

FINAL REGISTRATION REPORT

Part B

Section 5

Analytical Methods

Detailed summary of the risk assessment

Product code: SHA 4100 A

Product name(s): HIFEN

Chemical active substance:

Thifensulfuron-methyl, 750 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem Limited

Submission date: September 2023

Finalisation date: February 2024; February 2025

Version history

When	What
09.2023	Submission date
02.2024	zRMS assessment
02.2025	The final Registration Report.

Table of Contents

5	Analytical methods.....	4
5.1	Conclusion and summary of assessment.....	4
5.2	Methods used for the generation of pre-authorization data (KCP 5.1).....	4
5.2.1	Analysis of the plant protection product (KCP 5.1.1)	4
5.2.1.1	Determination of active substance and/or variant in the plant protection product (KCP 5.1.1).....	4
5.2.1.2	Description of analytical methods for the determination of relevant impurities (KCP 5.1.1).....	6
5.2.1.3	Description of analytical methods for the determination of formulants (KCP 5.1.1)	6
5.2.1.4	Applicability of existing CIPAC methods (KCP 5.1.1).....	6
5.2.2	Methods for the determination of residues (KCP 5.1.2).....	6
5.3	Methods for post-authorization control and monitoring purposes (KCP 5.2)	6
5.3.1	Analysis of the plant protection product (KCP 5.2)	6
5.3.2	Description of analytical methods for the determination of residues Thifensulfuron-methyl (KCP 5.2).....	7
5.3.2.1	Overview of residue definitions and levels for which compliance is required	7
5.3.2.2	Description of analytical methods for the determination of residues in plant matrices (KCP 5.2).....	8
5.3.2.3	Description of analytical methods for the determination of residues in animal matrices (KCP 5.2).....	9
5.3.2.4	Description of methods for the analysis of soil (KCP 5.2).....	9
5.3.2.5	Description of methods for the analysis of water (KCP 5.2).....	10
5.3.2.6	Description of methods for the analysis of air (KCP 5.2).....	11
5.3.2.7	Description of methods for the analysis of body fluids and tissues (KCP 5.2)	11
5.3.2.8	Other studies/ information	12
Appendix 1	Lists of data considered in support of the evaluation.....	13
Appendix 2	Detailed evaluation of submitted analytical methods	17
A 2.1	Analytical methods for Thifensulfuron-methyl	17
A 2.1.1	Methods used for the generation of pre-authorization data (KCP 5.1).....	17
A 2.1.2	Methods for post-authorization control and monitoring purposes (KCP 5.2)	17

5 Analytical methods

5.1 Conclusion and summary of assessment

Sufficiently sensitive and selective analytical method is available for the active substance in the plant protection product. The method is suitable for determining thifensulfuron-methyl in the test item SHA 4100 A (HIFEN) and has been successfully validated according to SANCO/3030/99 rev. 4 and rev.5.

Sufficiently sensitive and selective analytical methods are not available for all analytes included in the residue definitions.

Noticed data gaps are:

- Analytical methods for animal matrices and for body fluids and tissues (these methods were not provided during EU review).
- ILV method for drinking water (this method was not provided during EU review).

Above methods will be required when renewing the product.

Commodity/crop	Supported/ Not supported
High starch content (Winter cereals (wheat, barley, rye, oats, triticale))	Supported

5.2 Methods used for the generation of pre-authorization data (KCP 5.1)

5.2.1 Analysis of the plant protection product (KCP 5.1.1)

5.2.1.1 Determination of active substance and/or variant in the plant protection product (KCP 5.1.1)

An overview on the acceptable methods and possible data gaps for analysis of thifensulfuron-methyl in plant protection product is provided as follows:

Reference:	KCP 5.1.1
Report	Physico-Chemical Characterization of THIFENSULFURON MEHYL 75% WG. J. A. Escudero, 2017, Report No. 15-4150-19
Guideline(s):	SANCO/3030/99 rev. 4 and rev. 5
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

Before launching the analytical sequence, at least two 10 µl fractions of a solution are injected in the HPLC to check the stability of the chromatographic system

Confirmation of the identity of the analyte was performed by comparing the spectra of the analyte peak in

the sample of test item with a corresponding reference product. Spectra were registered in the range between 190 and 350 nm.

Analytical condition:

Column temperature: 30°C

Mobile phase: 70% acetonitrile – 30% water (0.1% phosphoric acid)

Flow rate: 1.4 ml/min

Wavelength: 248 nm

Injection volume: 10 µl

Retention time 1.9 min

Run time 5 min

Preparation of reference item solutions

25.10 mg of thifensulfuron methyl reference item were weighed on a 25 ml volumetric flask and brought to volume with acetonitrile HPLC. Sonicate.

From this stock solution (Cal-M stock solution of 986.932 mg/l) six solutions were prepared to develop the calibration curve to quantify the formulation.

Preparation of test item solutions

Weigh (to the nearest 0.1 mg) 10-20 mg of test item into a 50 ml volumetric flask and up to volume with acetonitrile. It was sonicated for 15 min. It was refrigerated and filtered through 0.45 µm filters before analysis. It was weighed five independent samples of test item.

Preparation of spiked solutions

Test item sample

80.73 mg of test item were weighed into a 50 ml volumetric flask and dilute to volume with acetonitrile. It was sonicate for 15 min. It was refrigerated and filtered through 0.45 µm filters.

- 80% Recovery

Pipette 1 ml of the test item solution into three 10 ml volumetric flask and add 2 ml of a stock solution of thifensulfuron methyl to each flask as to obtain a concentration of 160.184776 mg/l Up to volume with acetonitrile HPLC

- 120% Recovery

Pipette 1 ml of the test item solution into three 10 ml volumetric flasks and add 6 ml of a stock solution of thifensulfuron methyl to each flask as to obtain a concentration of 239.139336 mg/l. Up to volume with acetonitrile HPLC.

Validation - Results and discussions

Table 5.2-1: Methods suitable for the determination of active substance thifensulfuron-methyl in plant protection product HIFEN (SHA 4100 A)

	Thifensulfuron-methyl
Author(s), year	Jose Angel Escudero, 2017
Principle of method	HPLC-UV
Linearity (linear between mg/L / % range of the declared content) (correlation coefficient, expressed as r)	6 points 19.73864 – 394.77280 mg/L (6.25 – 125.47 % w/w) $y = 13216.92415x - 9491.005222$ $R = 0.99998$
Precision – Repeatability Mean n = 5 (%RSD)	74.8% w/w %RSD = 0.7 %RSD _R = 2.09

	Thifensulfuron-methyl
	Modified Horwitz – $\% \text{ RSDr} = \text{RSD} \times 0.67 = 0.47$ $\% \text{ RSDr} = 1.40$ $\text{Hr} = 0.50 \leq 1$
Accuracy ~~n=6~~ n= 3 for each level (% Recovery)	Level I: 80% w/w – 101.4% Level II: 120% w/w – 100.8% Average: 101.1 %
Interference/ Specificity	No interference according to blank, standards nad samples chromatograms, the method is specific.

Conclusion

The method of analysis of thifensulfuron-methyl in the test item has been successfully validated according to SANCO/3030/99 rev. 5. The method is suitable for determining thifensulfuron-methyl in the test product THIFENSULFURON METHYL 75% WG.

5.2.1.2 Description of analytical methods for the determination of relevant impurities (KCP 5.1.1)

Not relevant.

5.2.1.3 Description of analytical methods for the determination of formulants (KCP 5.1.1)

Not relevant.

5.2.1.4 Applicability of existing CIPAC methods (KCP 5.1.1)

A CIPAC method No. 452 is available for Thifensulfuron-methyl.

5.2.2 Methods for the determination of residues (KCP 5.1.2)

Please refer to post-registration methods.

5.3 Methods for post-authorization control and monitoring purposes (KCP 5.2)

5.3.1 Analysis of the plant protection product (KCP 5.2)

Analytical methods for the determination of the active substance and relevant impurities in the plant protection product shall be submitted, unless the applicant shows that these methods already submitted in accordance with the requirements set out in point 5.2.1 can be applied.

5.3.2 Description of analytical methods for the determination of residues Thifensulfuron-methyl (KCP 5.2)

5.3.2.1 Overview of residue definitions and levels for which compliance is required

Compared to the residue definition proposed in the Draft Assessment Report (incl. its addenda) the current legal residue definition is identical.

Table 5.3-1: Relevant residue definitions for monitoring/enforcement and levels for which compliance is required

Matrix	Residue definition	MRL / limit	Reference for MRL/level Remarks
Plant, high water content	Thifensulfuron-methyl	0.01 mg/kg	Regulation (EU) No. 617/2014
Plant, high acid content		0.01 mg/kg	Regulation (EU) No. 617/2014
Plant, high protein/high starch content (dry commodities)		0.01 mg/kg	Regulation (EU) No. 617/2014
Plant, high oil content		0.01 mg/kg	Regulation (EU) No. 617/2014
Plant, difficult matrices (hops, spices, tea)		0.05 mg/kg	Regulation (EU) No. 617/2014
Muscle	Thifensulfuron-methyl	0.01 mg/kg	Regulation (EU) No. 617/2014
Milk		0.01 mg/kg	Regulation (EU) No. 617/2014
Eggs		0.01 mg/kg	Regulation (EU) No. 617/2014
Fat		0.01 mg/kg	Regulation (EU) No. 617/2014
Liver, kidney		0.01 mg/kg	Regulation (EU) No. 617/2014
Soil (Ecotoxicology)	Thifensulfuron-methyl	0.05 mg/kg	common limit
Drinking water (Human toxicology)	Thifensulfuron-methyl	0.1 µg/L	general limit for drinking water
Surface water (Ecotoxicology)	Thifensulfuron-methyl	0.11 µg/L	Lowest NOEC for <i>Vallisneria americana</i>
Air	Thifensulfuron-methyl	21 µg/m ³	AOEL sys: 0.07 mg/kg bw/d
Tissue (meat or liver)	-	Not required	Not classified as T / T+
Body fluids		Not required	Not classified as T / T+

5.3.2.2 Description of analytical methods for the determination of residues in plant matrices (KCP 5.2)

An overview on the acceptable methods and possible data gaps for analysis of thifensulfuron-methyl in plant matrices is given in the following tables.

Table 5.3-2: Validated methods for food and feed of plant origin (required for all matrix types, “difficult” matrix only when indicated by intended GAP)

Component of residue definition: thifensulfuron-methyl				
Matrix type	Method type	Method LOQ	Principle of method (i.e. GC-MS or HPLC-UV)	Author(s), year / missing / EU agreed
High water content	Primary	0.01 mg/kg	LC-MS/MS	F. M. Brookey, G. L. Westberg, 2007, Report No. DuPont-5367, supplement No. 1 RAR, UK, 2014 EU Agreed
	ILV	0.01 mg/kg	LC-MS/MS	A. M. Pentz, F. Q. Bramble, 2005 Report No. DuPont-13412, Rev. 1 RAR, UK, 2014 EU Agreed
	Confirmatory (if required)	-	-	LC/MS/MS is highly selective method, therefore no confirmatory method is required.
High acid content	Primary	0.01 mg/kg	LC-MS/MS	T. J. Devine, S. C. Nanina, 2007 Report No. DuPont-13412, Supplement No. 1 RAR, UK, 2014 EU Agreed
	ILV	0.01 mg/kg	LC-MS/MS	B. Plastringe, 2006 Report No. DuPont-17207 RAR, UK, 2014 EU Agreed
	Confirmatory (if required)	-	-	LC/MS/MS is highly selective method, therefore no confirmatory method is required.
High oil content	Primary	0.01 mg/kg	LC-MS/MS	A. M. Pentz, F. Q. Bramble, 2005 Report No. DuPont-13412, Rev. 1 RAR, UK, 2014 EU Agreed
	ILV	0.01 mg/kg	LC-MS/MS	E. Charles, A. M. Doran, 2004 Report No. DuPont-13398 RAR, UK, 2014 EU Agreed
	Confirmatory (if required)	-	-	LC/MS/MS is highly selective method, therefore no confirmatory method is required.
High protein/high starch content (dry)	Primary	0.01 mg/kg	LC-MS/MS	J. S. Amoo, W. Jones, 2001, Report No. DuPont-5367 RAR, UK, 2014 EU Agreed

Component of residue definition: thifensulfuron-methyl				
Matrix type	Method type	Method LOQ	Principle of method (i.e. GC-MS or HPLC-UV)	Author(s), year / missing / EU agreed
	ILV	0.01 mg/kg	LC-MS/MS	A. M. Pentz, F. Q. Bramble, 2005 Report No. DuPont-8054 RAR, UK, 2014 EU Agreed
	Confirmatory (if required)	-	-	LC/MS/MS is highly selective method, therefore no confirmatory method is required.
	Primary	0.02 mg/kg	LC-MS/MS	C. Seck, 2008 Report No. QG/07/021 RAR, UK, 2014 EU Agreed
	ILV	0.02 mg/kg	LC-MS/MS	G. Watson, 2010 Report No. S09-02905 RAR, UK, 2014 EU Agreed
	Confirmatory (if required)	-	-	LC/MS/MS is highly selective method, therefore no confirmatory method is required.

Table 5.3-3: Statement on extraction efficiency

	Method for products of plant origin
Not required, because:	No residues $\geq$ LOQ are expected.

5.3.2.3 Description of analytical methods for the determination of residues in animal matrices (KCP 5.2)

Conclusion drawn from EFSA Journal 2015;13(7):4201:

A method of analysis for products of animal origin is not required as no MRLs are proposed.

5.3.2.4 Description of methods for the analysis of soil (KCP 5.2)

An overview on the acceptable methods and possible data gaps for analysis of thifensulfuron-methyl in soil is given in the following tables.

Table 5.3-4: Validated methods for soil (if appropriate)

Component of residue definition: thifensulfuron-methyl			
Method type	Method LOQ	Principle of method (i.e. GC-MS or HPLC-UV)	Author(s), year / missing
Primary	0.05 µg/kg	LC-MS/MS	S. J. Hill, J. J. Stry, 2001 Report No. DuPont-5082, Rev. 1 RAR, UK, 2014 EU Agreed

Component of residue definition: thifensulfuron-methyl			
Method type	Method LOQ	Principle of method (i.e. GC-MS or HPLC-UV)	Author(s), year / missing
Confirmatory	-	-	LC/MS/MS is highly selective method, therefore no confirmatory method is required.
Primary	0.005 mg/kg	LC-MS/MS	L. Sandgrove, 2012 Report No. PII0022 RAR, UK, 2014 EU Agreed
Confirmatory	-	-	LC/MS/MS is highly selective method, therefore no confirmatory method is required.

5.3.2.5 Description of methods for the analysis of water (KCP 5.2)

An overview on the acceptable methods and possible data gaps for analysis of thifensulfuron-methyl in surface and drinking water is given in the following tables.

Table 5.3-5: Validated methods for water (if appropriate)

Component of residue definition: thifensulfuron-methyl				
Matrix type	Method type	Method LOQ	Principle of method (i.e. GC-MS or HPLC-UV)	Author(s), year / missing
Drinking water	Primary	0.05 µg/L	LC-MS/MS	T.J. Devine, L. Jin, 2004 Report No. DuPont-5491, Rev. 1 RAR, UK, 2014
	ILV	-	-	Not provided during EU review.
	Confirmatory	-	-	LC/MS/MS is highly selective method, therefore no confirmatory method is required.
	Primary	0.01 µg/L	LC-MS/MS	L. Sadgrove, 2012 Report No. PII0024 RAR, UK, 2014 EU Agreed
	ILV	-	-	Not provided during EU review.
	Confirmatory	-	-	LC/MS/MS is highly selective method, therefore no confirmatory method is required.
Surface water	Primary	0.05 µg/L	LC-MS/MS	T.J. Devine, L. Jin, 2004 Report No. DuPont-5491, Rev. 1 RAR, UK, 2014

Component of residue definition: thifensulfuron-methyl				
Matrix type	Method type	Method LOQ	Principle of method (i.e. GC-MS or HPLC-UV)	Author(s), year / missing
	Confirmatory	-	-	LC/MS/MS is highly selective method, therefore no confirmatory method is required.
	Primary	0.01 µg/L	LC-MS/MS	L. Sadgrove, 2012 Report No. PII0024 RAR, UK, 2014 EU Agreed
	Confirmatory	-	-	LC/MS/MS is highly selective method, therefore no confirmatory method is required.

5.3.2.6 Description of methods for the analysis of air (KCP 5.2)

An overview on the acceptable methods and possible data gaps for analysis of Thifensulfuron-methyl in air is given in the following tables.

Table 5.3-6: Validated methods for air (if appropriate)

Component of residue definition: Thifensulfuron-methyl			
Method type	Method LOQ	Principle of method (i.e. GC-MS or HPLC-UV)	Author(s), year / missing
Primary	2.8 µg/m ³	LC-MS/MS	R. Bacher, 2001 Report No. DuPont-4560 RAR, UK, 2014 EU Agreed
Confirmatory	-	-	LC/MS/MS is highly selective method, therefore no confirmatory method is required.
Primary	21 µg/m ³	LC-MS/MS	L. Sadgrove, 2012 Report No. PII0023 RAR, UK, 2014 EU Agreed
Confirmatory	-	-	LC/MS/MS is highly selective method, therefore no confirmatory method is required.

5.3.2.7 Description of methods for the analysis of body fluids and tissues (KCP 5.2)

Not relevant since thifensulfuron-methyl is neither classified as toxic or very toxic (EFSA Journal 2015;13(7):4201).

5.3.2.8 Other studies/ information

Not relevant.

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 5.1.1	J. A. Escudero	2017	Physico-Chemical Characterization of THIFENSULFURON MEHYL 75% WG. Laboratorios Munuera Report No. 15-4150-19 GLP Unpublished	N	Sharda Cropchem Limited

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 5.2/1	A. M. Pentz, F. Q. Bramble	2005	Analytical method for the determination of nicosulfuron, Thifensulfuron-methyl, ethametsulfuron methyl, rimsulfuron, tribenuron methyl and chlorimuron ethyl in oily crop matrices using SPE purification and LC/MS/MS detection Report No. DuPont-13412, Revision No. 1 Non-GLP Published	N	DuPont
	E. Charles, A. M.	2004	Independent laboratory validation of analytical method DuPont-13412 for the determination of Thifensul-	N	DuPont

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
	Doran		furon-methyl, ethametsulfuron methyl, rimsulfuron, tribenuron methyl and chlorimuron ethyl in oilseeds and soybean seed using SPE purification and LC/MS/MS detection Report No. DuPont-13398 GLP Published		
KCP 5.2/2	T. J. Devine, S. C. Nanita	2007	Multi-residues analytical method for the determination of sulfonylurea herbicides in oily, watery, acidic and dry crops using SPE purification and LC/MS/MS detection. Report DuPont-13412, Supplement No. 1 Non-GLP Published	N	DuPont
KCP 5.2/3	B. Plastringe	2006	Independent laboratory validation of a multi-residue method for the analysis of sulfonylurea herbicides in crops, DuPont-13412, Rev. 1. Report No. DuPont-17207 GLP Published	N	DuPont
KCP 5.2/4	F. M. Brookey, G. L. Westberg	2007	Analytical method for the determination of Thifensulfuron-methyl, metsulfuron methyl, chlorsulfuron, tribenuron methyl and flupyr-sulfuron methyl in lettuce and tribenuron methyl and bensulfuron methyl in citrus (oranges) Report No. DuPont-5367, Supplement No. 1 Non-GLP Published	N	DuPont
KCP 5.2/5	J. S. Amoo, W. Jones	2001	Analytical enforcement method for the determination of Thifensulfuron-methyl, metsulfuron methyl, chlorsulfuron, tribenuron methyl and flupyr-sulfuron methyl in cereals (wheat, grain, forage and straw) Report No. DuPont-5367 Non-GLP Published	N	DuPont
KCP 5.2/6	A. M. Pentz, F. Q. Bramble	2002	Independent Laboratory Validation of DuPont-5367, „Analytical enforcement method for the determination of Thifensulfuron-methyl and flupyr-sulfuron methyl in cereals (wheat grain, forage and straw)” in wheat grain barley grain, corn grain and tomato. Report No. Dupont-8054 GLP Published	N	DuPont
KCP 5.2/7	C. Seck	2008	Determination of Residues of Metsulfuron-methyl and Thifensulfuron-methyl in Cereal – Method Validation	N	DuPont

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			tion. Report No. QG/07/021 GLP Published		Cheminova ROTAM
KCP 5.2/8	G. Watson	2010	Independent Laboratory Validation of the analytical procedure detailed in the study performer under Rotam ID numer 7407047 „Determination of residues of metsulfuron-methyl and Thifensulfuron-methyl in cereal – method validation’ Report No. S09-02905 GLP Published	N	DuPont Cheminova ROTAM
KCP 5.2/9	S. J. Hill, J. J. Stry	2001	Analytical method for the determination of 13 DuPont sulfonylurea herbicides in soil using LC/MS/MS. Report No. DuPont-5082 Non-GLP Published	N	DuPont
KCP 5.2./10	L. Sadgrove	2012	Thifensulfuron-methyl and thifensulfuron-acid: Validation of methodology for the Determination of Residues in Soil. Report No. PII0022 and amendment 1 GLP Published	N	DuPont Cheminova ROTAM
KCP 5.2/11	T. J. Devine, L. Jin	2004	Analytical method for the determination and confirmation of 13 DuPont sulfonylurea herbicides in water using LC/MS/MS. Report No. DuPont-5491, Rev 1 Non-GLP Published	N	DuPont
KCP 5.2/12	L. Sadgrove	2012	Thifensulfuron-methyl and thifensulfuron-acid: Validation of Methodology for the Determination of Residues in Surface Water. Report No. PII0024 and amendment 1 GLP Published	N	DuPont Cheminova ROTAM
KCP 5.2/13	R. Bacher	2001	Development and validation of analytical methods for the determination of seven sulfonylurea herbicides in air (amended). Report DuPont-4560 GLP Published	N	DuPont
KCP	L. Sadgrove	2012	Thifensulfuron-methyl: Validation of methodology for the Determination of Residues in Air. Report No.	N	DuPont

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
5.2/14			PII0023 and amendment 1 GLP Published		Cheminova ROTAM

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
-	-	-	-	-	-

List of data relied on not submitted by the applicant but necessary for evaluation

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
-	-	-	-	-	-

Appendix 2 Detailed evaluation of submitted analytical methods

A 2.1 Analytical methods for Thifensulfuron-methyl

A 2.1.1 Methods used for the generation of pre-authorization data (KCP 5.1)

No new or additional studies have been submitted

A 2.1.2 Methods for post-authorization control and monitoring purposes (KCP 5.2)

A 2.1.2.1 Description of analytical methods for the determination of residues in plant matrices (KCP 5.2)

No new or additional studies have been submitted

A 2.1.2.2 Description of analytical methods for the determination of residues in animal matrices (KCP 5.2)

No new or additional studies have been submitted

A 2.1.2.3 Description of Methods for the Analysis of Soil (KCP 5.2)

No new or additional studies have been submitted

A 2.1.2.4 Description of Methods for the Analysis of Water (KCP 5.2)

No new or additional studies have been submitted

A 2.1.2.5 Description of Methods for the Analysis of Air (KCP 5.2)

No new or additional studies have been submitted

A 2.1.2.6 Description of Methods for the Analysis of Body Fluids and Tissues (KCP 5.2)

No new or additional studies have been submitted

A 2.1.2.7 A.2.A.9 Other Studies/ Information

No new or additional studies have been submitted