Month and year	Active Substance <sup>2</sup> (Name)	Notifier	Applicant
The Netherlands (took over the responsibility as RMS from UK)	August 2020	1-Methylcyclopropene	[REDACTED] [REDACTED]	[REDACTED]

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 8.3.2.2	[REDACTED] [REDACTED] [REDACTED]	(2013c)	A laboratory study to determine the effects of 1-METHYLCYCLOPROPENE (1-MCP) on the non-target arthropod Typhlodromus pyri (Acari: Phytoseiidae); according to IOBC (Blümel et al., 2000) modified for inhalation route of exposure. [REDACTED], AGR 4913 [REDACTED] study number: 168SRFR13C2 GLP Unpublished	N	[REDACTED] [REDACTED]	2013	1-MCP: [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] Study code: 3200162 GLP  Unpublished	According to “list if studies relied upon” the study was not claimed for data protection, due to above reason to the study shall not be required presentation of matching study  However, the equivalent study was done for product registration, so if required, could be provided.			Study not data protected so data matching not required. Acceptable.

**MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF 1-Methylcyclopropene (confidential)**

Rapporteur Member State	Month and year	Active Substance <sup>2</sup> (Name)	Notifier	Applicant
The Netherlands (took over the responsibility as RMS from UK)	August 2020	1-Methylcyclopropene	[REDACTED] [REDACTED]	[REDACTED]

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 8.4.1	[REDACTED]	2002 c	1 -Methylcyclopropene: A 14 -day acute toxicity test with the earthworm Eisenia fetida. [REDACTED] [REDACTED] Report No. 1007 -078 -630. ER Ref No: 8.11 US Ref No: 01RC-0284 GLP, Unpublished	N				Study by [REDACTED] was already evaluated in DAR from first inclusion, thus it is not protected.  According to "list if studies relied upon" the study was not claimed for data protection, due to above reason to the study shall not be required presentation of matching study			Study not data protected so data matching not required. Acceptable.

**MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF 1-Methylcyclopropene (confidential)**

Rapporteur Member State	Month and year	Active Substance <sup>2</sup> (Name)	Notifier	Applicant
The Netherlands (took over the responsibility as RMS from UK)	August 2020	1-Methylcyclopropene	[REDACTED] [REDACTED]	[REDACTED]

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision <sup>3,4</sup>	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 8.4.1	[REDACTED]	2013	1 -MCP: Acute Toxicity (LC50) to the Earthworm [REDACTED], AGR 4903 [REDACTED] Study nr. IMB0050 GLP Unpublished	N				Acute toxicity study on earthworms is no longer a formal requirement according to Reg. 283/2013, thus no matching is required.  According to "list if studies relied upon" the study was not claimed for data protection, due to above reason to the study shall not be required presentation of matching study			Study not data protected so data matching not required. Acceptable.

**MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF 1-Methylcyclopropene (confidential)**

Rapporteur Member State	Month and year	Active Substance <sup>2</sup> (Name)	Notifier	Applicant
The Netherlands (took over the responsibility as RMS from UK)	<b>August 2020</b>	<b>1-Methylcyclopropene</b>	[REDACTED] [REDACTED]	[REDACTED]