Evaluation of confirmatory data following the Article 12 MRL review for teflubenzuron

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Abstract

The applicant BASF Agro BV submitted a request to the competent national authority in United Kingdom to evaluate the confirmatory data that were identified for teflubenzuron in the framework of the maximum residue level (MRL) review under Article 12 of Regulation (EC) No 396/2005 as not available. To address the data gaps, a new metabolism study on leafy crops, a study investigating the nature of residues under standard hydrolytic conditions and a validated analytical method to determine residues of teflubenzuron in products of animal origin were submitted. The data gaps were considered satisfactorily addressed. The new information provided does not require a revision of risk assessment performed for teflubenzuron.

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Keywords: teflubenzuron, confirmatory data, pesticide, MRL review, risk assessment

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Summary

In 2014, when the European Food Safety Authority (EFSA) reviewed the existing maximum residue levels (MRLs) for teflubenzuron according to Article 12 of Regulation (EC) No 396/2005, EFSA identified some information as unavailable (data gaps) and derived tentative MRLs for those uses which were not fully supported by data but for which no risk to consumers was identified. The following data gaps were noted:

1) an independent laboratory validation (ILV) and a confirmatory method for enforcement of teflubenzuron in animal products;
2) a metabolism study in leafy vegetables with the radio-labelling on both the aniline and the benzoyl rings;
3) a confirmation that the Good Agricultural Practice (GAP) for head cabbage is on an artificial substrate or a closed hydroponic system (otherwise the GAP is not compliant with the approval restrictions);
4) eight residue trials supporting the indoor GAP on head cabbage;
5) a study addressing the nature of the residues under hydrolytic conditions representative of pasteurisation, boiling/brewing/baking and sterilisation (for tomatoes and apples in particular as they are the main contributors to the consumer exposure);
6) metabolism studies on ruminants and poultry with teflubenzuron radio-labelled at the benzoyl ring (required only if the calculated maximum dietary burden exceeds the trigger value of 0.1 mg/kg dry matter (DM)).

Tentative MRL proposals have been implemented in the MRL legislation by Commission Regulation (EU) No 2016/71, including footnotes related to data gaps number 1, 2, 5 and 6, indicating the type of information that should be provided by a party having an interest in maintaining the proposed tentative MRL by 27 January 2018. Data gaps number 3 and 4 were not implemented in the MRL regulation, because risk managers decided to set alternative MRLs that were sufficiently supported by data.

In accordance with the agreed procedure set out in the working document SANTE/10235/2016, BASF Agro BV submitted an application to the competent national authority in the United Kingdom (rapporteur Member State (RMS)) to evaluate the confirmatory data identified during the MRL review. The RMS assessed the new information in an evaluation report, which was submitted to the European Commission and forwarded to the EFSA on 8 March 2018. When assessing the evaluation report, EFSA identified points which needed further clarifications. On 1 May 2018, the evaluating Member State (EMS) submitted a revised evaluation report which addressed the points for clarification.

The summary table below provides an overview of the assessment of confirmatory data and the recommended MRL modifications to Regulation (EU) No 396/2005.

| Code(a) | Commodity       | Existing MRL(b) | Proposed MRL | Conclusion/recommendation |
|---------|-----------------|-----------------|--------------|---------------------------|
| 0130010 | Apples          | 1 (Ft 1)        | 1            | The submitted data addressed the data gap identified by EFSA. The MRL is confirmed. The previous conclusion on the consumer risk assessment is still valid |
| 0242010 | Brussels sprouts| 0.5 (Ft 2)      | 0.5          | The submitted data addressed the data gap identified by EFSA. The existing MRL is confirmed. The previous conclusion on the consumer risk assessment is still valid |
| 0242020 | Head cabbages   | 0.2 (Ft 2)      | 0.2          | The submitted data addressed the data gap identified by EFSA. The existing MRL is confirmed. The previous conclusion on the consumer risk assessment is still valid |
| Code<sup>(a)</sup> | Commodity | Existing MRL<sup>(b)</sup> | Proposed MRL | Conclusion/recommendation |
|-----------------|-----------|--------------------------|--------------|---------------------------|
| 1000000         | Products of animal origin – terrestrial animals | 0.05 (Ft 3) | 0.01* | The submitted analytical method for animal origin products was sufficiently validated for quantifying teflubenzuron residues at the LOQ of 0.01 mg/kg. No new livestock metabolism studies were submitted and are not required (the dietary burden expected from EU uses is below the trigger value of 0.1 mg/kg DM). EFSA recommends lowering the MRLs to the LOQ of 0.01 mg/kg, which corresponds to the CXLs set for teflubenzuron in products of animal origin. |

MRL: maximum residue level; CXL: Codex maximum residue limit.
*: LOQ: limit of quantification.
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(b): The footnote reported in Regulation (EC) No 396/2005 and the corresponding number of the data gap as per the data gaps listed above.

Ft 1: The European Food Safety Authority identified some information on hydrolysis study in processed commodities as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 27 January 2018, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gap No 5.)

Ft 2: The European Food Safety Authority identified some information on metabolism study in leafy crops as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 27 January 2018, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gap No 2.)

Ft 3: The European Food Safety Authority identified some information on analytical methods for animal origin products and metabolism studies in ruminant and poultry as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 27 January 2018, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gap No 1 and 6.)

(F): Fat-soluble.
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Assessment

In the framework of the maximum residue levels (MRL) review of teflubenzuron according to Article 12 of Regulation (EC) No 396/2005 (MRL review, EFSA, 2014), the European Food Safety Authority (EFSA) identified some information as unavailable (data gaps) and derived tentative MRLs for those uses not fully supported by data but for which no risk to consumers was identified.

The MRL modifications proposed following the MRL review have been implemented in Regulation (EC) No 396/2005 by Commission Regulation (EU) No 2016/71, including a footnote that specified for the relevant MRLs the type of information that was identified as missing. Any party having an interest in maintaining the proposed tentative MRL was requested to address the confirmatory data by 27 January 2018.

In accordance with the agreed procedure set out in a working document SANTE/10235/2016, BASF Agro BV submitted an application to the competent national authority in the United Kingdom (rapporteur Member State (RMS)) to evaluate the confirmatory data identified during the MRL review. To address the data gaps identified by EFSA, the applicant provided a new metabolism study on leafy crops, a study investigating the nature of residues under standard hydrolytic conditions and a validated analytical method to determine residues of teflubenzuron in products of animal origin.

The RMS assessed the new information in an evaluation report, which was submitted to the European Commission and forwarded to the EFSA on 8 March 2018. During the detailed assessment, EFSA identified points which needed further clarifications. On 1 May 2018, the evaluating Member State (EMS) submitted a revised evaluation report which addressed the points for clarification.

It is noted that the original application received covered not only the confirmatory data, but also requested the assessment of the setting of import tolerances for teflubenzuron in various crops (EFSA-Q-2018-00240). Since EFSA identified data gaps for the application on import tolerances, the assessment of confirmatory is performed in a separate reasoned opinion. A second reasoned opinion will be issued by EFSA, once the requested information for the import tolerance is provided.

EFSA based its assessment on the evaluation report submitted by the RMS (United Kingdom, 2018), the reasoned opinion on the MRL review according to Article 12 of Regulation (EC) No 396/2005, taking into account the additional assessments on teflubenzuron performed after the MRL review (EFSA, 2014, 2017).

For this application, the data requirements established in Regulation (EU) No 544/2011 and the guidance documents at the date of implementation of the confirmatory data requirements by Regulation (EU) No 2016/71 are applicable. The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011.

A selected list of end points of the studies assessed by EFSA in the framework of this confirmatory data application including the end points of relevant studies assessed previously, are presented in Appendix A.

The peer review of the renewal of approval of the active substance in accordance with Regulation (EC) No 1107/2009 is not yet finalised and therefore the conclusions reported in this reasoned opinion should be taken as provisional and might need to be reconsidered in the light of the outcome of the peer review.

The evaluation report submitted by the RMS (United Kingdom, 2018) is considered as a supporting document to this reasoned opinion and, thus, is made publicly available as a background document to this reasoned opinion.

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1 Chemical structure of the active substance is presented in Appendix B.
2 Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.
3 Commission Regulation (EU) 2016/71 of 26 January 2016 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 1-methylcyclobutene, flonicamid, flutriafol, indolylacetac acid, indolylbutyric acid, pethoxamid, pirimicarb, prothioconazole and teflubenzuron in or on certain products. OJ L 20, 27.1.2016, p. 1–47.
4 Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances. OJ L 155, 11.6.2011, p. 1–66.
5 Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.
1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

In order to address data gap number 2,6 a new metabolism study following foliar application in spinaches (leafy crop group) was submitted. Teflubenzuron was radiolabelled in either the aniline or the benzoyl ring. In immature and mature leaves, radioactivity was represented by unchanged parent compound (95.6–99.8% of identified total radioactive residue (TRR)) and a cleavage of the molecule was not observed. Details of the study are presented in Appendix A.

EFSA concluded that the data gap identified in the framework of the MRL review was addressed.

1.1.2. Nature of residues in rotational crops

Not relevant for the current assessment.

1.1.3. Nature of residues in processed commodities

To address data gap number 5,7 a new study investigating the effect of processing on the nature of teflubenzuron residues was submitted. The study was not carried out with radiolabelled material as it is normally the case for hydrolysis studies, and it did not test intermediate conditions simulating baking, brewing/baking (60 min, 100°C, pH 5). At the end of the study, the mean recoveries of teflubenzuron were 89% and 94% after pasteurisation and sterilisation standard conditions, respectively. Details of the study are presented in Appendix A.

Taking into account that teflubenzuron was shown to be stable under realistic heating processing conditions8 during the European Union (EU) pesticide peer review and the results of the hydrolysis study submitted, EFSA supports the conclusion of the RMS that the parent compound is expected to be stable following processing and that further data are not required in the framework of this assessment.

EFSA concluded that the data gap identified in the framework of the MRL review was addressed.

1.1.4. Methods of analysis in plants

Not relevant for the current assessment.

1.1.5. Stability of residues in plants

Not relevant for the current assessment.

1.1.6. Proposed residue definitions

Taking into account the results of the new metabolism study on spinaches and the new hydrolysis study submitted, EFSA confirms the previously derived residue definitions for enforcement and risk assessment as parent teflubenzuron can be extended to leafy crops and apply to processing products.

1.2. Magnitude of residues in plants

Not relevant for the current assessment.

Data gap number 4 requesting eight residue trials supporting the indoor Good Agricultural Practice (GAP) on head cabbage was not implemented in Regulation (EC) No 396/2005 as a footnote, because risk managers decided to take over the Codex maximum residue limit (CXL) for head cabbage, instead of setting an MRL for an EU use.

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6 Data gap number 2: a metabolism study in leafy vegetables with the radio-labelling on both the aniline and the benzoyl rings.
7 Data gap number 5: a study addressing the nature of the residues under hydrolytic conditions representative of pasteurisation, boiling/brewing/baking and sterilisation (for tomatoes and apples in particular as they are the main contributors to the consumer exposure).
8 In apple, 97% and 99% of the teflubenzuron present in the samples was retained in wet and dry pomace, respectively. Dried pomace was obtained at 90°C for several hours. In tomatoes, despite the sterilisation processes, teflubenzuron residues in canned tomatoes were identical to the levels recovered in peeled tomatoes (United Kingdom, 2007; EFSA, 2008).
2. Residues in livestock

2.1. Nature of residues

As regards data gap number 6,\(^9\) the applicant did not submit new information. The need to submit this study was linked to the EU use of teflubenzuron in head cabbage assessed under the MRL review (see Section 1.2).

Since the applicant did not support the use in head cabbages in the EU, which was the only potential feed item assessed in the MRL review, the studies are not required for the confirmatory data assessment. Exposure of livestock to teflubenzuron residues resulting from EU uses assessed in the MRL review is not expected.

Studies investigating the nature of residues in livestock with teflubenzuron radiolabelled at the benzoyl ring would be still required to derive a robust residue definition in products of animal origin if new uses are intended to be authorised which lead to a dietary exposure of livestock exceeding the trigger of 0.1 mg/kg dry matter (DM).

2.2. Methods of analysis in livestock

In order to address data gap number 1,\(^10\) the applicant proposed a modified version of the QuEChERS multiresidue method for the determination of teflubenzuron in commodities of animal origin. Residues were quantified by high-performance liquid chromatography coupled with tandem mass spectrometry detection (HPLC–MS/MS) using a selected ion transition for quantification and an additional transition for confirmation. The method was validated at the limit of quantification (LOQ) of 0.01 mg/kg in bovine muscle, fat, liver and milk and poultry eggs. An independent laboratory validation (ILV) was conducted which confirmed the suitability of the method for the analysis of muscle, fat, liver, milk and eggs at the LOQ of 0.01 mg/kg (United Kingdom, 2018).

EFSA concluded that the data gap identified in the framework of the MRL review for a validated analytical method for products of animal origin was addressed.

2.3. Magnitude of residues in livestock

The MRLs for animal commodities in the MRL regulation were tentatively set at a level of 0.05 mg/kg, requesting additional validation data for an analytical method (data gap number 1) and metabolism studies in ruminants and poultry (data gap number 6). Taking into account the conclusions derived under Sections 2.1 and 2.2, EFSA proposes to lower the MRLs for all products of animal origin to the LOQ of 0.01 mg/kg, which also corresponds to the existing Codex MRL.

3. Consumer risk assessment

The submitted confirmatory data did not trigger a modification of previous risk assessment performed in the framework of the most recent assessment of teflubenzuron (EFSA, 2017) and the conclusions derived are still valid.

4. Conclusion and Recommendations

To address data gaps identified in the framework of the MRL review (EFSA, 2014), a new metabolism study on leafy crops, a study investigating the nature of residues under standard hydrolytic conditions and a validated analytical method to determine residues of teflubenzuron in products of animal origin were submitted by the applicant. The data gaps were sufficiently addressed. The new information provided does not require a revision of risk assessment performed for teflubenzuron.

The overview of the assessment of confirmatory data and the recommended MRL modifications are summarised in Appendix A.4.

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\(^9\) Data gap number 6: metabolism studies on ruminants and poultry with teflubenzuron radio-labelled at the benzoyl ring, required only if the calculated maximum dietary burden exceeds the trigger value of 0.1 mg/kg DM.

\(^10\) Data gap number 1: an ILV and a confirmatory method for enforcement of teflubenzuron in animal products.
References

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United Kingdom, 2007. Draft assessment report on the active substance teflubenzuron prepared by the rapporteur Member State United Kingdom in the framework of Council Directive 91/414/EEC, compiled by EFSA, June 2007. Available online: www.efsa.europa.eu

United Kingdom, 2018. Evaluation report on the setting of Import tolerances for teflubenzuron in various commodities. February 2018, as revised in March 2018, 213 pp.

Abbreviations

a.s. active substance
CCPR Codex Committee on Pesticide Residues
CXL Codex maximum residue limit
DALA days after last application
DAT days after treatment
DM dry matter
EMS evaluating Member State
FAO Food and Agriculture Organization of the United Nations
GAP Good Agricultural Practice
HPLC-MS/MS high-performance liquid chromatography with tandem mass spectrometry
ILV independent laboratory validation
InChIKey International Chemical Identifier Key
IUPAC International Union of Pure and Applied Chemistry
LOQ limit of quantification
MRL maximum residue level
MW molecular weight
OECD Organisation for Economic Co-operation and Development
PBI plant-back interval
QuEChERS Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RA risk assessment
RD residue definition
EMS evaluating Member State
SANCO Directorate-General for Health and Consumers
SMILES simplified molecular-input line-entry system
TRR total radioactive residue
WHO World Health Organization
Appendix A – List of end points

A.1. Residues in plants

A.1.1. Nature of residues and methods of analysis in plants

### A.1.1.1. Metabolism studies, methods of analysis and residue definitions in plants

#### Primary crops (available studies)

| Crop groups | Crop(s)       | Application (s) | Sampling       | Comment/source                                      |
|-------------|---------------|-----------------|----------------|-----------------------------------------------------|
| Fruit crops | Apple         | Foliar, 3 × 20 g/L | 5, 6, 15, 21, 30 DALA | Radiolabelled a.s.: U-14C-aniline ring. Total rate: 0.9 mL/fruit EFSA (2008) |
| Root crops  | Potato        | Foliar, 4 × 90 g/ha | 63 DALA       | Radiolabelled a.s.: U-14C-aniline ring EFSA (2008) |
|             | Soil, 4 × 90 g/ha |                | 63 DALA       |                                                     |
| Leafy crops | Spinach       | Foliar, 1 × 60 g/ha | 0, 8, 15 DAT  | Radiolabelled a.s.: U-14C-aniline ring EFSA (2008) |
|             |               | Foliar, 1 × 100 g/ha | < 1, 15 (immature), 30 (mature DAT) | Radiolabelled a.s.: U-14C-aniline and benzoyl ring United Kingdom (2018) |
| Pulses/oilseeds | Cotton | Foliar, 2 × 156 g/ha | Not reported | Before the applications, unlabelled a.s applied at 81 g/ha EFSA (2014) |

#### Rotational crops (available studies)

| Crop groups | Crop(s)       | Application (s) | PBI (DAT) | Comment/source                                      |
|-------------|---------------|-----------------|-----------|-----------------------------------------------------|
| Root/tuber crops | Carrot | Indoor, 500 g/ha | 30, 121/120, 360/365 | Radiolabelled a.s.: 14C-aniline and benzoyl ring. Low application rate and insufficient identification of residues EFSA (2008) |
| Leafy crops | Lettuce       | Indoor, 500 g/ha | 30, 121/120, 360/365 |                                                     |
| Cereal (small grain) | Wheat | Indoor, 500 g/ha | 30, 121/120, 360/365 |                                                     |

#### Processed commodities (hydrolysis study)

| Conditions                                      | Stable? | Comment/Source                  |
|-------------------------------------------------|---------|----------------------------------|
| Pasteurisation (20 min, 90°C, pH 4)              | Yes     | Test substance not radiolabelled United Kingdom (2018) |
| Baking, brewing, boiling (60 min, 100°C, pH 5)   | Not tested |                                     |
| Sterilisation (20 min, 120°C, pH 6)              | Yes     |                                    |

Plant residue definition for monitoring (RD-Mo) Teflubenzuron

Plant residue definition for risk assessment (RD-RA) Teflubenzuron

DALA: days after last application; a.s.: active substance; DAT: days after treatment; PBI: plant-back interval.
A.1.1.2. Stability of residues in plants
Not applicable.

A.1.2. Magnitude of residues in plants
Not applicable.

A.2. Residues in livestock

A.2.1. Nature of residues and methods of analysis in livestock

A.2.1.1. Metabolism studies, methods of analysis and residue definitions in livestock

Metabolism studies not required for the confirmatory data assessment.
The applicant did not support the use in head cabbages in the EU, which was the only potential feed item assessed in the MRL review.

Methods of analysis for monitoring of residues (analytical technique, matrix, LOQs)

- Milk, eggs, muscle, fat, liver: HPLC–MS/MS (QuEChERS modification), LOQ 0.01 mg/kg. Confirmatory method available. ILV available (United kingdom, 2018)

A.2.1.2. Stability of residues in livestock
Not applicable.

A.2.2. Magnitude of residues in livestock
Not applicable.

A.3. Consumer risk assessment
Not applicable.

A.4. Recommended MRLs

| Code(a) | Commodity | Existing MRL(b) | Proposed MRL | Conclusion/recommendation |
|---------|-----------|----------------|--------------|---------------------------|
| 0130010 | Apples    | 1 (Ft 1)       | 1            | The submitted data addressed the data gap identified by EFSA. The MRL is confirmed. The previous conclusion on the consumer risk assessment is still valid |
| 0242010 | Brussels sprouts | 0.5 (Ft 2)   | 0.5          | The submitted data addressed the data gap identified by EFSA. The existing MRL is confirmed. The previous conclusion on the consumer risk assessment is still valid |
| 0242020 | Head cabbages | 0.2 (Ft 2)   | 0.2          | The submitted data addressed the data gap identified by EFSA. The existing MRL is confirmed. The previous conclusion on the consumer risk assessment is still valid |
| 1000000 | Products of animal origin - terrestrial animals | 0.05 (Ft 3) | 0.01* | The submitted analytical method for animal origin products was sufficiently validated for quantifying teflubenzuron residues at the LOQ of 0.01 mg/kg No new livestock metabolism studies were submitted and are not required (the dietary burden expected from EU uses is below the trigger value of 0.1 mg/kg DM) EFSA recommends lowering the MRLs to the LOQ of 0.01 mg/kg, which corresponds to the CXL set for teflubenzuron in products of animal origin |

HPLC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method; LOQ: limit of quantification; ILV: independent laboratory validation.)
MRL: maximum residue level; CXL: Codex maximum residue limit.
*: LOQ: limit of quantification.
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(b): The footnote reported in Regulation (EC) No 396/2005 and the corresponding number of the data gap as per the data gaps listed above.

Ft 1: The European Food Safety Authority identified some information on hydrolysis study in processed commodities as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 27 January 2018, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gap No 5.)

Ft 2: The European Food Safety Authority identified some information on metabolism study in leafy crops as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 27 January 2018, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gap No 2.)

Ft 3: The European Food Safety Authority identified some information on analytical methods for animal origin products and metabolism studies in ruminant and poultry as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 27 January 2018, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gap No 1 and 6.)

(F): Fat-soluble.
### Appendix B – Used compound codes

| Code/trivial name<sup>(a)</sup> | IUPAC name/SMILES notation/InChiKey<sup>(a)</sup> | Structural formula<sup>(b)</sup> |
|---------------------------------|-----------------------------------------------|---------------------------------|
| teflubenzuron                   | 1-(3,5-dichloro-2,4-difluorophenyl)-3-(2,6-difluorobenzoyl)urea Clc2cc(NC(=O)NC(=O)c1c(F)cccc1F)c(F)c(Cl)c2F CJDWRQLODFKPEL-UHFFFAOYSA-N | ![Structural formula](image) |

IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system; InChiKey: International Chemical Identifier Key.

<sup>(a)</sup> ACD/Name 2015 ACD/Labs 2015 Release (File version N20E41, Build 75170, 19 December 2014).

<sup>(b)</sup> ACD/ChemSketch 2015 ACD/Labs 2015 Release (File version C10H41, Build 75059, 17 December 2014).