# REGISTRATION REPORT

# Part B

# Section 5

# Analytical Methods

Detailed summary of the risk assessment

Product code: RNB 072 A

Product name(s): **MATLAM**

Chemical active substance:

Florasulam, 50 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: XXXX

Submission date: June 2024

Evaluation date: February 2025

MS Finalisation date: May 2025

# Version history

| When | What |
|---|---|
| February 2025 | Version evaluated by zRMS PL |
| | |
| | |
| | |

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# 5 Analytical methods

## 5.1 Conclusion and summary of assessment

Sufficiently sensitive and selective analytical methods are available for the active substance(s) and relevant impurities in the plant protection product.
Noticed data gaps are:

**RMS conclusion on the composition equivalence to the Kantor 050 SC and Floras 50 SC.**
From physicochemical perspective **MATLAM is not considered equivalent/ comparable to already registered Kantor 050 SC in Poland under Composition's comparison in accordance with Article 34 of Regulation 1107/2009.** So, unprotected physicochemical data taken from Kantor 050 SC cannot be used to support Matlam registration in Poland.

From physicochemical perspective **MATLAM is considered equivalent/ comparable to already registered Floras 50 SC in Poland** under Composition's comparison**.** Applicant has provided the letter of access to the Floras 50 SC data .So, physicochemical data taken from Floras 50 SC can be used to support Matlam registration in Poland.

Sufficiently sensitive and selective analytical methods are available for all analytes included in the residue definitions. The residue definition for risk assessment and enforcement purposes in cereals and grass can be established as florasulam. Analytical methods for enforcement of the residue definition are reported with an LOQ of 0.01 mg/kg in high water content, high fat content, acidic and dry commodities (EFSA Journal 2012;10(3):2626). In the context of the authorisation request data gaps are none.

| Commodity/crop | Supported/ Not supported |
|---|---|
| Cereals | 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 Florasulam in plant protection product is provided as follows:

| | |
|---|---|
| Comments of zRMS: | Accepted |

| | |
|---|---|
| Reference: | KCP 5.1.1-1 |
| Report | Floras 50 SC Stage I: Determination of pchysicochemical properties of the initial preparation, after accelerated and low temperature storage, Kupiec J., 2022, Report No. BF-21/22 |

| | |
|---|---|
| Guideline(s): | SANCO/3030/99 rev. 5 |
| Deviations: | No |
| GLP: | Yes |
| Acceptability: | Yes |

**Materials and methods**

| | |
|---|---|
| Test item: | Florasulam 50 g/L SC |
| Reference materials: | Florasulam, CAS No. 145701-23-1, IPO 940, Series 2A/21, Purity 99.7 % |

**Florasulam**

Chromatographic conditions

| | | | |
|---|---|---|---|
| Instrument: | Shimadzu liquid chromatograph with UV-VIS detector | | |
| Column: | Arion Plus C18, 250x4.6mm, 5µm | | |
| Column temperature: | 30 ºC | | |
| Mobile phase A: | Methanol | | |
| Mobile phase B: | 0.1 % $H_3PO_4$ | | |
| Gradient: | Time [min] | A [%] | B [%] |
| | 0.01 – 2.30 | 70 | 30 |
| | 2.31 – 5.00 | 28 | 72 |
| | 5.01 – 8.00 | 70 | 30 |
| Flow rate: | 1.0 mL/min | | |
| Wavelength: | λ = 260 nm | | |
| Injection volume: | 5 µL | | |
| Retention time: | 4.2 min ± 0.3 min | | |

Standard solutions

Florasulam standard was weighed (with the accuracy of 0.01 mg) into the 10 mL volumetric flask and acetonitrile was added. The flask was put into the ultrasonic bath for 5 min. After cooling, acetonitrile was added to the nominal volume and solution was diluted. Standards solutions of Florasulam was in the concentration range from 0.3018 mg/mL to 0.7545 mg/mL and analyzed.

Specimen solutions

About 100 mg of examined specimen was weighed (with the accuracy of 0.01 mg) into the 10 mL volumetric flask. 2 mL water was added, stirred and the flask was put into the ultrasonic bath for 5 min. After cooling, acetonitrile was added to the nominal volume, solutions of examined specimen were passed through syringe filters and analyzed.

**Validation - Results and discussions**

**Table 5.2-1: Methods suitable for the determination of active substances Florasulam in plant protection product MATLAM/RNB 072 A**

| | **Florasulam** |
|---|---|
| **Author(s), year** | Kupiec J., 2022 |
| **Principle of method** | HPLC-UV/VIS |
| **Linearity (linear between mg/L / % range of the declared content) (correlation coefficient, expressed as r)** | 0.3018 - 0.7545 mg/mL<br>n = 5<br>y = 8365610.324x - 5909.439<br>$R^2$ = 0.999 |

| | **Florasulam** |
|---|---|
| **Precision – Repeatability Mean<br>n = 6<br>(%RSD)** | Mean conc.: 4.83 %<br>RSD = 0.61 %<br>$RSD_r$ = 2.11 %<br>$H_r$ = 0.29, $H_r \leq 1$ |
| **Accuracy<br>n = 2 in in 6 repetitions<br>(% Recovery)** | Total recovery<br>Average 101.92 % |
| **Interference/ Specificity** | No interferences between the analyte and other compounds, the method is specific. |
| **Comment** | - |

**Conclusion**

According to SANCO/3030/99 rev. 5 the presented method was sufficiently validated and is suitable for determination of Florasulam content in the test item Florasulam 50 g/L SC.

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

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

| Comments of zRMS: | Accepted |
|---|---|

| | |
|---|---|
| Reference: | KCP 5.1.1-1 |
| Report | Floras 50 SC Stage I: Determination of pchysicochemical properties of the initial preparation, after accelerated and low temperature storage, Kupiec J., 2022, Report No. BF-21/22 |
| Guideline(s): | SANCO/3030/99 rev. 5 |
| Deviations: | No |
| GLP: | Yes |
| Acceptability: | Yes |

**Materials and methods**

| | |
|---|---|
| Test item: | Florasulam 50 g/L SC |
| Reference materials: | 2,6-difluoroaniline (2,6-DFA), Sigma-Aldrich, Batch no. STBH3159, Purity ≥ 97 % |

**2,6-DFA**

Chromatographic conditions

| | |
|---|---|
| Instrument: | Sciex QTRAP 4500 mass spectrometer with UHPLC |
| Column: | Luna Omega Polar PS C18, 100 × 2,1 mm, Phenomenex |
| Column temperature: | 30 ºC |
| Mobile phase A: | 5 mmol aqueous solution of ammonium formate + 0,1% aqueous solution of formic acid |
| Mobile phase B: | 5 mmol acetonitrile solution of ammonium formate + 0,1% |

| | | | |
|---|---|---|---|
| | acetonitrile solution of formic acid | | |
| Gradient: | Time [min] | A [%] | B [%] |
| | 0.00 | 95 | 5 |
| | 1.00 | 95 | 5 |
| | 5.00 | 5 | 95 |
| | 9.00 | 5 | 95 |
| | 10.00 | 95 | 5 |
| | 12.00 | 95 | 5 |
| Flow rate: | 0.4 mL/min | | |
| Precursor ion m/z: | 130.1 | | |
| Product ions m/z: | 110.1* and 90.1 (* used for calculation) | | |
| Collision energy (CE) (eV): | 20 and 22 respectively to product ion | | |
| Delustering potential (DP): | 30 | | |
| Injection volume: | 10 µL | | |
| Retention time: | 3.91 min ± 0.2 min | | |

Standard solutions
51.67 mg of 2.6 - difluoroaniline standard was weighed (with the accuracy of 0.01 mg) into 50 mL flask and acetonitryle was added up to the volume. The flask was put into the ultrasonic bath for 2 min. The solution was appropriate diluted by mobile phase A and analysed.

Specimen solutions
About 100 mg of preparation was weighed (with the accuracy of 0.01 mg) into a 10 mL flask and mobile phase A was added up to the volume. The flask was put into the ultrasonic bath for 2 min. After cooling, the solution was analysed.

**Validation - Results and discussions**

**Table 5.2-2: Methods suitable for the determination of the relevant impurities in plant protection product (PPP) MATLAM/RNB 072 A**

| | **2,6-DFA**<br>**max. 0.1 g/L in PPP** |
|---|---|
| **Author(s), year** | Kupiec J., 2022 |
| **Principle of method** | UHPLC-MS/MS |
| **Linearity**<br>**(linear between**<br>**mg/L)**<br>**(correlation coefficient, expressed as r)** | 0.0002 - 0.01103 mg/mL<br>n = 6<br>y = 2225855.9670x + 2962.9829<br>$R^2$ = 0.9994 |
| **Precision – Repeatability Mean**<br>**n = 6**<br>**(%RSD)** | Mean conc.: < LOQ %<br><br>In none of the examined samples, 2,6-DFA was detected above the LOQ. Therefore, for the determination of repeatability five portions of placebo were fortified with 2,6-DFA at one level 0.0029 mg/mL and analyzed.<br>n = 1<br>Mean conc.: ~ 0.00029 %<br>RSD = 0.87 %<br>$RSD_r$ = 9.13 %<br>$H_r$ = 0.09, $H_r \leq 1$ |
| **Accuracy**<br>**n = 2 in 5 replicates**<br>**(% Recovery)** | Total recovery<br>Average 108.9 % |

| | **2,6-DFA**<br>**max. 0.1 g/L in PPP** |
|---|---|
| **Interference/ Specificity** | No interferences between the analyte and other compounds, the method is specific. |
| **LOQ** | 0.00020 mg/mL (0.00000010 g/kg of PPP) |
| **Comment** | - |

**Conclusion**

According to SANCO/3030/99 rev. 5 the presented method was sufficiently validated and is suitable for determination of 2,6-DFA content in the test item Florasulam 50 g/L SC.

### 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)

The CIPAC method No. 616 is available for Florasulam.

### 5.2.2 Methods for the determination of residues (KCP 5.1.2)

Please refer to the post-registration method.

## 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 of Florasulam (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 | Florasulam | 0.01 mg/kg | Reg. (EU) 2022/1363 |
| Plant, high acid content | | 0.01 mg/kg | Reg. (EU) 2022/1363 |
| Plant, high protein/high starch content (dry commodities) | | 0.01 mg/kg | Reg. (EU) 2022/1363 |
| Plant, high oil content | | 0.01 mg/kg | Reg. (EU) 2022/1363 |
| Plant, difficult matrices (hops, spices, tea) | | 0.05 mg/kg | Reg. (EU) 2022/1363 |
| Muscle | Florasulam | 0.01 mg/kg | Reg. (EU) 2022/1363 |
| Milk | | 0.01 mg/kg | Reg. (EU) 2022/1363 |
| Eggs | | 0.01 mg/kg | Reg. (EU) 2022/1363 |
| Fat | | 0.01 mg/kg | Reg. (EU) 2022/1363 |
| Liver, kidney | | 0.01 mg/kg | Reg. (EU) 2022/1363 |
| Soil (Ecotoxicology) | Florasulam | 0.05 mg/kg | Common limit |
| Drinking water (Human toxicology) | Florasulam | 0.1 µg/L | General limit for drinking water |
| Surface water (Ecotoxicology) | Florasulam | 0.63 µg/L | Lowest NOEC from *Lemna gibba* study EFSA Journal 2015; 13(1):3984 |
| Air | Florasulam | 15 µg/m$^3$ | AOEL sys/AOEL inhal: 0.05 mg/kg bw/d Reg. (EU) 2015/1397 |
| Tissue (meat or liver) | Florasulam | 0.01 mg/kg | Common limit |
| Body fluids | | 0.05 mg/L | EFSA Journal 2015; 13(1):3984 |

### 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 Florasulam 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: Florasulam | | | | |
|---|---|---|---|---|
| **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 | Rodrigues Junior A., 2011 amended 2014, Report No. 110535, Addendum to the RAR, Poland, 2014, EU agreed |
| | ILV | 0.01 mg/kg | LC-MS/MS | Bacher R., 2011, Report No. 110536, RAR, Poland, 2013, EU agreed |
| | Confirmatory (if required) | 0.01 mg/kg | LC-MS/MS | Rodrigues Junior A., 2011 amended 2014, Report No. 110535, Addendum to the RAR, Poland, 2014, EU agreed |
| High acid content | Primary | 0.01 mg/kg | LC-MS/MS | Rodrigues Junior A., 2011 amended 2014, Report No. 110535, Addendum to the RAR, Poland, 2014, EU agreed |
| | ILV | - | - | Bacher R., 2011, Report No. 110536, RAR, Poland, 2013, EU agreed |
| | Confirmatory (if required) | 0.01 mg/kg | LC-MS/MS | Rodrigues Junior A., 2011 amended 2014, Report No. 110535, Addendum to the RAR, Poland, 2014, EU agreed |
| High oil content | Primary | 0.01 mg/kg | LC-MS/MS | Rodrigues Junior A., 2011 amended 2014, Report No. 110535, Addendum to the RAR, Poland, 2014, EU agreed |
| | ILV | - | - | Bacher R., 2011, Report No. 110536, RAR, Poland, 2013, EU agreed |
| | Confirmatory (if required) | 0.01 mg/kg | LC-MS/MS | Rodrigues Junior A., 2011 amended 2014, Report No. 110535, Addendum to the RAR, Poland, 2014, EU agreed |
| High protein/high starch content (dry) | Primary | 0.01 mg/kg | LC-MS/MS | Rodrigues Junior A., 2011 amended 2014, Report No. 110535, Addendum to the RAR, Poland, 2014, EU agreed |
| | ILV | - | - | Bacher R., 2011, Report No. 110536, RAR, Poland, 2013, EU agreed |
| | Confirmatory (if required) | 0.01 mg/kg | LC-MS/MS | Rodrigues Junior A., 2011 amended 2014, Report No. 110535, Addendum to the RAR, Poland, 2014, EU agreed |

**Table 5.3-3: Statement on extraction efficiency**

| | **Method for products of plant origin** |
|---|---|
| Required, available from: | - |
| Not required, because: | Residues ≥ LOQ are not expected. |

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

An overview on the acceptable methods and possible data gaps for analysis of Florasulam in animal matrices is given in the following tables.

**Table 5.3-4: Validated methods for food and feed of animal origin (if appropriate)**

| **Component of residue definition: Florasulam** | | | | |
|---|---|---|---|---|
| **Matrix type** | **Method type** | **Method LOQ** | **Principle of method (*i.e.* GC-MS or HPLC-UV)** | **Author(s), year / missing** |
| Milk | Primary | 0.01 mg/kg | LC-MS/MS | Bacher R., 2011, Report No. 110540, RAR, Poland, 2013, EU agreed |
| | ILV | 0.01 mg/kg | LC-MS/MS | David Robaugh A., 2012 amended 2014, Report No. 110541, Addendum to the RAR, Poland, 2014, EU agreed |
| | Confirmatory (if required) | 0.01 mg/kg | LC-MS/MS | Bacher R., 2011, Report No. 110540, RAR, Poland, 2013, EU agreed |
| Eggs | Primary | 0.01 mg/kg | LC-MS/MS | Bacher R., 2011, Report No. 110540, RAR, Poland, 2013, EU agreed |
| | ILV | 0.01 mg/kg | LC-MS/MS | David Robaugh A., 2012 amended 2014, Report No. 110541, Addendum to the RAR, Poland, 2014, EU agreed |
| | Confirmatory (if required) | 0.01 mg/kg | LC-MS/MS | Bacher R., 2011, Report No. 110540, RAR, Poland, 2013, EU agreed |
| Muscle | Primary | 0.01 mg/kg | LC-MS/MS | Bacher R., 2011, Report No. 110540, RAR, Poland, 2013, EU agreed |
| | ILV | 0.01 mg/kg | LC-MS/MS | David Robaugh A., 2012 amended 2014, Report No. 110541, Addendum to the RAR, Poland, 2014, EU agreed |
| | Confirmatory (if required) | 0.01 mg/kg | LC-MS/MS | Bacher R., 2011, Report No. 110540, RAR, Poland, 2013, EU agreed |
| Fat | Primary | 0.01 mg/kg | LC-MS/MS | Bacher R., 2011, Report No. 110540, RAR, Poland, 2013, EU |

| Component of residue definition: Florasulam | | | | |
|---|---|---|---|---|
| **Matrix type** | **Method type** | **Method LOQ** | **Principle of method (*i.e.* GC-MS or HPLC-UV)** | **Author(s), year / missing** |
| | | | | agreed |
| | ILV | 0.01 mg/kg | LC-MS/MS | David Robaugh A., 2012 amended 2014, Report No. 110541, Addendum to the RAR, Poland, 2014, EU agreed |
| | Confirmatory (if required) | 0.01 mg/kg | LC-MS/MS | Bacher R., 2011, Report No. 110540, RAR, Poland, 2013, EU agreed |
| Kidney, liver | Primary | 0.01 mg/kg | LC-MS/MS | Bacher R., 2011, Report No. 110540, RAR, Poland, 2013, EU agreed |
| | ILV | 0.01 mg/kg | LC-MS/MS | David Robaugh A., 2012 amended 2014, Report No. 110541, Addendum to the RAR, Poland, 2014, EU agreed |
| | Confirmatory (if required) | 0.01 mg/kg | LC-MS/MS | Bacher R., 2011, Report No. 110540, RAR, Poland, 2013, EU agreed |

**Table 5.3-5: Statement on extraction efficiency**

| | **Method for products of animal origin** |
|---|---|
| Required, available from: | - |
| Not required, because: | Residues ≥ LOQ are not expected. |

### 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 Florasulam in soil is given in the following tables.

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

| Component of residue definition: Florasulam | | | |
|---|---|---|---|
| **Method type** | **Method LOQ** | **Principle of method (*i.e.* GC-MS or HPLC-UV)** | **Author(s), year / missing** |
| Primary | 0.05 µg/kg (for Florasulam and 5-OH Florasulam) | LC-MS/MS | Bacher R., 2011, Report No. 110537, RAR, Poland, 2013, EU agreed |
| Confirmatory | 0.05 µg/kg (for Florasulam and 5-OH Florasulam) | LC-MS/MS | Bacher R., 2011, Report No. 110537, RAR, Poland, 2013, EU agreed |

### 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 Florasulam in surface and drinking water is given in the following tables.

**Table 5.3-7: Validated methods for water (if appropriate)**

| Component of residue definition: Florasulam | | | | |
|---|---|---|---|---|
| **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 (for Florasulam and 5-OH Florasulam) | LC-MS/MS | Class T., 2011, Report No. 110538, RAR, Poland, 2013, EU agreed |
| | ILV | 0.05 µg/L (for Florasulam and 5-OH Florasulam) | LC-MS/MS | Souza N., 2011, Report No. 110539, RAR, Poland, 2013 EU agreed |
| | Confirmatory | 0.05 µg/L (for Florasulam and 5-OH Florasulam) | LC-MS/MS | Class T., 2011, Report No. 110538, RAR, Poland, 2013, EU agreed |
| Surface water | Primary | 0.05 µg/L (for Florasulam and 5-OH Florasulam) | LC-MS/MS | Class T., 2011, Report No. 110538, RAR, Poland, 2013, EU agreed |
| | Confirmatory | 0.05 µg/L (for Florasulam and 5-OH Florasulam) | LC-MS/MS | Class T., 2011, Report No. 110538, RAR, Poland, 2013, EU agreed |
| Ground water | Primary | 0.05 µg/L (for Florasulam and 5-OH Florasulam) | LC-MS/MS | Class T., 2011, Report No. 110538, RAR, Poland, 2013, EU agreed |
| | Confirmatory | 0.05 µg/L (for Florasulam and 5-OH Florasulam) | LC-MS/MS | Class T., 2011, Report No. 110538, RAR, Poland, 2013, EU agreed |

### 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 Florasulam in air is given in the following tables.

**Table 5.3-8: Validated methods for air (if appropriate)**

| Component of residue definition: Florasulam | | | |
|---|---|---|---|
| **Method type** | **Method LOQ** | **Principle of method (i.e. GC-MS or HPLC-UV)** | **Author(s), year / missing** |
| Primary | 1.5 µg/m$^3$ | LC-MS/MS | Class T., 2011, Report No. 110282, RAR, Poland, 2013, EU agreed |
| Confirmatory | 1.5 µg/m$^3$ | LC-MS/MS | Class T., 2011, Report No. 110282, RAR, Poland, 2013, EU agreed |

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

An overview on the acceptable methods and possible data gaps for analysis of Florasulam in body fluids and tissues is given in the following table.

**Table 5.3-9: Methods for body fluids and tissues (if appropriate)**

| Component of residue definition: Florasulam | | | |
|---|---|---|---|
| **Method type** | **Method LOQ** | **Principle of method (i.e. GC-MS or HPLC-UV)** | **Author(s), year / missing** |
| Primary | 0.05 mg/L(in blood, urine) | LC-MS/MS | Class T., Gocer M., 2011, Report No. 110283, RAR, Poland, 2013, EU agreed |
| Confirmatory | 0.05 mg/L(in blood, urine) | LC-MS/MS | Class T., Gocer M., 2011, Report No. 110283, RAR, Poland, 2013, EU agreed |

According to SANTE/2020/12830 Rev.2 suitable methods for body tissues could be available from methods for food of animal origin since the residue definition is covered.

### 5.3.2.8 Other studies/ information

No other studies/ information.

# Appendix 1 Lists of data considered in support of the evaluation

**List of data submitted by the applicant and relied on**

| Data point | Author(s) | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Vertebrate study Y/N | Owner |
|---|---|---|---|---|---|
| KCP 5.1.1-1 | Kupiec J. | 2022 | Floras 50 SC Stage I: Determination of pchysicochemical properties of the initial preparation, after accelerated and low temperature storage.<br>Report No. BF-21/22<br>Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Warsaw<br>GLP<br>Unpublished | N | Elvita Sp. z o.o. |

**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<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Vertebrate study Y/N | Owner |
|---|---|---|---|---|---|
| KCP 5.2 | Rodrigues Junior A. | 2011<br>Amended 2014 | Residue Method Validation for the Determination of Florasulam in Agricultural Commodities.<br>Dow AgroSciences Ind. Ltda., Mogi Mirim Reg. Lab., Rod. SP 147, km 71.5, Mogi Mirim, SP, Brazil<br>Report No. 110535<br>GLP<br>Published | N | Dow AgroSciences |
| KCP 5.2 | Bacher R. | 2011 | Florasulam: Independent Laboratory Validation of a Residue Method for the Determination of Florasulam in Agricultural Commodities.<br>PTRL Europe GmbH, Helmholtzstr. 22, Science Park, D-89081 Ulm, Germany<br>Report No. 110536<br>GLP<br>Published | N | Dow AgroSciences |

| Data point | Author(s) | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Vertebrate study Y/N | Owner |
|---|---|---|---|---|---|
| KCP 5.2 | Bacher R. | 2011 | Method Validation Study for the Determination of Residues of Florasulam in Foodstuffs of Animal Origin by Liquid Chromatography with Tandem Mass Spectrometry.<br>PTRL Europe GmbH, Helmholtzstr. 22, Science Park, D-89081 Ulm, Germany.<br>Report No. 110540<br>GLP<br>Published | N | Dow AgroSciences |
| KCP 5.2 | David Robaugh A. | 2012, Amended 2014 | Independent Laboratory Validation Study for the determination of Residues of Florasulam in Bovine and Poultry Tissues by Liquid Chromatography with Tandem Mass Spectrometry.<br>Pyxant Labs Inc., 4720 Forge Road, Suite 108, Colorado Springs, CO 80907.<br>Report No. 110541<br>GLP<br>Published | N | Dow AgroSciences |
| KCP 5.2 | Bacher R. | 2011 | Method Validation Study for the Determination of Residues of Florasulam and its 5-OH Metabolite in Soil by Liquid Chromatography with Tandem Mass Spectrometry.<br>PTRL Europe GmbH, Helmholtzstr. 22, Science Park, D-89081 Ulm, Germany.<br>Report No. 110537<br>GLP<br>Published | N | Dow AgroSciences |
| KCP 5.2 | Class T. | 2011 | Method Validation Study for the Determination of Residues of Florasulam and its 5-OH Metabolite in Surface Water, Ground Water and Drinking Water by Liquid Chromatography with Tandem Mass Spectrometry.<br>PTRL Europe GmbH, Helmholtz str. 22, Science Park, D-89081 Ulm, Germany.<br>Report No. 110538<br>GLP<br>Published | N | Dow AgroSciences |
| KCP 5.2 | Souza N. | 2011 | Independent Laboratory Validation of Dow AgroSciences LLC Method − Determination of Residues of Florasulam and its 5-OH Metabolite in Drinking Water, Ground Water and Surface Water by Liquid Chromatography with Tandem Mass Spectrometric Detection.<br>Dow AgroSciences Ind. Ltda. – Rod. SP147, km71,5 Mogi Mirim, SP, Brazil 13800-9700<br>Report No. 110539<br>GLP | N | Dow AgroSciences |

| Data point | Author(s) | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Vertebrate study Y/N | Owner |
|---|---|---|---|---|---|
| | | | Published | | |
| KCP 5.2 | Class T. | 2011 | The Development and Validation of a Method for the Analysis of Florasulam in Air.<br>PTRL Europe GmbH, Helmholtzstr. 22, Science Park, D-89081Ulm, Germany.<br>Report No. 110282<br>GLP<br>Published | N | Dow AgroSciences |
| KCP 5.2 | Class T., Gocer M. | 2011 | Florasulam: Development of an Analytical Method for the Determination of Florasulam in Body Fluid(s).<br>PTRL Europe GmbH, Helmholtzstr. 22, Science Park, D-89081 Ulm, Germany.<br>Report No. 110283<br>GLP<br>Published | N | Dow AgroSciences |

# Appendix 2 Detailed evaluation of submitted analytical methods

## A 2.1 Analytical methods for Florasulam

### 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.