FINAL REGISTRATION REPORT

# Part B

# Section 7

# Metabolism and Residues

Detailed summary of the risk assessment

Product code: A18385B

Product name: SPANDIS 54 WG

Chemical active substances:

Dicamba, 400 g/kg
Nicosulfuron, 100 g/kg
Prosulfuron, 40 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(new authorization)

Applicant: Syngenta

Submission date: 26/11/2020

MS Finalisation date: 11/07/2022

# Version history

| When | What |
|---|---|
| February 2021 | Dossier sent for evaluation |
| August 2021 | zRMS evaluation of dRR |
| July 2022 | Final version prepared by zRMS after Commenting period |

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# 7 Metabolism and residue data (KCA section 6)

## 7.1 Summary and zRMS Conclusion

The text of the applicant was not rewritten. The zRMS text is on grey background.

### 7.1.1 Critical GAP(s) and overall conclusion

**Selection of critical uses and justification**

The critical GAPs with respect to consumer intake and risk assessment for the preparation A18385B are presented in Table 7.1-1. They have been selected from the individual GAPs in the NEU for maize. A list of all intended uses within the NEU is given in Part B, Section 0.

The selected critical GAPs are representative GAPs for prosulfuron, nicosulfuron and dicamba (please, see SANTE/10682/2015 Rev 3; SANCO/3780/07– rev.1; SANCO/829/08 – rev. 2).

**Overall conclusion**

The data available are considered sufficient for risk assessment. An exceedance of the current maize MRL of 0.01 mg/kg for prosulfuron, 0.01 mg/kg for nicosulfuron and 0.5 mg/kg for dicamba as laid down in Reg. (EU) 396/2005 is not expected.

The chronic and the short-term intakes of prosulfuron, nicosulfuron and dicamba residues are unlikely to present a public health concern.

As far as consumer health protection is concerned, zRMS agrees with the authorization of the intended use in maize.

According to available data, no specific mitigation measures should apply.

**Data gaps**

Noticed data gaps are: none

**Table 7.1-1: Acceptability of critical GAPs (and respective fall-back GAPs, if applicable)**

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | | 8 | | | | 9 | | | 10 | 11 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **GAP number (see part B.0)*** | **Crop and/ or situation **** | **Zone** | **Product code** | **F, Fn, Fpn G, Gn, Gpn or I***** | **Pests or Group of pests controlled** | **Formulation** | | **Application** | | | | **Application rate per treatment** | | | **PHI (days)** | **Conclusion** |
| | | | | | | **Type** | **Conc. of as$** | **method kind** | **growth stage & season** | **number min max** | **interval between applica-tions (min)** | **kg ppp/ha$ min max** | **water L/ha min max** | **kg as/ha$ min max** | | |
| **1, 2** | Maize | CEU | A18385B | F | Annual/ perennial broad leave weeds and grasses | WG | 1) 40g/kg<br>2) 100g/kg<br>3) 400g/kg | Foliar spray | BBCH 12-18 | 1 (1 appl. every 3rd year) | N/A | 0,5 kg/ha | 200-400 | 1) 0.016-0.020<br>2) 0.04-0.05<br>3) 0.160-0.200 | n.s. | |

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
** Use also code numbers according to Annex I of Regulation (EU) No 396/2005
*** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
$ 1) prosulfuron 2) nicosulfuron 3) dicamba
n.s. not specified (the applicant means: the PHI is covered by the time remaining between application and harvest; consequently "F" should be used)

Explanation for Column 11 "Conclusion"

| | |
|---|---|
| A | Exposure acceptable without risk mitigation measures, safe use |
| R | Further refinement and/or risk mitigation measures required |
| N | Exposure not acceptable, no safe use |

### 7.1.2 Summary of the evaluation

The preparation A18385B is composed of prosulfuron, nicosulfuron and dicamba.

**Table 7.1-2: Toxicological reference values for the dietary risk assessment of prosulfuron, nicosulfuron and dicamba**

| Reference value | Source | Year | Value | Study relied upon | Safety factor |
|---|---|---|---|---|---|
| **Prosulfuron - Parent compound** | | | | | |
| ADI | EFSA | 2014 | 0.02 mg/kg bw/day | 1-year, dog and 18-month, mouse | 100 |
| ARfD | EFSA | 2014 | 0.1 mg/kg bw | Developmental toxicity, rabbit | 100 |
| **Nicolsulfuron - Parent compound** | | | | | |
| ADI | EFSA | 2007 | 2 mg/kg bw/day | Chronic rat, supported by subchronic dog (28-day, 90-day and 1-year) | 100 |
| ARfD | EFSA | 2007 | Not needed | N/A | N/A |
| **Dicamba - Parent compound** | | | | | |
| ADI | EFSA | 2011 | 0.3 mg/kg bw/day | Rat, 2-generation study | 100 |
| ARfD | EFSA | 2011 | 0.3 mg/kg bw | Rabbit, teratology study | 100 |

#### 7.1.2.1 Summary for prosulfuron

**Table 7.1-3: Summary for prosulfuron**

| Use-No.* | Crop | Plant metabolism covered? | Sufficient residue trials? | PHI sufficiently supported? | Sample storage covered by stability data? | MRL compliance | Chronic risk for consumers identified? | Acute risk for consumers identified? |
|---|---|---|---|---|---|---|---|---|
| 1,2 | Maize | Yes | Yes (28 NEU) | Yes | Yes | Yes | No | No |

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

No new data related to the nature of residues in primary or rotational crops, processed commodities or livestock are submitted in the framework of this application. The available data sufficiently addresses the proposed uses of prosulfuron in the product A18385B.

In all maize whole plant, leaf, stalk, fodder, cob and grain specimens collected in residue trials, residues of prosulfuron were below the LOQ. The data available shows that no exceedance of the existing MRL will occur. The use on maize is considered acceptable.

### 7.1.2.2 Summary for nicosulfuron

**Table 7.1-4: Summary for nicosulfuron**

| Use-No.* | Crop | Plant metabolism covered? | Sufficient residue trials? | PHI sufficiently supported? | Sample storage covered by stability data? | MRL compliance | Chronic risk for consumers identified? | Acute risk for consumers identified? |
|---|---|---|---|---|---|---|---|---|
| 1,2 | Maize | Yes | Yes (18 NEU) | Yes | Yes | Yes | No | No |

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

No new data related to the nature of residues in primary or rotational crops, processed commodities or livestock are submitted in the framework of this application. The available data sufficiently addresses the proposed uses of nicosulfuron in the product A18385B.

In all maize whole plant (fodder), ears and grain specimens collected in residue trials, residues of nicosulfuron were below the LOQ (except for 1 whole plant sample each in NEU and SEU - 0.015, 0.013 mg/kg, respectively). Thus, the sufficient data are available to show that no exceedance of the existing MRL will occur. The use of A18385B on maize is considered acceptable.

### 7.1.2.3 Summary for dicamba

**Table 7.1-5: Summary for dicamba**

| Use-No.* | Crop | Plant metabolism covered? | Sufficient residue trials? | PHI sufficiently supported? | Sample storage covered by stability data? | MRL compliance | Chronic risk for consumers identified? | Acute risk for consumers identified? |
|---|---|---|---|---|---|---|---|---|
| 1,2 | Maize | Yes | Yes (9 NEU) | Yes | Yes | Yes | No | No |

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

No new data related to the nature of residues in primary or rotational crops, processed commodities or livestock are submitted in the framework of this application. The available data sufficiently addresses the proposed use of dicamba in the product A18385B. Moreover, the proposed use does not modify the theoretical maximum daily intake for animals, while the new mode of calculation does, but regarding available feeding data, there is no risk for animal MRL to be exceeded.

In all maize grain specimens collected in residue trials, residues of dicamba were below the LOQ. Thus, the sufficient data are available to show that no exceedance of the existing MRL will occur. The use of dicamba in A18385B on maize is considered acceptable.

An additional 4 SEU trials were submitted with the MRL Compilation dossier for dicamba. These trials were performed with a lower application rate of about 0.280 kg a.s./ha, in compliance with the most recent overall cGAP (see Appendix 2). These trials are not relevant for NEU.

### 7.1.2.4 Summary for A18385B

**Table 7.1-4: Information on A18385B (KCA 6.8)**

| Crop | PHI for A18385B proposed by applicant | PHI/ Withholding period* sufficiently supported for | | | PHI for A18385B proposed by zRMS | zRMS Comments (if different PHI proposed) |
|---|---|---|---|---|---|---|
| | | Prosulfuron | Nicosulfuron | Dicamba | | |
| Maize | F | F | F | F | F | No comment |

NR: not relevant
* Purpose of withholding period to be specified
** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

**Table 7.1-5: Waiting periods before planting succeeding crops**

| Waiting period before planting succeeding crops | | | | Overall waiting period proposed by zRMS for A18385B |
|---|---|---|---|---|
| Crop group | Led by prosulfuron | Led by nicosulfuron | Led by dicamba | |
| … | NR | NR | NR | NR |

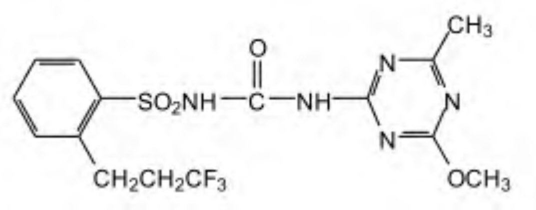
NR: not relevant (residue levels in rotational commodities are not expected to exceed 0.01 mg/kg for all the actives).

**Assessment**

## 7.2 Prosulfuron

General data on prosulfuron are summarized in the table below (last updated 2020/09/08).

**Table 7.2-1: General information on prosulfuron**

| | |
|---|---|
| Active substance (ISO Common Name) | Prosulfuron |
| IUPAC | 1-(4-methoxy-6-methyl-triazin-2-yl)-3-[2-(3,3,3-trifluoropropyl)phenylsulfonyl]urea |
| Chemical structure |  |
| Molecular formula | $C_{15}H_{16}F_3N_5O_4S$ |
| Molar mass | 419.4 g/mol |
| Chemical group | Triazinylsulfonylurea compound |
| Mode of action (if available) | Inhibition of the enzyme acetolactose synthase |
| Systemic | Yes |
| Company (ies) | Syngenta |
| Rapporteur Member State (RMS) | France |
| Approval status | Approved<br>Regulation (EU) 2017/375 |
| Restriction | Restricted to uses as herbicide |
| Review Report | SANTE/10682/2015 Rev. 3, 24 January 2017 |
| Current MRL regulation | Regulation (EU) No 617/2014 |
| Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed | Yes |
| EFSA Journal: Conclusion on the peer review | Yes (EFSA, 2014, 2020) |
| EFSA Journal: Conclusion on article 12 | Yes (EFSA, 2012) |
| Current MRL applications on intended uses | No MRL applications are pending |

### 7.2.1 Stability of Residues (KCA 6.1)

#### 7.2.1.1 Stability of residues during storage of samples

**Available data**

*References: France, 1998, 2013*

No new data submitted in the framework of this application.

**Table 7.2-2: Summary of stability data achieved at ≤ - 18°C (unless stated otherwise)**

| Commodity category | Commodity | Acceptable maximum storage period | Report Reference | Source |
|---|---|---|---|---|
| **EU reviewed data** | | | | |

| Commodity category | Commodity | Acceptable maximum storage period | Report Reference | Source |
|---|---|---|---|---|
| **Plant products** | | | | |
| High water content | Maize, forage | 25 months | ABR-94051 | France, 2013 |
| | Maize, whole plant[(a)] | 24 months | ABR-94046 | France, 2013 |
| | Sweet corn, whole plant[(a)] | 24 months | | |
| High oil content | Maize, oil | 12 months [(b)] | ABR-94051 | France, 2013 |
| High starch content | Maize, grain | 25 months | | |
| **Animal Products** | | | | |
| Meat | Ruminant | 25 months | ABR-97044 | France, 2013 |
| Liver | Ruminant | 25 months | | |
| Milk | Ruminant | 25 months | | |
| Eggs | Poultry | 16 months | ABR-93055 | France, 1998 |

(a): Field-incurred residues
(b): Residue levels in maize oil measured after 19, 25 and 25.6 months are below 70% recovery

**Conclusion on stability of residues during storage**

The potential for degradation of residues during storage has been previously assessed in the framework of the peer review for prosulfuron. Storage stability of prosulfuron was demonstrated for the following periods in the commodities listed in the table above when frozen (approximately -18°C).

### 7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

Stability of residues in sample extracts is confirmed by the procedural recovery samples analysed as part of each analytical batch of residue samples. Data are expected to be within the usual limits of recovery as defined within analytical method validation. No additional information is available or required.

## 7.2.2 Nature of residues in plants, livestock and processed commodities

### 7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

**Available data**

*Reference: France, 1998*

No new data submitted in the framework of this application.

**Table 7.2-3: Summary of plant metabolism studies**

| Crop Group | Crop | Label position | Application and sampling details | | | | Report Reference | Source |
|---|---|---|---|---|---|---|---|---|
| | | | Method, F or G [(a)] | Rate (kg a.s./ha) | No | Sampling (DAT) | | |
| **EU reviewed data** | | | | | | | | |
| **Cereals** | Maize | 4,6-$^{14}$C-triazine U-$^{14}$C-phenyl | Cell suspension and callus culture, G | n.r. | 1 | 7 | ABR-93048 | France, 1998 |

| Crop Group | Crop | Label position | Application and sampling details | | | | Report Reference | Source |
|---|---|---|---|---|---|---|---|---|
| | | | Method, F or G [(a)] | Rate (kg a.s./ha) | No | Sampling (DAT) | | |
| | | 4,6-$^{14}$C-triazine U-$^{14}$C-phenyl | Stem injection, G | 0.5 mg per plant at 64 and 84 days post-planting | 2 | Foliage, stalks, cobs, grain: 77 after the first injection | ABR-93048 | |
| | | 4,6-$^{14}$C-triazine U-$^{14}$C-phenyl | Foliar spray, G | 0.04 | 1 | Whole plant: 0, 1, 30, 45 Stalks: 69 | ABR-93048 ABR-93050 | |
| | | 4,6-$^{14}$C-triazine U-$^{14}$C-phenyl | Foliar spray, F | 0.04 | 1 | Leaves: 0 Forage: 30 Silage: 46 Stalks, cob, grain: 93 | ABR-93047 | |

(a): Outdoor/field application (F) or glasshouse/protected/indoor application (G)
n.r.: Not reported

**Summary of plant metabolism studies reported in the EU**

*Reference: EFSA, 2012*

"In maize, the outdoor study, which was representative of the GAP, residues were investigated in more detail as they were at a higher level than the corresponding glasshouse study. The highest TRR was identified in leaves, on the day of treatment (3.3-3.4 mg eq/kg). The residues declined to a much lower level in forage after 30 days (0.03-0.09 mg eq/kg) and silage after 46 days (0.03-0.05 mg eq/kg). After 93 days at harvest, residues were low in stalks (0.009-0.05 mg eq/kg), and at levels too low for further characterisation or identification in cobs and grain (<0.003 mg eq/kg). Metabolism proceeded rapidly. Residues were highly extractable in the leaves sampled on the day of treatment (95%, where parent prosulfuron accounted for up to 64% of the TRR) and were less readily extractable in the mature stalks sampled at harvest (36-43%). Parent prosulfuron accounted for up to 0.2% of the TRR in the 30 DAT samples only. The majority of the low level extractable residues in stalks were glucose conjugates of phenyl, triazine ring hydroxylated products and a sulfonylurea bridge cleavage product.

The metabolism studies in maize indicate that the parent compound is rapidly degraded and that there are no metabolites at significant amounts in the studies of relevance to the GAP. In mature stalks, the triazine metabolites CGA188838 and G28533 were the most prevalent metabolites found together at 23% TRR and 0.002 mg/kg mg eq/kg. In maize forage, the same metabolites were the most prevalent found together at a level of 30% TRR and 0.009 mg/kg mg eq/kg. Other metabolites found above 10% TRR (total of free and conjugated form) were CGA300408 and CGA304060. Due to the low levels at which they were found, none of the metabolites are expected to contribute significantly to the toxicological burden.

The stem injection study aided the identification of metabolites. After stem injection triazine labelled metabolites were preferentially transported to the cobs and grain which resulted in a five-fold higher level of TRR compared to the corresponding phenyl labelled investigation.

Based on the identified metabolites, it was concluded in the DAR that metabolism of prosulfuron proceeds via the following steps: hydroxylation of the phenyl ring to form the 5-hydroxy-phenyl derivative (CGA300408), mainly present as the sugar conjugate; methoxy ether cleavage to form the 5-hydroxy-phenyl-4-hydroxy-triazine derivative; hydrolytic cleavage of the urea bridge to form CGA159902, CGA304060, and various triazine metabolites following reactions including deamination and oxidation of the triazine ring methyl group. Conjugation of CGA304060 to a polyamine derivative and sugar conjugation of the various hydroxy metabolites also occurs."

**Conclusion on metabolism in primary crops**

The metabolism of prosulfuron in plants following foliar application is sufficiently addressed to support the proposed uses of the product A18385B.

### 7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

**Available data**

*Reference: France, 1998*

No new data submitted in the framework of this application.

**Table 7.2-4: Summary of metabolism studies in rotational crops**

| Crop group | Crop | Label position | Application and sampling details | | | | Report reference | Source |
|---|---|---|---|---|---|---|---|---|
| | | | Method, F or G (a) | Rate (kg a.s./ha) | Sowing intervals (DAT) | Harvest Intervals (DAT) (b) | | |
| **EU reviewed data** | | | | | | | | |
| **Leafy vegetables** | Lettuce | 4,6-$^{14}$C-triazine U-$^{14}$C-phenyl | Bare soil, F | 0.04 | 91<br>300 | 127 (IL), 152 (NY)<br>348 (IL), 341 (NY) | HWI 6117-219 | France, 1998 |
| | Spinach | | | | 30 (IL) 51 (NY)<br>91<br>300 | 79, 88 (IL) 92, 133 (NY)<br>127 (IL), 182 (NY)<br>348, 361 (IL), 341, 356 (NY) | | |
| **Root and tuber vegetables** | Radish | | | | 30 (IL) 51 (NY)<br>91<br>300 | 63, 85 (IL) 92, 133 (NY)<br>121, 128 (IL), 152, 182 (NY)<br>361, 395 (IL), 336, 344 (NY) (leaves, tops) | | |
| **Cereals** | Winter wheat | | | | 91 | Forage: 151 (IL), 152 (NY) | | |
| | Spring wheat | | | | 300 | Forage, stalks, hulls, grain: 361, 395, 411 (IL) 342, 361, 403 (NY) | | |

(a): Outdoor/field application (F) or glasshouse/protected/indoor application (G)
(b): IL: Illinois, USA; NY: New York, USA

**Summary of metabolism studies in rotational crops reported in the EU**

*Reference: EFSA, 2012*

"The TRR in the rotational crops were fairly low, with the highest residues observed for the 30 or 51 DAT interval, degrading substantially by the 300 DAT interval (where residues were either below the LOQ of <0.001 mg/kg or were found at up to 0.013 mg/kg in spring wheat stalks). Residues were slightly higher in the Illinois location compared to New York, although residues were still very low. The highest TRR observed across all the rotated crops was for spinach foliage at half-maturity stage of 0.021 mg/kg. Due to the low residues only a limited amount of characterisation and identification was possible. No aqueous or organic fraction contained any individual component greater than 0.013 mg/kg or 0.009 mg/kg respectively. Parent prosulfuron was not detectable in any commodity. CGA150829, CGA304060, CGA188838 and a trace amount of a further metabolite were the only metabolites that could be characterised".

**Conclusion on metabolism in rotational crops**

Metabolism in primary and rotational crops was found to be similar and a specific residue definition for rotational crops is not deemed necessary.

### 7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

**Available data**

Studies investigating the nature of residues in processed commodities were not conducted. No new data submitted in the framework of this application.

**Conclusion on nature of residues in processed commodities**

*Reference: EFSA, 2012*

"As quantifiable residues of prosulfuron are not expected in the treated crops, there is no need to investigate the effect of industrial and/or household processing. In addition, the chronic exposure does not exceed 10% of the ADI".

### 7.2.2.4 Conclusion on the nature of residues in commodities of plant origin (KCA 6.7.1)

**Table 7.2-5: Summary of the nature of residues in commodities of plant origin**

| **Endpoints** | |
|---|---|
| Plant groups covered | Cereals (maize) |
| Rotational crops covered | Cereals (wheat), Root vegetables (radish), Leafy vegetables (lettuce, spinach) – application to bare soil |
| Metabolism in rotational crops similar to metabolism in primary crops? | Yes |
| Processed commodities | Not necessary |
| Residue pattern in processed commodities similar to pattern in raw commodities? | - |
| Plant residue definition for monitoring | Prosulfuron (Draft subject to the data gap on the genotoxicity of CGA150829) (EFSA, 2014, 2020) |
| Plant residue definition for risk assessment | Prosulfuron (Draft subject to the data gap on the genotoxicity of CGA150829) (EFSA, 2014, 2020) |
| Conversion factor from enforcement to RA | None (EFSA, 2014, 2020) |

### 7.2.2.5 Nature of residues in livestock (KCA 6.2.2-6.2.5)

**Available data**

*Reference: France, 1998*

No new data submitted in the framework of this application.

**Table 7.2-6: Summary of animal metabolism studies**

| Group | Species | Label position | No of animal | Application details | | Sample details | | Report reference | Refer-ence |
|---|---|---|---|---|---|---|---|---|---|
| | | | | Rate (mg/kg bw/d) | Duration (days) | Commo-dity | Time of samp-ling | | |
| **EU reviewed data** | | | | | | | | | |
| **Lactating rumi-nants** | Goat | 4,6-$^{14}$C-triazine U-$^{14}$C-phenyl | 2 (each label) | 3.1 | 4 | Milk | Twice daily | ABR-93041 ABR-93042 | France, 1998 |
| | | | | | | Urine and faeces | Daily | | |
| | | | | | | Tissues | At sac-rifice (6-7 hrs) | | |
| **Laying poultry** | Hen | 4,6-$^{14}$C-triazine U-$^{14}$C-phenyl | 5 (each label) | 5.0 | 8 | Eggs | Daily | F-00115 F-00116 | France, 1998 |
| | | | | | | Excreta | Daily | | |
| | | | | | | Tissues | At sac-rifice (6 hrs) | | |

**Summary of animal metabolism studies reported in the EU**

*Reference: EFSA, 2012*

"Lactating goats and laying hens were dosed with 3.1-5.0 mg/kg bw per day of prosulfuron, corresponding to approximately 1,500 times the exposure of meat ruminant and 10,000 times the exposure of poultry. Studies demonstrate that transfer of residues to milk, eggs and tissues is insignificant in view of the exaggerated rates of the studies. Highest residue levels were found in liver, kidney, bile and blood in goats (up to 4.4 mg/kg) and hens (up to 5.9 mg/kg). A plateau was observed in egg yolks and whites at 6 days. In goats the main component was parent prosulfuron at 73-94% TRR across all the tissue matrices analysed (kidney, liver, muscle, fat, milk). The main metabolites observed in the various goat matrices were either CGA273437 (in both labels and all tissues analysed at up to 8% TRR) or CGA150829 (in triazine label only at 21% in milk and 13% TRR in muscle only). Parent prosulfuron was similarly the main residue in poultry tissues. In egg yolk, CGA159902 (up to 9% TRR) and CGA150829 (up to 18% TRR) were also prevalent. These two metabolites were also found at varying levels in tissues and eggs (<0.2% TRR to 24% TRR).

The metabolic reactions observed were hydroxylation of the triazinyl methyl to an alcohol (CGA273437), O-demethylation of the triazinyl methoxy group (CGA300406) and hydrolysis of the sulfonylurea bridge producing the heterocyclic triazine amine (CGA150829) and the benzene sulphonamide (CGA159902)."

**Conclusion on metabolism in livestock**

The metabolism of prosulfuron in livestock is sufficiently addressed to support the proposed uses of the product A18385B.

### 7.2.2.6 Conclusion on the nature of residues in commodities of animal origin

**(KCA 6.7.1)**

**Table 7.2-7: Summary on the nature of residues in commodities of animal origin**

| **Endpoints** | |
|---|---|
| Animals covered | Lactating goats, laying hens |
| Time needed to reach a plateau concentration | Milk: not assessed<br>Eggs: 2 days (egg white), 6 days (egg yolk) |
| Animal residue definition for monitoring | Prosulfuron (EFSA, 2014, 2020) |
| Animal residue definition for risk assessment | Prosulfuron (EFSA, 2014, 2020) |
| Conversion factor | None (EFSA, 2014, 2020) |
| Metabolism in rat and ruminant similar | Yes |
| Fat soluble residue | No (log $P_{ow}$ = -0.21 at pH 6) |

## 7.2.3 Magnitude of residues in plants (KCA 6.3)

### 7.2.3.1 Summary of European data and new data supporting the intended uses

A summary of the critical GAP for the intended uses of A18385B in the Central European Zone are summarised in the table below.

**Table 7.2-8: Summary of the cGAP for the intended uses of A18385B in the Central Zone**

| Crop | Field (F) or Glass-house (G) use | Growth stage | Maximum number of applica-tions per year | Minimum interval between treatments [days] | Water [L/ha] | Application rate per treatment [kg a.s./ha] | Minimum PHI [days] |
|---|---|---|---|---|---|---|---|
| Maize | F | BBCH 12-18 | 1 | -- | 200-400 | 0.020[(a)] | n.s. |

n.s. Not specified; the PHI is covered by the time remaining between application and harvest
(a): 0.020 kg/ha prosulfuron, 0.050 kg/ha nicosulfuron and 0.200 kg/ha dicamba
A18385B is applied with a tank-mixed oil-based adjuvant (e.g Adigor @ 1.0-1.5 L/ha)

No new data are submitted in the framework of this application.

**Table 7.2-9: Summary of EU reported and new data supporting the intended uses of A18385B and conformity to existing MRL**

| Commodity | Source | Residue zone (N-EU, S-EU, EU, outside EU) | Evaluation<br>GAP<br>Residue levels (mg/kg)<br>E = according to enforcement residue definition<br>RA = according to risk assessment residue definition | STMR (mg/kg) | HR (mg/kg) | Unrounded OECD calculator MRL (mg/kg) | Current EU MRL (mg/kg)[a] | MRL compliance |
|---|---|---|---|---|---|---|---|---|
| **Maize** (grain) | EFSA, 2014 | N-EU | GAP on which MRL/EU a.s. assessment is based: 1 × 0.02 kg a.s./ha, BBCH 12-18, PHI 90 d, outdoor<br>E/RA: 8 × <0.01, 4 × <0.02 | N/A | | | | |
| | | S-EU | GAP on which MRL/EU a.s. assessment is based: 1 × 0.02 kg a.s./ha, BBCH 12-18, PHI 90 d, outdoor<br>E/RA: 4 × <0.01, 3 × <0.02 | N/A | | | | |
| | France, 2014[b] | N-EU | GAP on which MRL/EU a.s. assessment is based: 1 × 0.02 kg a.s./ha, BBCH 12-18, PHI 90 d, outdoor<br>E/RA: 16 × <0.01 | N/A | | | | |
| | | S-EU | GAP on which MRL/EU a.s. assessment is based: 1 × 0.02 kg a.s./ha, BBCH 12-18, PHI 90 d, outdoor<br>E/RA: 15 × <0.01 | N/A | | | | |
| | Overall supporting data for cGAP | N-EU | E/RA: 24 × <0.01, 4 × <0.02 | 0.01 | 0.02 | 0.02* | 0.01* | Yes[c] |
| | | S-EU | E/RA: 19 × <0.01, 3 × <0.02 | 0.01 | 0.02 | 0.02* | 0.01* | Yes[c] |
| **Maize** (forage, silage, whole plant BBCH 73-85) | France, 1998 | N-EU | GAP on which MRL/EU a.s. assessment is based: 1 × 0.02 kg a.s./ha, BBCH 12-18, PHI 60 d, outdoor<br>E/RA: 6 × <0.01, 6 × <0.02 | N/A | | | | |
| | | S-EU | GAP on which MRL/EU a.s. assessment is based: 1 × 0.02 kg a.s./ha, BBCH 12-18, PHI 60 d, outdoor<br>E/RA: 4 × <0.01, <0.02 | N/A | | | | |
| | France, 2014[b] | N-EU | GAP on which MRL/EU a.s. assessment is based: 1 × 0.02 kg a.s./ha, BBCH 12-18, PHI 60 d, outdoor<br>E/RA: 16 × <0.01 | N/A | | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | S-EU | GAP on which MRL/EU a.s. assessment is based: 1 × 0.02 kg a.s./ha, BBCH 12-18, PHI 60 d, outdoor<br>E/RA: 16 × <0.01 | N/A | | |
| | Overall supporting data for cGAP | N-EU | E/RA: 22 × <0.01, 6 × <0.02 | 0.01 | 0.02 | No MRL set for feed item |
| | | S-EU | E/RA: 20 × <0.01, <0.02 | 0.01 | 0.02 | No MRL set for feed item |

(a): Source of EU MRL: Reg. (EU) No 617/2014 amending Reg. (EC) No 396/2005.
(b): Trials that were submitted in the RAR (France, 2014) but were not considered in the overall summary of residue trials as they do not modify the conclusion reach during first evaluation of prosulfuron. These trials have been evaluated previously either for EU MRL setting (EU Commission Directive 2007/56/EC) or in national authorisation dossiers.
(c): The RMS (France, 2014) concluded that an MRL of 0.01* mg/kg could be set
(*): Indicates that the MRL is set at the limit of analytical quantification.

### 7.2.3.2 Conclusion on the magnitude of residues in plants

Maize is a major crop in both northern and southern Europe and therefore normally requires eight trials in each region to support an EU MRL (SANCO 7525/VI/95 rev. 10.3). A total of 19 trials are available from the first evaluation of prosulfuron (France, 1998), 12 conducted in Northern Europe and 7 in Southern Europe. An additional 31 trials (16 N-EU, 15 S-EU) were submitted for the Annex I renewal of prosulfuron (France, 2014). However, the rapporteur Member State did not consider these new trials in the re-evaluation as they do not provide further information to the residue situation on maize. It is stated in the Renewal Assessment Report: "Moreover, trials that were not assessed in the original EU review were submitted by the applicant. However these trials have been evaluated previously either for EU MRL setting (EU Commission Directive 2007/56/EC) or in national authorisation dossiers. These trials are presented below but were not considered in the overall summary of residue trials as they do not modify the conclusion reach during first evaluation of prosulfuron" (France, 2014).

In all maize whole plant, leaf, stalk, fodder, cob and grain specimens collected in these trials, residues of prosulfuron were below the level of analytical quantification (<0.01 or <0.02 mg/kg). It is therefore concluded that sufficient data are available which show that no exceedance of the existing MRL will occur. The uses on maize are considered acceptable.

### 7.2.4 Magnitude of residues in livestock

### 7.2.4.1 Dietary burden calculation

The use of A18385B may result in residues of prosulfuron in animal feed items, therefore the possible transfer of residues in animal commodities from the proposed uses should be considered. Livestock intake calculations (Animal Model 2017) and feeding studies undertaken are provided below.

**Table 7.2-10: Input values for the dietary burden calculation (considering the uses evaluated in Art. 12 procedure and the uses under consideration)**

| Feed Commodity | Median dietary burden | | Maximum dietary burden | |
|---|---|---|---|---|
| | Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
| **Risk assessment residue definition:** Prosulfuron | | | | |
| Barley straw | 0.01 | Median residue | 0.01 | Highest residue |
| Maize silage | 0.01 | Median residue | 0.01 | Highest residue |
| Maize stover (fodder) | 0.01 | Extrapolated from maize silage as worst case | 0.01 | Extrapolated from maize silage as worst case |
| Corn, pop, stover (fodder) | 0.01 | Extrapolated from maize silage as worst case | 0.01 | Extrapolated from maize silage as worst case |
| Wheat/triticale straw | 0.01 | Median residue | 0.01 | Highest residue |
| Barley grain | 0.01 | Median residue | 0.01 | Median residue |
| Maize grain | 0.01 | Median residue | 0.01 | Median residue |
| Corn, pop, grain | 0.01 | Extrapolated from maize grain | 0.01 | Extrapolated from maize grain |
| Wheat/triticale grain | 0.01 | Median residue | 0.01 | Median residue |
| Brewer's grain, dried | 0.03 | Median residue barley grain × default PF 3.3 | 0.03 | Median residue barley grain × default PF 3.3 |
| Corn, field, milled by-pdts | 0.01 | Median residue maize grain × PF 1 [a)] | 0.01 | Median residue maize grain × PF 1 [a)] |
| Corn, field, hominy meal | 0.01 | Median residue maize grain × PF 1 [a)] | 0.01 | Median residue maize grain × PF 1 [a)] |

| Feed Commodity | Median dietary burden | | Maximum dietary burden | |
|---|---|---|---|---|
| | Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
| Corn, field, gluten feed | 0.01 | Median residue maize grain × PF 1[a)] | 0.01 | Median residue maize grain × PF 1[a)] |
| Corn, field, gluten, meal | 0.01 | Median residue maize grain × PF 1[a)] | 0.01 | Median residue maize grain × PF 1[a)] |
| Distiller's grain, dried | 0.03 | Median residue wheat grain × default PF 3.3 | 0.03 | Median residue wheat grain × default PF 3.3 |

a) Default PF waived as residues in RAC <LOQ

Prosulfuron falls under old data requirements. The results of the calculations are reported in Table 7.2-11. Since the calculated dietary burdens for all groups of livestock were found to be below the trigger value of 0.1 mg/kg DM, further investigation of residues in commodities of animal origin is not necessary.

**Table 7.2-11: Results of the dietary burden calculation**

| Animal species | Median dietary burden (mg/kg bw/d) | Maximum dietary burden (mg/kg bw/d) | Highest contributing commodity | Max dietary burden (mg/kg DM) | Trigger exceeded (Y/N) |
|---|---|---|---|---|---|
| **Risk assessment residue definition:** Prosulfuron | | | | | |
| Beef cattle | 0.001 | 0.001 | Wheat milled bypdts | 0.04 | N |
| Dairy cattle | 0.002 | 0.002 | Wheat milled bypdts | 0.04 | N |
| Ram/ewe | 0.001 | 0.001 | Wheat milled bypdts | 0.04 | N |
| Lamb | 0.002 | 0.002 | Wheat milled bypdts | 0.05 | N |
| Breeding swine | 0.001 | 0.001 | Wheat milled bypdts | 0.05 | N |
| Finishing swine | 0.001 | 0.001 | Wheat milled bypdts | 0.05 | N |
| Broiler poultry | 0.002 | 0.002 | Wheat milled bypdts | 0.02 | N |
| Layer poultry | 0.002 | 0.002 | Wheat milled bypdts | 0.03 | N |
| Turkey | 0.002 | 0.002 | Wheat milled bypdts | 0.02 | N |

### 7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Feeding studies in livestock (poultry/ruminants) are not triggered.

No new data were submitted in the framework of this application.

### 7.2.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) (KCA 6.5.2-6.5.3)

Data/information on processing studies was reviewed during the approval of prosulfuron and considered sufficient. No further studies have been performed.

As quantifiable residues of prosulfuron are not expected in the treated crops and the TMDI is <10% (see also 7.2.8), there is no need to investigate the effect of industrial and/or household processing.

#### 7.2.5.1 Available data for all crops under consideration

*Reference: France, 1998*

No new data submitted in the framework of this application.

**Table 7.2-12: Overview of the available processing studies**

| Processed commodity | Number of studies | Median PF (a) | Median CF (b) | Comments | Report reference | Source |
|---|---|---|---|---|---|---|
| **EU reviewed data** | | | | | | |
| **Enforcement residue definition:** Prosulfuron | | | | | | |
| Maize, flour | 1 | 1 | 1 | A default processing factor of 1 is derived from the processing data as no residues of prosulfuron (<0.01 mg/kg) were quantified in both raw agricultural commodities and any processed fractions. | MW-HR-103-92 (field maize) MW-HR-702-92 (sweet corn) | France, 1998 |
| Maize, germ | 1 | 1 | 1 | | | |
| Maize, crude oil | 1 | 1 | 1 | | | |
| Maize, refined oil | 1 | 1 | 1 | | | |
| Maize, forage, silage | 2 | 1 | 1 | | | |
| Maize, flour | 1 | 1 | 1 | | | |

(a): The median processing factor is obtained by calculating the median of the individual processing factors of each processing study.
(b): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors of each processing study.

#### 7.2.5.2 Conclusion on processing studies

*Reference: EFSA, 2012*

"Although not required, studies investigating the magnitude of residues in processed commodities of maize grain and sweetcorn grain were reported in the framework of the initial peer review (France, 1998). No robust processing factors for enforcement and risk assessment could be derived as there were no residues (<0.01 mg/kg) found in both the raw agricultural commodities (maize grain and forage) as well as all the processed fractions analysed. The processing factors reported should therefore be considered as indicative only."

### 7.2.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

Considering available data dealing with nature of residues in rotational crops (see section 7.2.2.2), no study dealing with magnitude of residues in succeeding crops is needed.

#### 7.2.6.1 Field rotational crop studies (KCA 6.6.2)

**Available data**

Studies investigating the magnitude of residues in succeeding crops were not conducted. No new data submitted in the framework of this application.

**Conclusion on rotational crops studies**

Based on the confined rotational crop study and considering that the application rate of prosulfuron within the EU ranges between 0.015-0.025 kg a.s./ha and the fact that prosulfuron was applied to a bare soil (interception of prosulfuron by the plants is expected in practice), it can be concluded that prosulfuron residue levels in rotational commodities are not expected to exceed 0.01 mg/kg, provided that prosulfuron is applied in compliance with the GAPs supported for this submission.

### 7.2.7 Other / special studies (KCA6.10, 6.10.1)

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of A18385B. According to SANTE/11956/2016 rev.9, maize is a crop with no melliferous capacity. Therefore, other special studies are not needed.

### 7.2.8 Estimation of exposure through diet and other means (KCA 6.9)

Toxicological reference values relevant for dietary risk assessment are reported in the summary of the evaluation (see section 7.1.2).

#### 7.2.8.1 Input values for the consumer risk assessment

Syngenta uses, values corresponding to actual EU MRLs and several animal matrices were considered for IEDI calculation.

**Table 7.2-13: Input values for the consumer risk assessment**

| Commodity | Chronic risk assessment | | Acute risk assessment | |
|---|---|---|---|---|
| | Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
| **Risk assessment residue definition:** Prosulfuron | | | | |
| Sweet corn | 0.01 | MRL (Reg. (EU) No 617/2014) | Not relevant, the acute risk assessment only corresponds to crops on the formulation's GAP table, i.e. maize. | |
| Maize | 0.01 | MRL (Reg. (EU) No 617/2014) | 0.01 | MRL (Reg. (EU) No 617/2014) |
| Ruminant muscle | 0.02 | MRL (Reg. (EU) No 617/2014) | 0.02 | MRL (Reg. (EU) No 617/2014) |
| Ruminant fat | 0.02 | MRL (Reg. (EU) No 617/2014) | 0.02 | MRL (Reg. (EU) No 617/2014) |
| Ruminant liver | 0.05 | MRL (Reg. (EU) No 617/2014) | 0.05 | MRL (Reg. (EU) No 617/2014) |
| Ruminant kidney | 0.02 | MRL (Reg. (EU) No 617/2014) | 0.02 | MRL (Reg. (EU) No 617/2014) |
| Ruminant edible offals | 0.05 | MRL (Reg. (EU) No 617/2014) | 0.05 | MRL (Reg. (EU) No 617/2014) |
| Ruminant others | 0.05 | MRL (Reg. (EU) No 617/2014) | 0.05 | MRL (Reg. (EU) No 617/2014) |
| Pig muscle | 0.02 | MRL (Reg. (EU) No 617/2014) | 0.02 | MRL (Reg. (EU) No 617/2014) |
| Pig fat | 0.02 | MRL (Reg. (EU) No 617/2014) | 0.02 | MRL (Reg. (EU) No 617/2014) |
| Pig liver | 0.05 | MRL (Reg. (EU) No | 0.05 | MRL (Reg. (EU) No |

| Commodity | Chronic risk assessment | | Acute risk assessment | |
|---|---|---|---|---|
| | **Input value (mg/kg)** | **Comment** | **Input value (mg/kg)** | **Comment** |
| | | 617/2014) | | 617/2014) |
| Pig kidney | 0.02 | MRL (Reg. (EU) No 617/2014) | 0.02 | MRL (Reg. (EU) No 617/2014) |
| Pig edible offals | 0.05 | MRL (Reg. (EU) No 617/2014) | 0.05 | MRL (Reg. (EU) No 617/2014) |
| Pig others | 0.05 | MRL (Reg. (EU) No 617/2014) | 0.05 | MRL (Reg. (EU) No 617/2014) |
| Poultry muscle | 0.02 | MRL (Reg. (EU) No 617/2014) | 0.02 | MRL (Reg. (EU) No 617/2014) |
| Poultry fat | 0.02 | MRL (Reg. (EU) No 617/2014) | 0.02 | MRL (Reg. (EU) No 617/2014) |
| Poultry liver | 0.05 | MRL (Reg. (EU) No 617/2014) | 0.05 | MRL (Reg. (EU) No 617/2014) |
| Poultry kidney | 0.02 | MRL (Reg. (EU) No 617/2014) | 0.02 | MRL (Reg. (EU) No 617/2014) |
| Poultry edible offals | 0.05 | MRL (Reg. (EU) No 617/2014) | 0.05 | MRL (Reg. (EU) No 617/2014) |
| Poultry others | 0.05 | MRL (Reg. (EU) No 617/2014) | 0.05 | MRL (Reg. (EU) No 617/2014) |
| Milk | 0.02 | MRL (Reg. (EU) No 617/2014) | 0.02 | MRL (Reg. (EU) No 617/2014) |
| Eggs | 0.02 | MRL (Reg. (EU) No 617/2014) | 0.02 | MRL (Reg. (EU) No 617/2014) |

### 7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

**Table 7.2-14: Consumer risk assessment**

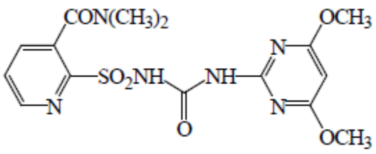
| | |
|---|---|
| TMDI (% ADI) according to EFSA PRIMo rev. 3.1 | Not shown, please refer to IEDI calculations |
| IEDI (% ADI) according to EFSA PRIMo rev. 3.1 | 7% (based on NL toddler) |
| IESTI (% ARfD) according to EFSA PRIMo rev. 3.1 | Maize/oil: 0.2% (based on NL toddler)<br>Milk: 2% (based on UK infant)<br>Other animal matrices: ≤0.8% |

The proposed uses of prosulfuron in A18385B do not represent unacceptable acute and chronic risks for the consumer.

## 7.3 Nicosulfuron

General data on nicosulfuron are summarized in the table below (last updated 2020/09/09).

**Table 7.3-1: General information on nicosulfuron**

| | |
|---|---|
| Active substance (ISO Common Name) | Nicosulfuron |
| IUPAC | 2-[(4,6-dimethoxypyrimidin-2-ylcarbamoyl)sulfamoyl]-N,N-dimethylnicotinamide<br>or<br>1-(4,6-dimethoxypyrimidin-2-yl)-3-(3-dimethylcarbamoyl-2-pyridylsulfonyl)urea |
| Chemical structure |  |
| Molecular formula | $C_{15}H_{18}N_6O_6S$ |
| Molar mass | 410.4 g/mol |
| Chemical group | Sulfonylurea compound |
| Mode of action (if available) | Inhibition of the enzyme acetolactate synthase |
| Systemic | Yes |
| Company (ies) | ISK Biosciences Europe S.A. |
| Rapporteur Member State (RMS) | United Kingdom |
| Approval status | Approved<br>Date of 01/01/2009<br>Commission Directive 2008/40/EC - Commission Regulation (EU) No 540/2011 |
| Restriction | Restricted to uses as herbicide |
| Review Report | SANCO/3780/07 – rev. 1<br>22/01/2008 |
| Current MRL regulation | Regulation (EU) No 617/2014 |
| Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed | Yes |
| EFSA Journal: Conclusion on the peer review | Yes (EFSA, 2007) |
| EFSA Journal: conclusion on article 12 | Yes (EFSA, 2012) |
| Current MRL applications on intended uses | No MRL applications are pending |

### 7.3.1 Stability of Residues (KCA 6.1)

#### 7.3.1.1 Stability of residues during storage of samples

**Available data**

*References: United Kingdom, 2006; EFSA, 2012*

No new data submitted in the framework of this application.

**Table 7.3-2: Summary of stability data achieved at ≤ -18°C (unless stated otherwise)**

| Commodity category | Commodity | Acceptable maximum storage period | Report Reference | Source |
|---|---|---|---|---|
| **EU reviewed data** | | | | |
| **Plant products** | | | | |
| High water content | Maize, whole plant | 9 months[(a)] | 304762 | United Kingdom, 2006 |
| High starch content | Maize, grain | 9 months[(a)] | 304762 | United Kingdom, 2006 |

(a): Storage stability was tested for a period of 30 months; the RMS concluded that the results demonstrated that nicosulfuron residues are stable (recovery >70%) for 9 months when stored at -20°C in the dark.

**Conclusion on stability of residues during storage**

The storage stability of nicosulfuron has been investigated in different groups, including commodities with high water and high starch content. Sufficient stability has been demonstrated to support the residue data presented in the submission. A residue definition for animal products has not been proposed (see section 7.3.2.6), since the uses of nicosulfuron will not lead to significant residues in any edible animal tissue, milk or eggs. Thus, no stability data in commodities of animal origin are required.

#### 7.3.1.2 Stability of residues in sample extracts (KCA 6.1)

Stability of residues in sample extracts is confirmed by the procedural recovery samples analysed as part of each analytical batch of residue samples. Data are expected to be within the usual limits of recovery as defined within analytical method validation. No additional information is available or required.

### 7.3.2 Nature of residues in plants, livestock and processed commodities

#### 7.3.2.1 Nature of residue in primary crops (KCA 6.2.1)

**Available data**

*References: United Kingdom, 2006; EFSA, 2007; EFSA, 2012*

No new data submitted in the framework of this application.

**Table 7.3-3: Summary of plant metabolism studies**

| Crop Group | Crop | Label position | Application and sampling details | | | | Report Reference | Source |
|---|---|---|---|---|---|---|---|---|
| | | | Method, F or G (a) | Rate (kg a.s./ha) | No | Sampling (DAT) | | |
| **EU reviewed data** | | | | | | | | |
| **Cereals** | Maize | 5-$^{14}$C-pyrimidinyl | Foliar, G | 60, 300 | 1 | Silage: 0, 14, 30, 60 Harvest: 102 | 274173 | United Kingdom, 2006 |
| | | 2-$^{14}$C-pyridyl | Foliar, G | 60, 300 | 1 | Silage: 0, 14, 30, 60 Harvest: 102 | 272158 | United Kingdom, 2006 |

(a): Outdoor/field application (F) or glasshouse/protected/indoor application (G)

**Summary of plant metabolism studies reported in the EU**

*Reference: EFSA, 2012*

"In maize, 102 days after application, the highest TRR was identified in straw (0.082-0.13 mg eq/kg), whereas in grain the TRR was low (0.001-0.003 mg eq/kg) for pyridyl and pyrimidinyl labels respectively. In both studies, nicosulfuron was the predominant residue for all harvest times, accounting for 29% (0.03 mg eq/kg) and 54% TRR (0.06 mg eq/kg) 102 days after treatment for pyridyl and pyrimidinyl labels respectively [… in the silage samples].

Immediately after application, in the pyrimidinyl study, a considerable metabolisation had already occurred, metabolites ranging from 4% TRR (0.11 mg/kg) for HMUD[1] to 27.7% TRR (0.79 mg/kg) for M2 [AUSN[2]]. At day 60, the metabolite profile had changed considerably. Among the four metabolites identified (up to 12.6% TRR; 0.007 mg/kg for M1 [unknown metabolite]), two were not present initially (DMPU[3] 5.9% TRR and ADMP[4] 5.5% TRR). At the 102 day harvest point, the residue profile was very similar to the 60 day harvest; however some slight increases in parent levels were noted which is deemed a result of a decrease in water content (54% TRR, 0.055 mg/kg). In the pyridyl labelled study at day 0, six metabolite fractions were characterised and three were identified as AUSN (20.4% TRR; 0.32 mg eq/kg), HMUD (3.6% TRR; 0.056 mg eq/kg) and ASDM[5] (17.3% TRR; 0.27 mg eq/kg). AUSN and ASDM were not identified in the pyrimidinyl study since cleavage of the ring structures has occurred. At day 60, the main identified metabolites were AUSN at 13.5% TRR (0.008 mg eq/kg) and ASDM at 16.7% TRR (0.01 mg eq/kg.). At the 102 day interval, the M1 metabolite fraction had increased from 0.1% TRR to 29% TRR. In spite of further work [was] undertaken to clarify how metabolite M1 was formed, the reason [for its formation] was still unclear. However, M1 was shown to be a fraction of metabolites (partially conjugates of parent and ASDM) rather than one single metabolite and residues were generally low. Of the metabolites identified, none of them are considered to be toxicologically significant as they are found in the rat metabolism or are conjugates of rat metabolites."

"Metabolism studies indicate that pirimicarb in plants undergoes extensive metabolism yielding diverse range of metabolites. The early stages of metabolism involve modification of the dimethylamino moiety and loss of carbamate moiety which subsequently results in hydroxypyrimidine metabolites. Parent pirimicarb is the major residue of concern in plants. The carbamate metabolite desmethyl pirimicarb

[1] HMUD = 2-{[(4-hydroxy-6-methoxypyrimidin-2-yl)carbamoyl]sulfamoyl}-*N*,*N*-dimethylpyridine-3-carboxamide
[2] AUSN = 2-[(carbamimidoylcarbamoyl)sulfamoyl]-N,N-dimethylpyridine-3-carboxamide
[3] DMPU = (4,6-dimethoxypyrimidin-2-yl) urea
[4] ADMP = 4,6-dimethoxypyrimidin-2-amine
[5] ASDM = *N*,*N*-dimethyl-2-sulfamoylpyridine-3-carboxamide

(R34836) was found in significant levels only in lettuce. Other carbamate metabolites were also present but at lower levels than the parent compound: R35140 and desmethylformamido pirimicarb (R34885). Even though these two carbamate metabolites were present in lower amounts than desmethyl pirimicarb (R34836), they represent a similar toxicological burden due to their higher acute toxicity."

**Conclusion on metabolism in primary crops**

The metabolism of nicosulfuron in plants following foliar application is sufficiently addressed to support the proposed uses of the product A18385B.

### 7.3.2.2 Nature of residue in rotational crops (KCA 6.6.1)

**Available data**

*Reference: EFSA, 2012*

No new data submitted in the framework of this application.

**Summary of metabolism studies in rotational crops reported in the EU**

*Reference: EFSA, 2012*

"Maize and sweet corn may be grown in rotation and according to the soil degradation from field studies evaluated in the framework of the peer review, $DT_{90}$ values of nicosulfuron range between 30 and 210 days, and relevant soil metabolites ASDM, AUSN and UCSN[6] have $DT_{90}$s higher than 365 days exceeding the trigger value of 100 days. According to the European guidelines on rotational crops, further investigation of residues in rotational crops is relevant.

In spite of high persistence however, lysimeter studies where crops of wheat and rye were grown following maize treated at the proposed application rate of 60 g/ha indicated low uptake of parent and metabolites by the following cereal plants (TRR <0.01 mg/kg). Moreover, it was shown that the phytotoxic effect of nicosulfuron and its soil metabolites on dicotyledone plants leads to a self-limitation in the re-planting period. After a plant back interval of 27 to 30 days and with the exception of maize, marked phytotoxic effects were observed in the following crops (cereals, sugar beet, maize, oilseed rape and clover) while residues of nicosulfuron and its soil metabolites were found to be below the LOQ (0.01 mg/kg). Thus the following crops could not be grown until the following spring at which time residues in soil of nicosulfuron and relevant metabolites have decreased to <0.001 mg/kg. Furthermore, ASDM and AUSN are also found in maize but are not toxicological relevant. As UCSN metabolite has a similar toxicological profile as AUSN, it is considered non relevant as well.

Consequently, these studies are considered sufficient by EFSA to demonstrate the absence of residues in rotational crops, provided that nicosulfuron is applied in compliance with the GAPs."

**Conclusion on metabolism in rotational crops**

A specific residue definition for rotational crops is not deemed necessary due to the very low residue levels expected.

### 7.3.2.3 Nature of residues in processed commodities (KCA 6.5.1)

**Available data**

*Reference: EFSA, 2012*

"As quantifiable residues of nicosulfuron are not expected in the treated crops and the chronic exposure does not exceed 10% of the ADI, there is no need to investigate the effect of industrial and/or household processing."

[6] UCSN = N,N-Dimethyl-2-(ureidocarbonyl-sulfamoyl)-nicotinamide

No new data submitted in the framework of this application.

**Conclusion on nature of residues in processed commodities**

The nature of residues of nicosulfuron in processed products has not been investigated.

### 7.3.2.4 Conclusion on the nature of residues in commodities of plant origin (KCA 6.7.1)

**Table 7.3-4: Summary of the nature of residues in commodities of plant origin**

| **Endpoints** | |
|---|---|
| Plant groups covered | Cereals (Maize) |
| Rotational crops covered | Not required. Lysimeter studies indicated low uptake by cereal plants (TRR <0.01 mg/kg) and the phytotoxic effect of nicosulfuron and its soil metabolites on dicot plants leads to a self-limitation in the re-planting period. |
| Metabolism in rotational crops similar to metabolism in primary crops? | Not applicable |
| Processed commodities | No data supplied or required |
| Residue pattern in processed commodities similar to pattern in raw commodities? | Not applicable |
| Plant residue definition for monitoring | Nicosulfuron (Regulation (EU) No 617/2014) |
| Plant residue definition for risk assessment | Nicosulfuron (EFSA, 2007) |
| Conversion factor from enforcement to RA | None |

### 7.3.2.5 Nature of residues in livestock (KCA 6.2.2-6.2.5)

**Available data**

*References: United Kingdom, 2006; EFSA, 2012*

No new data submitted in the framework of this application.

**Table 7.3-5: Summary of animal metabolism studies**

| Group | Species | Label position | No of animal | Application details | | Sample details | | Report reference | Reference |
|---|---|---|---|---|---|---|---|---|---|
| | | | | Rate (mg/kg bw/d) | Duration (days) | Commodity | Time of sampling | | |
| **EU reviewed data** | | | | | | | | | |
| **Lactating ruminants** | Goat | $^{14}C$-pyridyl | 1 | 8.3 | 3 | Milk | Twice daily | 358323 | United Kingdom, 2007 |
| | | | | | | Urine and faeces | Daily | | |
| | | | | | | Tissues | After sacrifice | | |
| | | $^{14}C$-pyrimidinyl | 1 | 8.6 | 3 | Milk | Twice daily | 358312 | |
| | | | | | | Urine and faeces | Daily | | |
| | | | | | | Tissues | After sacrifice | | |
| | | $^{14}C$-pyrimidinyl | 1 | 0.007 | 3 | Milk | Twice daily | 367356 | |
| | | | | | | Urine and faeces | Daily | | |
| | | | | | | Tissues | After sacrifice | | |

**Summary of animal metabolism studies reported in the EU**

*Reference: EFSA, 2012*

"Lactating goats were dosed with nicosulfuron ranging from 0.007 to 8.6 mg/kg bw per d, corresponding to approximately 2 to 2700 times the exposure of meat ruminant. Studies demonstrate that the majority of radioactivity was rapidly excreted (from 69 to 91% AR). In the highest dosed studies, parent nicosulfuron was the most abundant component found in tissues for both radiolabels with up to 66% TRR (0.62 mg eq/kg) in kidney. Two major metabolites were detected in tissues: ASDM with up to 18% TRR (0.11 mg eq/kg) in kidney and ADMP with up to 16% TRR (0.11 mg eq/kg) in liver. In addition the pyridine ring specific compounds SNA and ODPD were found in significant levels in liver for the pyridine labelled study (24 and 13% TRR; 0.09 and 0.05 mg eq/kg respectively). For milk, nicosulfuron and ADMP were found in equal amounts in the pyridil labelled study (30% TRR; 0.05 mg eq/kg). In the pyrimidinyl labelled study, Mi 12 was the most abundant compound found at levels twice those of nicosulfuron. In the lowest dose level study (2N), no significant residues were detected in tissues and milk (<0.001 mg/kg)."

**Conclusion on metabolism in livestock**

The metabolism of nicosulfuron in livestock is sufficiently addressed to support the proposed uses of the product A18385B.

### 7.3.2.6 Conclusion on the nature of residues in commodities of animal origin (KCA 6.7.1)

**Table 7.3-6: Summary on the nature of residues in commodities of animal origin**

| **Endpoints** | |
|---|---|
| Animals covered | Lactating goats |
| Time needed to reach a plateau concentration | Unable to assess due to low total radioactive residues |
| Animal residue definition for monitoring | Nicosulfuron (Regulation (EU) No 617/2014)<br>Unable to propose, however intakes are not significant (<0.1 mg/kg diet) (EFSA, 2007) |
| Animal residue definition for risk assessment | Unable to propose, however intakes are not significant (<0.1 mg/kg diet) (EFSA, 2007) |
| Conversion factor | None |
| Metabolism in rat and ruminant similar | Yes |
| Fat soluble residue | No |

## 7.3.3 Magnitude of residues in plants (KCA 6.3)

### 7.3.3.1 Summary of European data and new data supporting the intended uses

A summary of the critical GAP for the intended uses of A18385B in the Central European Zone are summarised in the table below.

**Table 7.3-7: Summary of the cGAP for the intended uses of A18385B in the Central Zone**

| Crop | Field (F) or Glass-house (G) use | Growth stage | Maximum number of applica-tions per year | Minimum interval between treatments [days] | Water [L/ha] | Application rate per treatment [kg a.s./ha] | Minimum PHI [days] |
|---|---|---|---|---|---|---|---|
| Maize | F | BBCH 12-18 | 1 | -- | 200-400 | 0.050[(a)] | n.s. |

n.s. Not specified; the PHI is covered by the time remaining between application and harvest
(a): 0.050 kg/ha nicosulfuron, 0.020 kg/ha prosulfuron and 0.200 kg/ha dicamba
A18385B is applied with a tank-mixed oil-based adjuvant (e.g Adigor @ 1.0-1.5 L/ha)

No new data are submitted in the framework of this application.

**Table 7.3-8: Summary of EU reported and new data supporting the intended uses of A18385B and conformity to existing MRL**

| Commodity | Source | Residue zone (N-EU, S-EU, EU, outside EU) | Evaluation<br>GAP<br>Residue levels (mg/kg)<br>E = according to enforcement residue definition<br>RA = according to risk assessment residue definition | STMR (mg/kg) | HR (mg/kg) | Unrounded OECD calculator MRL (mg/kg) | Current EU MRL (mg/kg)[(a)] | MRL compliance |
|---|---|---|---|---|---|---|---|---|
| **Maize** (grain) | EFSA, 2007 | N-EU | GAP on which MRL/EU a.s. assessment is based: 1 x 0.06 kg a.s./ha, BBCH 12-18, PHI n.s., outdoor<br>E/RA: 18x <0.01 | N/A | | | | |
| | | S-EU | GAP on which MRL/EU a.s. assessment is based: 1 x 0.06 kg a.s./ha, BBCH 12-18, PHI n.s., outdoor<br>E/RA: 15x <0.01 | | | | | |
| | Overall supporting data for cGAP | N-EU | E/RA: 18x <0.01 | 0.01 | 0.01 | 0.01* | 0.01* | Yes |
| | | S-EU | E/RA: 15x <0.01 | 0.01 | 0.01 | 0.01* | 0.01* | Yes |
| **Maize** (forage/whole plant) | EFSA, 2007 | N-EU | GAP on which MRL/EU a.s. assessment is based: 1 x 0.06 kg a.s./ha, BBCH 12-18, PHI n.s., outdoor<br>17x <0.01, 0.015 | N/A | | | | |
| | | S-EU | GAP on which MRL/EU a.s. assessment is based: 1 x 0.06 kg a.s./ha, BBCH 12-18, PHI n.s., outdoor<br>E/RA: 14x <0.01, 0.013 | | | | | |
| | Overall supporting data for cGAP | N-EU | E/RA: 17x <0.01, 0.015 | 0.01 | 0.015 | No MRL set for feed item | | |
| | | S-EU | E/RA: 14x <0.01, 0.013 | 0.01 | 0.013 | No MRL set for feed item | | |

(a): Source of EU MRL: Reg. (EU) No 617/2014 amending Reg. (EC) No 396/2005.

(*): Indicates that the MRL is set at the limit of analytical quantification. The European Food Safety Authority identified some information on analytical methods as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 11 June 2016, or, if that information is not submitted by that date, the lack of it.

### 7.3.3.2 Conclusion on the magnitude of residues in plants

Maize is a major crop in both northern and southern Europe and therefore normally requires eight trials in each region to support an EU MRL (SANCO 7525/VI/95 rev. 10.3). A total of 33 trials are available from the first evaluation of nicosulfuron (United Kingdom, 2006), 18 conducted in Northern Europe and 15 in Southern Europe. No additional trials have been performed.

In all maize whole plant (fodder), ears and grain specimens collected in these trials, residues of nicosulfuron were below the level of analytical quantification (<0.01 mg/kg), except for one whole plant sample each in Northern and Southern Europe with residues of 0.015 and 0.013 mg/kg, respectively. It is therefore concluded that sufficient data are available which show that no exceedance of the existing MRL will occur. The uses of A18385B on maize are considered acceptable.

### 7.3.4 Magnitude of residues in livestock

### 7.3.4.1 Dietary burden calculation

The use of A18385B may result in residues of nicosulfuron in animal feed items, therefore the possible transfer of residues in animal commodities from the proposed uses should be considered. Livestock intake calculations (Animal Model 2017) and feeding studies undertaken are provided below.

**Table 7.3-9: Input values for the dietary burden calculation (considering the uses evaluated in Art. 12 procedure and the uses under consideration)**

| Feed Commodity | Median dietary burden | | Maximum dietary burden | |
|---|---|---|---|---|
| | Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
| **Risk assessment residue definition:** Nicosulfuron | | | | |
| Maize silage | 0.01 | Median residue (EFSA, 2012) | 0.015 | Highest residue (EFSA, 2012) |
| Maize stover (fodder) | 0.01 | Extrapolated from maize silage as worst case | 0.015 | Extrapolated from maize silage as worst case |
| Corn, pop, stover (fodder) | 0.01 | Extrapolated from maize silage as worst case | 0.015 | Extrapolated from maize silage as worst case |
| Maize grain | 0.01 | Median residue (EFSA, 2012) | 0.01 | Median residue (EFSA, 2012) |
| Corn, pop, grain | 0.01 | Extrapolated from maize grain | 0.01 | Extrapolated from maize grain |
| Corn, field, milled by-pdts | 0.01 | Median residue maize grain × PF 1[(a)] | 0.01 | Median residue maize grain × PF 1[(a)] |
| Corn, field, hominy meal | 0.01 | Median residue maize grain × PF 1[(a)] | 0.01 | Median residue maize grain × PF 1[(a)] |
| Corn, field, gluten feed | 0.01 | Median residue maize grain × PF 1[(a)] | 0.01 | Median residue maize grain × PF 1[(a)] |
| Corn, field, gluten, meal | 0.01 | Median residue maize grain × PF 1[(a)] | 0.01 | Median residue maize grain × PF 1[(a)] |
| Distiller's grain, dried | 0.01 | Median residue maize grain × PF 1[(a)] | 0.01 | Median residue maize grain × PF 1[(a)] |

(a) Default PF waived as residues in RAC <LOQ

Nicosulfuron falls under old data requirements. The results of the calculations are reported in

Table 7.3-10 below. Since the calculated dietary burdens for all groups of livestock were found to be below the trigger value of 0.1 mg/kg DM, further investigation of residues in commodities of animal origin is not necessary.

**Table 7.3-10: Results of the dietary burden calculation**

| Animal species | Median dietary burden (mg/kg bw/d) | Maximum dietary burden (mg/kg bw/d) | Highest contributing commodity | Max dietary burden (mg/kg DM) | Trigger exceeded (Y/N) |
|---|---|---|---|---|---|
| **Risk assessment residue definition:** Nicosulfuron | | | | | |
| Beef cattle | 0.001 | 0.001 | Maize silage | 0.04 | N |
| Dairy cattle | 0.001 | 0.001 | Maize silage | 0.03 | N |
| Ram/ewe | 0.0004 | 0.0004 | Corn, field, gluten feed | 0.01 | N |
| Lamb | 0.0005 | 0.0005 | Corn, field, gluten feed | 0.01 | N |
| Breeding swine | 0.0003 | 0.0004 | Maize silage | 0.02 | N |
| Finishing swine | 0.0003 | 0.0003 | Corn, field, milled by-pdts | 0.01 | N |
| Broiler poultry | 0.001 | 0.001 | Corn, field, milled by-pdts | 0.01 | N |
| Layer poultry | 0.001 | 0.001 | Maize silage | 0.01 | N |
| Turkey | 0.001 | 0.001 | Corn, field, milled by-pdts | 0.01 | N |

#### 7.3.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Feeding studies in livestock (poultry/ruminants) are not triggered.

No new data were submitted in the framework of this application.

### 7.3.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) (KCA 6.5.2-6.5.3)

Data/information on processing studies was reviewed during the approval of nicosulfuron and considered sufficient. No further studies have been performed.

As quantifiable residues of nicosulfuron are not expected in the treated crops and the TMDI is <10% (see section 7.3.8), there is no need to investigate the effect of industrial and/or household processing.

### 7.3.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

Considering available data dealing with nature of residues in rotational crops (see section 7.3.2.2), no study dealing with magnitude of residues in succeeding crops is needed.

#### 7.3.6.1 Field rotational crop studies (KCA 6.6.2)

**Available data**

Studies investigating the magnitude of residues in succeeding crops were not conducted. No new data submitted in the framework of this application.

**Conclusion on rotational crops studies**

Based on the lysimeter studies (where crops of wheat and rye were grown following maize treated at the proposed application rate of 60 g/ha) and the phytotoxic effect of nicosulfuron and its soil metabolites on dicotyledone plants, preventing re-planting until the following spring at which time residues in soil of nicosulfuron and relevant metabolites have decreased to <0.001 mg/kg, and considering that the application rate of nicosulfuron ranges between 0.050-0.060 kg a.s./ha, it can be concluded that nicosulfuron residue levels in rotational commodities are not expected to exceed 0.01 mg/kg, provided that nicosulfuron is applied in compliance with the GAPs supported for this submission.

## 7.3.7 Other / special studies (KCA6.10, 6.10.1)

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of A18385B. According to SANTE/11956/2016 rev.9, maize is a crop with no melliferous capacity. Therefore, other special studies are not needed.

## 7.3.8 Estimation of exposure through diet and other means (KCA 6.9)

Toxicological reference values relevant for dietary risk assessment are reported in the summary of the evaluation (see section 7.1.2).

As ARfD was not deemed necessary, acute risk assessment is not relevant.

### 7.3.8.1 Input values for the consumer risk assessment

Syngenta uses, values corresponding to actual EU MRLs and several animal matrices were considered for IEDI calculation.

**Table 7.3-11: Input values for the consumer risk assessment**

| Commodity | Chronic risk assessment | |
|---|---|---|
| | Input value (mg/kg) | Comment |
| **Risk assessment residue definition:** Nicosulfuron | | |
| Maize | 0.01* | MRL (Reg. (EU) No 617/2014) |
| Ruminant muscle | 0.02* | MRL (Reg. (EU) No 617/2014) |
| Ruminant fat | 0.02* | MRL (Reg. (EU) No 617/2014) |
| Ruminant liver | 0.05* | MRL (Reg. (EU) No 617/2014) |
| Ruminant kidney | 0.02* | MRL (Reg. (EU) No 617/2014) |
| Ruminant edible offals | 0.05* | MRL (Reg. (EU) No 617/2014) |
| Ruminant others | 0.05* | MRL (Reg. (EU) No 617/2014) |
| Pig muscle | 0.02* | MRL (Reg. (EU) No 617/2014) |
| Pig fat | 0.02* | MRL (Reg. (EU) No 617/2014) |
| Pig liver | 0.05* | MRL (Reg. (EU) No 617/2014) |
| Pig kidney | 0.02* | MRL (Reg. (EU) No 617/2014) |
| Pig edible offals | 0.05* | MRL (Reg. (EU) No 617/2014) |
| Pig others | 0.05* | MRL (Reg. (EU) No 617/2014) |
| Poultry muscle | 0.02* | MRL (Reg. (EU) No 617/2014) |
| Poultry fat | 0.02* | MRL (Reg. (EU) No 617/2014) |
| Poultry liver | 0.05* | MRL (Reg. (EU) No 617/2014) |
| Poultry kidney | 0.02* | MRL (Reg. (EU) No 617/2014) |

| Commodity | Chronic risk assessment | |
|---|---|---|
| | Input value (mg/kg) | Comment |
| Poultry edible offals | 0.05* | MRL (Reg. (EU) No 617/2014) |
| Poultry others | 0.05* | MRL (Reg. (EU) No 617/2014) |
| Milk | 0.02* | MRL (Reg. (EU) No 617/2014) |
| Eggs | 0.02* | MRL (Reg. (EU) No 617/2014) |

#### 7.3.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

**Table 7.3-12: Consumer risk assessment**

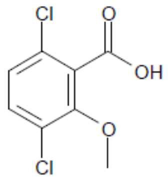
| | |
|---|---|
| TMDI (% ADI) according to EFSA PRIMo rev. 3.1 | Not shown, please refer to IEDI calculations |
| IEDI (% ADI) according to EFSA PRIMo rev. 3.1 | 0.1% (based on NL toddler) |
| IESTI (% ARfD) according to EFSA PRIMo rev. 3.1 | Not applicable |

The proposed uses of nicosulfuron in A18385B do not represent unacceptable acute and chronic risks for the consumer.

## 7.4 Dicamba

General data on dicamba are summarized in the table below (last updated 2020/09/09).

**Table 7.4-1: General information on dicamba**

| | |
|---|---|
| Active substance (ISO Common Name) | Dicamba |
| IUPAC | 3,6-dichloro-2-methoxybenzoic acid |
| Chemical structure |  |
| Molecular formula | $C_8H_6Cl_2O_3$ |
| Molar mass | 221.0 g/mol |
| Chemical group | Benzoic acid |
| Mode of action (if available) | Plant growth regulator (unclassified) |
| Systemic | Yes |
| Company (ies) | Syngenta |
| Rapporteur Member State (RMS) | Denmark |
| Approval status | Approved<br>Date of 01/01/2009<br>Commission Directive 2008/69/EC - Commission Regulation (EU) No 540/2011 – Commission Regulation (EU) No 1100/2011 |
| Restriction | Restricted to uses as herbicide |
| Review Report | SANCO/829/08 – rev. 2<br>07/03/2008<br>SANCO/829/08 – final rev. 2<br>12/07/2016 |
| Current MRL regulation | Regulation (EU) No 2015/845 |
| Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed | Pending (EFSA-Q-2009-00102) |
| EFSA Journal: Conclusion on the peer review | Yes (EFSA, 2011a) |
| EFSA Journal: Conclusion on article 12 | No |
| Current MRL applications on intended uses | No MRL applications are pending |

### 7.4.1 Stability of Residues (KCA 6.1)

#### 7.4.1.1 Stability of residues during storage of samples

**Available data**

*References: Denmark, 2007*

No new data submitted in the framework of this application.

**Table 7.4-2: Summary of stability data achieved at ≤ -18°C (unless stated otherwise) - dicamba**

| Commodity category | Commodity | Acceptable maximum storage period | Report Reference | Source |
|---|---|---|---|---|
| **EU reviewed data** | | | | |
| **Plant products** | | | | |
| High water content | Maize, forage | 36 months | 127 | Denmark, 2007 |
| | Maize, silage | 36 months | | |
| | Maize, fodder | 36 months | | |
| High starch content | Maize, grain | 36 months | 127 | Denmark, 2007 |
| **Animal Products** | | | | |
| Meat | Ruminant | 18 months[(a)] | 151 | Denmark, 2007 |
| Fat | Ruminant | 18 months[(a)] | | |
| Liver | Ruminant | 18 months[(a)] | | |
| Kidney | Ruminant | 18 months[(a)] | | |
| Milk | Ruminant | 18 months[(a)] | | |

(a): Animal commodities were stored at -12°C

**Table 7.4-3: Summary of stability data achieved at ≤ -18°C (unless stated otherwise) – 5-OH-dicamba**

| Commodity category | Commodity | Acceptable maximum storage period | Report Reference | Source |
|---|---|---|---|---|
| **EU reviewed data** | | | | |
| **Plant products** | | | | |
| High water content | Maize, forage | 36 months | 127 | Denmark, 2007 |
| | Maize, silage | 24 months[(a)] | | |
| | Maize, fodder | 36 months | | |
| High starch content | Maize, grain | 36 months | 127 | Denmark, 2007 |

(a): The stability of 5-OH-dicamba in silage was tested for up to 24 months

**Conclusion on stability of residues during storage**

The storage stability of dicamba and its relevant metabolite 5-OH-dicamba has been investigated in different groups, including commodities with high water and high starch content and animal matrices (dicamba only). Sufficient stability has been demonstrated to support the residue data presented in the submission.

### 7.4.1.2 Stability of residues in sample extracts (KCA 6.1)

Stability of residues in sample extracts is confirmed by the procedural recovery samples analysed as part of each analytical batch of residue samples. Data are expected to be within the usual limits of recovery as defined within analytical method validation. No additional information is available or required.

For animal matrices, the stability of dicamba and DCSA (NOA414746) in final extracts stored at 4ºC (between 0 and 9ºC) was assessed in eggs during the ILV of method GRM022.03A. Samples were re-analysed after a 12 day interval. Results determined from this matrix at the 12 day interval were similar to those from the original analysis (the mean recovery rate was in the range 70-110%). The results indicate the stability of dicamba and NOA414746 in final extracts when stored at 4ºC.

**Table 7.4-4: Stability results from independent laboratory validation of dicamba and DCSA (NOA414746) using analytical method GRM022.03A**

| Storage interval (days) | Fortification level (mg/kg) | Recovery (%) | Mean Recovery (%) | RSD (%) | Recovery Range (%) |
|---|---|---|---|---|---|
| **Dicamba (Target ion 184 *m/z*)** | | | | | |
| 1 | 0.01 | 94, 97, 100, 96, 94 | 96 | 3 | 94-100 |
| 12 | 0.01 | 77, 82, 81, 76, 77 | 79 | 4 | 76-82 |
| **NOA414746 (Target ion 227 *m/z*)** | | | | | |
| 1 | 0.01 | 92, 95, 101, 95, 93 | 95 | 4 | 92-101 |
| 12 | 0.01 | 82, 86, 90, 84, 84 | 85 | 4 | 82-90 |

## 7.4.2 Nature of residues in plants, livestock and processed commodities

### 7.4.2.1 Nature of residue in primary crops (KCA 6.2.1)

**Available data**

*References: Denmark, 2007*

No new data submitted in the framework of this application.

**Table 7.4-5: Summary of plant metabolism studies**

| Crop Group | Crop | Label position | Application and sampling details | | | | Report Reference | Source |
|---|---|---|---|---|---|---|---|---|
| | | | Method, F or G (a) | Rate (kg a.s./ha) | No | Sampling (DAT) | | |
| **EU reviewed data** | | | | | | | | |
| **Pulses and oilseeds** | Soybean | Phenyl-(U)-$^{14}$C | Local leaf application, F | 5.17 µg/plant (ca. 1.7 g a.s./ha(b)) | 1 (early growth stage) | Leaves: 0, 7, 14 | 39 | Denmark, 2007 |
| | | | | 5.17 µg/plant (ca. 1.7 g a.s./ha(b)) | 1 (late growth stage) | Leaves: 6 | | |
| | Cotton | Phenyl-(U)-$^{14}$C | Local leaf application, F | 60 µg/plant (ca. 5.9 g a.s./ha(b)) | 1 (green boll stage) | Whole plant: 0, 7, 14 | 44 70 | Denmark, 2007 |
| **Cereals, grass plants** | Spring wheat | Phenyl-(U)-$^{14}$C | Foliar spray, F | 144 g a.s./ha | 1 (BBCH 29) | Forgae: 18 Grain, straw: 85 | 97SV01 | Denmark, 2007 |

| Crop Group | Crop | Label position | Application and sampling details | | | | Report Reference | Source |
|---|---|---|---|---|---|---|---|---|
| | | | Method, F or G [(a)] | Rate (kg a.s./ha) | No | Sampling (DAT) | | |
| | Sugar cane | Phenyl-(U)-$^{14}$C | Local leaf application, G | 3.06 mg/plant (ca. 1120 g a.s./ha[(b)]) | 1 (8-9 leaves) | Whole plant: 0, 1, 2, 5, 12, 21, 28 | 24 13 | Denmark, 2007 |

(a): Outdoor/field application (F) or glasshouse/protected/indoor application (G).
(b): Rates per ha should be considered as rough estimates since derived from local application on leaves using micro-syringe.

**Summary of plant metabolism studies reported in the EU**

*Reference: EFSA, 2011a*

"Metabolism in plants was investigated in cereals (wheat, sugar cane) and in the pulse/oilseed plant group (soya, cotton), using $^{14}$C-dicamba labelled on the phenyl moiety applied by foliar spraying (wheat), or by droplet applications by means of a micro-syringe to a limited number of leaves (sugar cane, soya, cotton). In sugar cane, soya and cotton, where the characterization of the residues was investigated shortly after the application (6 to 28 days), dicamba remains the major component of the residues, accounting for 22 - 29% of the TRR in sugar cane leaves, 44 - 94% of the TRR in soya beans, and 72% of the TRR in cotton seed. Other identified metabolites were observed in low proportions (< 2% TRR), except 5-OH-dicamba, which represented 47% and 20% of the TRR in sugar cane leaves, 12 and 28 days after application, respectively. In wheat, dicamba seems to be more extensively metabolised, accounting for 10% of the TRR in immature plant (forage), and 2% and 16% of the TRR respectively in straw and grain at harvest. 5-OH-dicamba is detected as the major metabolite in wheat forage (65% TRR), but it represents less than 4% TRR in grain and straw at harvest. Both the parent compound and 5-OH-dicamba were observed in free and conjugated form.

Considering the different structures identified, the following metabolic pathway in plants was proposed. The metabolism of dicamba proceeds first by hydroxylation to form 5-OH-dicamba, or by demethylation to the DCSA metabolite, both compounds being further degraded to DCGA. Based on these studies, it was proposed to define the residue for monitoring as dicamba and its salts (free and conjugates). For risk assessment, the PRAPeR TC 50 discussed whether 5-OH-dicamba should be included additionally in the residue definition, since it was not observed at significant levels in the edible parts used for human consumption. Finally, and considering the conclusion of the PRAPeR meeting on mammalian toxicology (PRAPeR 83) stating that 5-OH-dicamba is not of higher toxicity than the parent compound, and having regard to the important levels at which this metabolite was observed in the residue trials conducted on pasture, it was agreed to include this metabolite in the residue definition for risk assessment."

**Conclusion on metabolism in primary crops**

The metabolism of dicamba in plants following foliar application is sufficiently addressed to support the proposed uses of dicamba in the product A18385B.

### 7.4.2.2 Nature of residue in rotational crops (KCA 6.6.1)

**Available data**

*Reference: Denmark, 2007*

No new data submitted in the framework of this application.

**Table 7.4-6: Summary of metabolism studies in rotational crops**

| Crop group | Crop | Label position | Application and sampling details | | | | Report reference | Source |
|---|---|---|---|---|---|---|---|---|
| | | | Method, F or G (a) | Rate (kg a.s./ha) | Sowing intervals (DAT) | Harvest Intervals (DAT) | | |
| **EU reviewed data** | | | | | | | | |
| **Leafy vegetables** | Mustard | phenyl-(U)-$^{14}C$ | Soil application, F | 560 g a.s./ha | 32, 131, 369 | Maturity (tops) | 16 | Denmark, 2007 |
| | Collard | phenyl-(U)-$^{14}C$ | Soil application, F | 840 g a.s./ha | 30, 120 | Maturity (tops) | 22 | |
| **Root and tuber vegetables** | Turnip | phenyl-(U)-$^{14}C$ | Soil application, F | 560 g a.s./ha | 32, 131, 369 | Maturity (tops and roots) | 16 | Denmark, 2007 |
| | Carrot | phenyl-(U)-$^{14}C$ | Soil application, F | 840 g a.s./ha | 30, 120 | Maturity (roots) | 22 | |
| **Pulses and oilseeds** | Soybean | phenyl-(U)-$^{14}C$ | Soil application, F | 840 g a.s./ha | 120 | Immature (forage) Maturity (grain, straw, chaff) | 22 | Denmark, 2007 |
| **Cereals** | Wheat | phenyl-(U)-$^{14}C$ | Soil application, F | 560 g a.s./ha | 32, 131, 369 | Immature, forage: 32, 396 Maturity, grain, straw, chaff: 131 | 16 | Denmark, 2007 |
| | Barley | phenyl-(U)-$^{14}C$ | Soil application, F | 840 g a.s./ha | 30, 120, 365 | Immature (forage) Maturity (seed, hay) | 22 | |

(a): Outdoor/field application (F) or glasshouse/protected/indoor application (G)

**Summary of metabolism studies in rotational crops reported in the EU**

*Reference: Denmark, 2007*

“No dicamba, DCSA or 5-OH-dicamba was found in amounts of >0.01 mg/kg at 32, 131 and 365 DAT, respectively.

Barley, carrots and collard greens were planted as rotational crops to maize treated with $^{14}C$-dicamba, equivalent to 0.840 kg a.s./ha and corresponding to about twice the rate according to the intended use for maize and pasture. TRR was <0.04 mg/kg at 120 DAT. TRR at 30 DAT was high (1.022 mg/kg in carrot roots and 0.272 mg/kg in barley grain). Since no residues of dicamba, DCSA and 5-OH-dicamba were found in the study, where wheat, turnips and mustard were used as rotational crops it is not expected either that the residues found in barley, carrots and collard greens 30 DAT will be due to dicamba, DCSA or 5-OH-dicamba. This could be due to incorporation of $^{14}CO_2$ or other breakdown products into plant constituents such as lignin or cellulose.

There will therefore be no restriction of planting or sowing succeeding and rotational crops.”

*Reference: EFSA 2013b*

“The soil degradation studies demonstrated that the degradation rate of dicamba and its identified soil metabolites is rapid with a $DT_{90}$ estimated to be below the trigger value of 100 days (Denmark, 2007/EFSA, 2011[a]). Thus, no further studies investigating the nature and magnitude of the compound uptake in rotational crops are required […]. Moreover, in a confined rotational crop study where dicamba was applied to the bare soil at a dose rate of 840 g a.s./ha (ca. 4N), TRRs were all below 0.04 mg/kg in the plant commodities for the plant back intervals of 120 and 360 days.”

**Conclusion on metabolism in rotational crops**

No parent, 5-OH-dicamba and DCSA were identified in the rotational crops; DCSA was identified in soil. Radioactive residues are assumed to be due to incorporation of $^{14}CO_2$ or other breakdown products into plant constituents such as lignin or cellulose. Thus a specific residue definition for rotational crops is not deemed necessary.

### 7.4.2.3 Nature of residues in processed commodities (KCA 6.5.1)

**Available data**

*Reference: Denmark, 2007*

No new data submitted in the framework of this application.

**Table 7.4-7: Nature of the residues in processed commodities**

| Conditions | Identified compound(s) (%) | Report reference | Source |
|---|---|---|---|
| **EU reviewed data** | | | |
| Pasteurisation (20 minutes, 90°C, pH 4) | Dicamba (100.7%[(a)]) | RJ3333B | Denmark, 2007 |
| Baking, boiling, brewing (60 minutes, 100°C, pH 5) | Dicamba (105.1%) | RJ3333B | Denmark, 2007 |
| Sterilisation (20 minutes, 120°C, pH 6) | Dicamba (106.6%) | RJ3333B | Denmark, 2007 |

(a): Mean value of two replicate samples

**Conclusion on nature of residues in processed commodities**

The nature of residues of dicamba in processed products has been investigated. Dicamba is hydrolytically stable under the representative processing conditions and the same residue definitions as for raw agricultural commodities apply.

### 7.4.2.4 Conclusion on the nature of residues in commodities of plant origin (KCA 6.7.1)

**Table 7.4-8: Summary of the nature of residues in commodities of plant origin**

| **Endpoints** | |
|---|---|
| Plant groups covered | Cereals (Wheat and sugar cane)<br>Pulses/oilseeds (Soybean and cotton) |

| | |
|---|---|
| Rotational crops covered | Lefy crops (mustard and collard greens), Root vegetables (carrot and turnips), Pulses/oilseeds (soybean) and cereals (wheat and barley) –application to bare soil |
| Metabolism in rotational crops similar to metabolism in primary crops? | No parent, 5-OH-dicamba and DCSA identified in the rotational crops. DCSA identified in soil. |
| Processed commodities | a.s. is stable under standard hydrolysis conditions |
| Residue pattern in processed commodities similar to pattern in raw commodities? | Yes |
| Plant residue definition for monitoring | Dicamba (parent only) (Regulation (EU) 2015/845)<br>Dicamba and its salts (free and and conjugated), expressed as dicamba (EFSA, 2011a) |
| Plant residue definition for risk assessment | Dicamba + 5-OH-dicamba (free and conjugated) (EFSA, 2011a) |
| Conversion factor from enforcement to RA | None |

### 7.4.2.5 Nature of residues in livestock (KCA 6.2.2-6.2.5)

**Available data**

*Reference: Denmark, 2007*

No new data submitted in the framework of this application.

**Table 7.4-9: Summary of animal metabolism studies**

| Group | Species | Label position | No of animal | Application details | | Sample details | | Report reference | Reference |
|---|---|---|---|---|---|---|---|---|---|
| | | | | Rate (mg/kg bw/d) | Duration (days) | Commodity | Time of sampling | | |
| **EU reviewed data** | | | | | | | | | |
| **Lactating ruminants** | Cow | phenyl-(U)-$^{14}C$ | 1 | 2.2 mg/kg bw/day | 5 | Milk | Twice daily | J. Agric. Food Chem. Vol. 28, No. 4, 1980 | Denmark, 2007 |
| | | | | | | Urine<br>Faeces | Twice daily<br>Daily | | |
| | | | | | | Tissues | At sacrifice | | |
| | Goat | phenyl-(U)-$^{14}C$ | 2 | Goat A: 10 mg/kg feed<br>Goat B: 1000 mg/kg feed[(a)] | 4 | Milk | Twice daily | 28 | Denmark, 2007 |
| | | | | | | Urine and faeces | Twice daily | | |
| | | | | | | Tissues | At sacrifice | | |
| **Laying poultry** | Hens | phenyl-(U)-$^{14}C$ | 12 (3 groups) | Group A: 1 mg/kg bw<br>Group B: 100 mg/kg bw<br>Group C: 1 mg/kg | 1 | Eggs | Not collected | 65 | Denmark, 2007 |
| | | | | | | Excreta | 2 animals per group: 0.5, 1, 2, 4, 6 and 7h after dosing; Rest: 1, 2, 3 and 4 days after dosing | | |

| Group | Species | Label position | No of animal | Application details | | Sample details | | Report reference | Reference |
|---|---|---|---|---|---|---|---|---|---|
| | | | | Rate (mg/kg bw/d) | Duration (days) | Commodity | Time of sampling | | |
| | | | | bw (IV)[b] | | Tissues | After sacrifice (24h and 96h after dosing; 2 animals per group) | | |
| | Hens | phenyl-(U)-$^{14}$C | 8 (2 groups) | Group A (5 hens): 0.6mg/kg bw/day Group B (3 hens): 30 mg/kg bw/day | 4 | Eggs | Daily | 25 | Denmark, 2007 |
| | | | | | | Excreta | Daily | | |
| | | | | | | Tissues | After sacrifice | | |

(a): Notifiers explain that Goat A was used for metabolite characterisation and Goat B was used to generate metabolites for instrumental analysis. In this study only results from Goat A are presented.
(b): Groups A and B: oral dosing (intubation); Group C: intravenous injection.

**Summary of animal metabolism studies reported in the EU**

*Reference: EFSA, 2011a*

"The transfer in fat, milk and eggs was limited, the highest TRRs being observed in kidney and liver. Dicamba (free and conjugated) was by far the major compound identified in all animal matrices, accounting for more than 50% of the TRR. In addition, DCSA was also observed in ruminants, but only in kidney and liver, up to 21% of the TRR. 5-OH-dicamba was not detected in animal matrices, except in urine and excreta, but at insignificant levels and proportions (<0.01% TRR). Having regard to the high levels of 5-OH-dicamba in grass, and consequently its significant intake by ruminants (c.a. 1.5 mg/kg bw/day), the PRAPeR TC 50 meeting of experts discussed whether a specific metabolism study using this metabolite needs to be required. The experts were of the opinion that a similar pathway to the parent is expected for 5-OH-dicamba, this metabolite being probably more extensively excreted than the parent compound since it is more polar. This assertion is supported by the results of the cow feeding study conducted with 5-OH-dicamba, where this metabolite was almost not detected in any matrices, except in kidney, at the 5N dose rate. It was therefore concluded that a specific ruminant metabolism study should not be required for 5-OH-dicamba."

**Conclusion on metabolism in livestock**

The metabolism of dicamba in livestock is sufficiently addressed to support the proposed uses of dicamba in the product A18385B.

### 7.4.2.6 Conclusion on the nature of residues in commodities of animal origin (KCA 6.7.1)

| **Endpoints** | |
|---|---|
| Animals covered | Lactating cow and goats, laying hens |
| Time needed to reach a plateau concentration | <14 days in milk and eggs (based on metabolism studies) |

| | |
|---|---|
| Animal residue definition for monitoring | Dicamba (Regulation (EU) 2015/845)<br>Dicamba and its salts (free and and conjugated), expressed as dicamba (EFSA, 2011a) |
| Animal residue definition for risk assessment | Dicamba (free and conjugated) (EFSA, 2011a) |
| Conversion factor | Not applicable |
| Metabolism in rat and ruminant similar | Yes |
| Fat soluble residue | No |

## 7.4.3 Magnitude of residues in plants (KCA 6.3)

### 7.4.3.1 Summary of European data and new data supporting the intended uses

A summary of the critical GAP for the intended uses of A18385B in the Central European Zone are summarised in the table below.

**Table 7.4-10: Summary of the cGAP for the intended uses of A18385B in the Central Zone**

| Crop | Field (F) or Glass-house (G) use | Growth stage | Maximum number of applica-tions per year | Minimum interval between treatments [days] | Water [L/ha] | Application rate per treatment [kg a.s./ha] | Minimum PHI [days] |
|---|---|---|---|---|---|---|---|
| Maize | F | BBCH 12-18 | 1 | -- | 200-400 | 0.200[(a)] | n.s. |

n.s. Not specified; the PHI is covered by the time remaining between application and harvest
(a): 0.200 kg/ha dicamba, 0.020 kg/ha prosulfuron and 0.050 kg/ha nicosulfuron
A18385B is applied with a tank-mixed oil-based adjuvant (e.g Adigor @ 1.0-1.5 L/ha)

New studies on the magnitude of residue, not previously considered within an EU peer review process, have been submitted by the applicant in the framework of this application. These studies are summarized in the table below. The detailed assessment of these studies is presented in Appendix 2.

**Table 7.4-11: Summary of EU reported and new data supporting the intended uses of A18385B and conformity to existing MRL**

| Commodity | Source | Residue zone (N-EU, S-EU, EU, outside EU) | Evaluation<br>GAP<br>Residue levels (mg/kg)<br>E = according to enforcement residue definition<br>RA = according to risk assessment residue definition | STMR (mg/kg) | HR (mg/kg) | Unrounded OECD calculator MRL (mg/kg) | Current EU MRL (mg/kg)[a] | MRL compliance |
|---|---|---|---|---|---|---|---|---|
| **Maize** (grain) | Denmark, 2007<br>EFSA, 2011a | N-EU | GAP on which MRL/EU a.s. assessment is based: 1 x 0.36 kg a.s./ha, up to BBCH 16, PHI n.s., outdoor<br>E: 6x <0.01, 3x <0.05; additionally not considered: <0.01<br>RA: 6x <0.02, 3x <0.1; additionally not considered: <0.02 | N/A | | | | |
| | | S-EU | GAP on which MRL/EU a.s. assessment is based: 1 x 0.36 kg a.s./ha, up to BBCH 16, PHI n.s., outdoor<br>E: 4x <0.01; additionally not considered: 4x <0.01<br>RA: 4x <0.02; additionally not considered: 4x <0.02 | | | | | |
| | New trials** (MRL Compilation Dossier, 2011; R10305 & R96-032) | S-EU | Trials GAP: 1 x 0.28 kg a.s./ha, BBCH 16-18, PHI n.s., outdoor<br>E: 4x <0.01<br>RA: 4x <0.02 | | | | | |
| | Overall supporting data for cGAP | N-EU | E : 7x <0.01, 3x <0.05<br>RA: 7x <0.02, 3x <0.1 | E: 0.01<br>RA: 0.02 | E: 0.05<br>RA: 0.1 | 0.05* | 0.5 | Yes |
| | | S-EU | E : 12x <0.01<br>RA: 12x <0.02 | E: 0.01<br>RA: 0.02 | E: 0.01<br>RA: 0.02 | 0.01* | 0.5 | Yes |
| **Maize** (forage; whole plant, stem with leaves, whole plant | Denmark, 2007[b] | N-EU | GAP on which MRL/EU a.s. assessment is based: 1 x 0.36 kg a.s./ha, up to BBCH 16, PHI n.s., outdoor<br>E : 3x <0.01, 2x 0.011, 0.017, 0.03, 0.039, 0.066, 0.476<br>RA: 3x <0.02, 2x 0.021, 0.027, 0.07, 0.065, 0.076, 0.525 | N/A | | | | |
| | | S-EU | GAP on which MRL/EU a.s. assessment is based: 1 x 0.36 kg | | | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| without cob or straw taken closest to crop maturity) | | | a.s./ha, up to BBCH 16, PHI n.s., outdoor<br>E : 5x <0.01, 0.01, 0.02, 0.03<br>RA: 2x <0.02, 0.02, 0.029, 2x 0.03, 0.04, 0.05 | | | |
| | New trials[**] (MRL Compilation Dossier, 2011; R10305 & R96-032) | S-EU | Trials GAP: 1 x 0.28 kg a.s./ha, BBCH 16-18, PHI n.s., outdoor<br>E : 2x <0.01, 0.02, 0.08<br>RA: 2x 0.02, 0.03, 0.10 | | | |
| | Overall supporting data for cGAP | N-EU | E : 3x <0.01, 2x 0.011, 0.017, 0.03, 0.039, 0.066, 0.476<br>RA: 3x <0.02, 2x 0.021, 0.027, 0.07, 0.065, 0.076, 0.525 | E: 0.014<br>RA: 0.024 | E: 0.48<br>RA: 0.525 | No MRL set for feed item |
| | | S-EU | E : 7x <0.01, 0.01, 2x 0.02, 0.03, 0.08<br>RA: 2x <0.02, 3x 0.02, 0.029, 3x 0.03, 0.04, 0.05, 0.10 | E: 0.01<br>RA: 0.03 | E: 0.08<br>RA: 0.10 | No MRL set for feed item |

(a): Source of EU MRL: Reg. (EU) 2015/845 amending Reg. (EC) No 396/2005.
(b): Studies reported in DAR but slightly different values were reported.
(*): Indicates that the MRL is set at the limit of analytical quantification.
(**): New studies, not evaluated during Annex I renewal of the active substance or during zonal / MS registration and submitted to support the new registration of the formulation A18385B in Poland.

### 7.4.3.2 Conclusion on the magnitude of residues in plants

Maize is a major crop in both northern and southern Europe and therefore normally requires eight trials in each region to support an EU MRL (SANCO 7525/VI/95 rev. 10.3). A total of 18 trials are available from the first evaluation of dicamba (Denmark, 2007), 10 conducted in Northern Europe and 8 in Southern Europe. Only 13 trials were considered for MRL derivation by the rapporteur Member State and EFSA (9 NEU and 4 SEU). An additional 4 SEU trials were submitted with the MRL Compilation dossier for dicamba. These trials were performed with a lower application rate of about 0.280 kg a.s./ha, in compliance with the most recent overall cGAP (see Appendix 2).

In all maize grain specimens collected in these trials, residues of dicamba were below the level of analytical quantification (<0.01 or <0.05 mg/kg). It is therefore concluded that sufficient data are available which show that no exceedance of the existing MRL will occur. The uses of dicamba in A18385B on maize are considered acceptable.

### 7.4.4 Magnitude of residues in livestock

### 7.4.4.1 Dietary burden calculation

The use of A18385B may result in residues of dicamba in animal feed items, therefore the possible transfer of residues in animal commodities from the proposed uses should be considered. Livestock intake calculations (Animal Model 2017) and feeding studies undertaken are provided below.

**Table 7.4-12: Input values for the dietary burden calculation (considering the uses authorized within the zone and the uses under consideration)**

| Feed Commodity | Median dietary burden | | Maximum dietary burden | |
|---|---|---|---|---|
| | Input value[(a)] (mg/kg) | Comment | Input value[(a)] (mg/kg) | Comment |
| **Risk assessment residue definition:** Dicamba and 5-OH-dicamba (free and conjugated)<br>Note: Input values are based on the residue definition for enforcement, i.e. dicamba (parent) residues | | | | |
| Barley/rye straw | 0.05 | Median residue (MRL Compilation dossier, 2011) | 0.16 | Highest residue (MRL Compilation dossier, 2011) |
| Maize forage/silage | 0.014 | Median residue (this application) | 0.48 | Highest residue (this application) |
| Maize stover (fodder) | 0.014 | Extrapolated from maize silage as worst case | 0.48 | Extrapolated from maize silage as worst case |
| Corn, pop, stover (fodder) | 0.014 | Extrapolated from maize silage as worst case | 0.48 | Extrapolated from maize silage as worst case |
| Grass forage (fresh) | 5.12 | Median residue (EFSA, 2011a) | 13.8 | Highest residue (EFSA, 2011a) |
| Grass hay | 17.9 | Median residue grass forage × default PF 3.5 | 48.3 | Highest residue grass forage × default PF 3.5 |
| Grass silage | 8.19 | Median residue grass forage × default PF 1.6 | 22.1 | Highest residue grass forage × default PF 1.6 |
| Oat straw | 0.07 | Median residue (MRL Compilation dossier, 2011) | 0.16 | Highest residue (MRL Compilation dossier, 2011) |

| Feed Commodity | Median dietary burden | | Maximum dietary burden | |
|---|---|---|---|---|
| | Input value[(a)] (mg/kg) | Comment | Input value[(a)] (mg/kg) | Comment |
| Wheat/triticale straw | 0.03 | Median residue (MRL Compilation dossier, 2011) | 0.12 | Highest residue (MRL Compilation dossier, 2011) |
| Barley/rye grain | 0.02 | Median residue (MRL Compilation dossier, 2011) | 0.02 | Median residue (MRL Compilation dossier, 2011) |
| Maize grain | 0.01 | Median residue (this application) | 0.01 | Median residue (this application) |
| Corn, pop, grain | 0.01 | Extrapolated from maize grain | 0.01 | Extrapolated from maize grain |
| Oat grain | 0.12 | Median residue (MRL Compilation dossier, 2011) | 0.12 | Median residue (MRL Compilation dossier, 2011) |
| Wheat/triticale grain | 0.01 | Median residue (MRL Compilation dossier, 2011) | 0.01 | Median residue (MRL Compilation dossier, 2011) |
| Brewer’s grain, dried | 0.07 | Median residue barley grain × default PF 3.3 | 0.07 | Median residue barley grain × default PF 3.3 |
| Corn, field, milled by-pdts | 0.01 | Median residue maize grain × PF 1[(b)] | 0.01 | Median residue maize grain × PF 1[(b)] |
| Corn, field, hominy meal | 0.01 | Median residue maize grain × PF 1[(b)] | 0.01 | Median residue maize grain × PF 1[(b)] |
| Corn, field, gluten feed | 0.01 | Median residue maize grain × PF 1[(b)] | 0.01 | Median residue maize grain × PF 1[(b)] |
| Corn, field, gluten, meal | 0.01 | Median residue maize grain × PF 1[(b)] | 0.01 | Median residue maize grain × PF 1[(b)] |
| Distiller's grain, dried | 0.03 | Median residue wheat grain × default PF 3.3 | 0.03 | Median residue wheat grain × default PF 3.3 |
| Wheat gluten, meal | 0.02 | Median residue wheat grain × default PF 3.3 | 0.02 | Median residue wheat grain × default PF 3.3 |
| Wheat, milled by-pdts | 0.07 | Median residue wheat grain × default PF 3.3 | 0.07 | Median residue wheat grain × default PF 3.3 |

(a): EU uses were considered.
(b): Default PF waived as residues in RAC <LOQ

Dicamba falls under old data requirements. The results of the calculations are reported in Table 7.4-13. The calculated dietary burdens for ruminants and pigs were found to exceed the trigger value of 0.1 mg/kg DM. Further investigation of residues is therefore only required in these groups of livestock.

**Table 7.4-13: Results of the dietary burden calculation**

| Animal species | Median dietary burden (mg/kg bw/d) | Maximum dietary burden (mg/kg bw/d) | Highest contributing commodity | Max dietary burden (mg/kg DM) | Trigger exceeded (Y/N) |
|---|---|---|---|---|---|
| **Risk assessment residue definition:** Dicamba (free and conjugated) | | | | | |
| Beef cattle | 0.247 | 0.664 | Grass forage | 27.66 | Y |
| Dairy cattle | 0.475 | 1.276 | Grass silage | 33.17 | Y |
| Ram/ewe | 0.649 | 1.748 | Grass forage | 52.45 | Y |

| Animal species | Median dietary burden (mg/kg bw/d) | Maximum dietary burden (mg/kg bw/d) | Highest contributing commodity | Max dietary burden (mg/kg DM) | Trigger exceeded (Y/N) |
|---|---|---|---|---|---|
| Lamb | 0.438 | 1.176 | Grass forage | 27.67 | Y |
| Breeding swine | 0.097 | 0.257 | Grass forage | 11.14 | Y |
| Finishing swine | 0.004 | 0.004 | Oat grain | 0.12 | Y |
| Broiler poultry | 0.008 | 0.008 | Oat grain | 0.11 | Y |
| Layer poultry | 0.008 | 0.016 | Maize forage | 0.23 | Y |
| Turkey | 0.006 | 0.006 | Oat grain | 0.08 | N |

## 7.4.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

**Available data**

No new data were submitted in the framework of this application.

**Table 7.4-14: Overview of the values derived from livestock feeding studies**

| Commodity | Dietary burden | | Results of the livestock feeding study | | | | | | Median residue (mg/kg)[b] | Highest residue (mg/kg)[c] | Calculated MRL (mg/kg) | CF for RA[d] |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Med. (mg/kg bw/d) | Max. (mg/kg bw/d) | Dose Level (mg/kg bw/d)[a] | No | Result for enforcement | | Result for RA | | | | | |
| | | | | | Mean (mg/kg) | Max. (mg/kg) | Mean (mg/kg) | Max. (mg/kg) | | | | |
| **EU reviewed data (Denmark, 2007; Report No. 107-203 and 74)** | | | | | | | | | | | | |
| E: Dicamba and its salts (free and and conjugated), expressed as dicamba<br>RA: Dicamba (free and and conjugated) | | | | | | | | | | | | |
| **Pig meat[f]** | 0.097 | 0.257 | 0.9 | 3 | n.a. | n.a. | <0.01 | <0.01 | <0.01 | <0.01 | 0.01 | |
| | | | 2.8 | 3 | n.a. | n.a. | 0.012 | 0.014 | | | | |
| | | | 9.3 | 3 | n.a. | n.a. | 0.030 | 0.037 | | | | |
| **Pig fat[f]** | 0.097 | 0.257 | 0.9 | 3 | n.a. | n.a. | 0.023 | 0.046 | <0.01 | 0.013 | 0.015 | |
| | | | 2.8 | 3 | n.a. | n.a. | 0.025 | 0.034 | | | | |
| | | | 9.3 | 3 | n.a. | n.a. | 0.047 | 0.059 | | | | |
| **Pig liver[f]** | 0.097 | 0.257 | 0.9 | 3 | n.a. | n.a. | 0.026 | 0.029 | <0.01 | <0.01 | 0.01 | |
| | | | 2.8 | 3 | n.a. | n.a. | 0.066 | 0.070 | | | | |
| | | | 9.3 | 3 | n.a. | n.a. | 0.207 | 0.207 | | | | |
| **Pig kidney[f]** | 0.097 | 0.257 | 0.9 | 3 | n.a. | n.a. | 0.154 | 0.174 | 0.017 | 0.050 | 0.05 | |
| | | | 2.8 | 3 | n.a. | n.a. | 0.282 | 0.288 | | | | |
| | | | 9.3 | 3 | n.a. | n.a. | 0.646 | 0.885 | | | | |
| **Ruminant meat** | 0.649 | 1.748 | 0.9 | 3 | n.a. | n.a. | <0.01 | <0.01 | 0.010 | 0.012 | 0.015 (EFSA, 2011a proposed 0.02 mg/kg) | |
| | | | 2.8 | 3 | n.a. | n.a. | 0.012 | 0.014 | | | | |
| | | | 9.3 | 3 | n.a. | n.a. | 0.030 | 0.037 | | | | |
| **Ruminant fat** | 0.649 | 1.748 | 0.9 | 3 | n.a. | n.a. | 0.023 | 0.046 | 0.023 | 0.089 | 0.09 | |

| Commodity | Dietary burden | | Results of the livestock feeding study | | | | | | Median residue (mg/kg)[b] | Highest residue (mg/kg)[c] | Calculated MRL (mg/kg) | CF for RA[d] |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Med. (mg/kg bw/d) | Max. (mg/kg bw/d) | Dose Level (mg/kg bw/d)[a] | No | Result for enforcement | | Result for RA | | | | | |
| | | | | | Mean (mg/kg) | Max. (mg/kg) | Mean (mg/kg) | Max. (mg/kg) | | | | |
| | | | 2.8 | 3 | n.a. | n.a. | 0.025 | 0.034 | | (not realistic, residues were lower at higher feeding levels) | (not realistic, residues were lower at higher feeding levels; EFSA, 2011a proposed 0.05 mg/kg) | |
| | | | 9.3 | 3 | n.a. | n.a. | 0.047 | 0.059 | | | | |
| **Ruminant liver** | 0.649 | 1.748 | 0.9 | 3 | n.a. | n.a. | 0.026 | 0.029 | 0.020 | 0.056 | 0.06 (EFSA, 2011a proposed 0.1 mg/kg) | |
| | | | 2.8 | 3 | n.a. | n.a. | 0.066 | 0.070 | | | | |
| | | | 9.3 | 3 | n.a. | n.a. | 0.207 | 0.207 | | | | |
| **Ruminant kidney** | 0.649 | 1.748 | 0.9 | 3 | n.a. | n.a. | 0.154 | 0.174 | 0.15 | 0.34 (not realistic, residues were lower at higher feeding level) | 0.4 (not realistic, residues were lower at higher feeding level; EFSA, 2011a proposed 0.3 mg/kg) | |
| | | | 2.8 | 3 | n.a. | n.a. | 0.282 | 0.288 | | | | |
| | | | 9.3 | 3 | n.a. | n.a. | 0.646 | 0.885 | | | | |
| **Poultry meat** | 0.008 (0.11 mg/kg DM) | 0.016 (0.23 mg/kg DM) | 2 | 10 | n.a. | n.a. | n.a. | n.a. | <0.01 | <0.01 | 0.01 | |
| | | | 6 | 10 | n.a. | n.a. | <0.01 | <0.01 | | | | |
| | | | 20 | 10 | n.a. | n.a. | <0.01 | 0.013 | | | | |
| **Poultry fat** | 0.008 (0.11 mg/kg DM) | 0.016 (0.23 mg/kg DM) | 2 | 10 | n.a. | n.a. | <0.01 | <0.01 | <0.01 | <0.01 | 0.01 | |
| | | | 6 | 10 | n.a. | n.a. | <0.01 | <0.01 | | | | |
| | | | 20 | 10 | n.a. | n.a. | <0.01 | 0.025 | | | | |

| Commodity | Dietary burden | | Results of the livestock feeding study | | | | | | Median residue (mg/kg)[(b)] | Highest residue (mg/kg)[(c)] | Calculated MRL (mg/kg) | CF for RA[(d)] |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Med. (mg/kg bw/d) | Max. (mg/kg bw/d) | Dose Level (mg/kg bw/d)[(a)] | No | Result for enforcement | | Result for RA | | | | | |
| | | | | | Mean (mg/kg) | Max. (mg/kg) | Mean (mg/kg) | Max. (mg/kg) | | | | |
| **Poultry liver** | 0.008 (0.11 mg/kg DM) | 0.016 (0.23 mg/kg DM) | 2 | 10 | n.a. | n.a. | <0.01 | <0.01 | <0.01 | <0.01 | 0.01 | |
| | | | 6 | 10 | n.a. | n.a. | 0.015 | 0.023 | | | | |
| | | | 20 | 10 | n.a. | n.a. | 0.030 | 0.053 | | | | |
| **Milk** | 0.649 | 1.748 | 0.9 | 3 | n.a. | n.a. | 0.02[(e)(f)] | N/A | 0.011 | N/A | 0.03 (EFSA, 2011a proposed 0.05 mg/kg) | |
| | | | 2.8 | 3 | n.a. | n.a. | 0.05[(e)(f)] | N/A | | | | |
| | | | 9.3 | 3 | n.a. | n.a. | 0.36[(e)(f)] | N/A | | | | |
| **Eggs** | 0.008 (0.11 mg/kg DM) | 0.016 (0.23 mg/kg DM) | 2 | 10 | n.a. | n.a. | n.a. | n.a. | <0.01 | <0.01 | 0.01 | |
| | | | 6 | 10 | n.a. | n.a. | <0.01 | <0.01 | | | | |
| | | | 20 | 10 | n.a. | n.a. | <0.01 | <0.01 | | | | |

N/A: Not applicable – only the mean values are considered for calculating MRLs in milk.
n.r.: Not reported
n.a.: Not analysed
(*): Indicates that the MRL is set at the limit of analytical quantification.
(F): MRL is expressed as mg/kg of fat contained in the whole product.
(a): Based on a 643 kg animal consuming 15 kg feed DM/day. for ruminants. For poultry dose levels are given in mg/kg diet (DM).
(b): Median residue value according to the enforcement residue definition, derived by interpolation/extrapolation from the feeding study for the median dietary burden (FAO, 2009).
(c): Highest residue value (tissues, eggs) or mean residue value (milk) according to the enforcement residue definition, derived by interpolation/extrapolation of the maximum dietary burden between the relevant feeding groups of the study (FAO, 2009).
(d): The median conversion factor for enforcement to risk assessment.
(e): Mean residue level from day 1 until day 30 (3 cows, 8 sampling days).
(f): Total mean residues of dicamba and DCSA
(g): Extrapolated from ruminant feeding study.

In a separate study, lactating cows were dosed with 5-OH-dicamba at three feed levels (400, 1200 and 4000 mg/cow/day). No residues were found in milk above the LOQ except for one sample in the highest dose group. No residues were found in tissues in the lowest and medium dose groups except in the kidney where residues of 0.02 and 0.01 mg/kg were found, respectively. In the highest dose group low levels (0.02-0.06 mg/kg) besides the kidney and the blood were seen in all tissues. In blood and kidney average residues of 0.15 and 0.27 mg/kg were found, respectively. (Denmark, 2007)

EFSA, 2011a: "Additional intake of 5-OH-dicamba estimated to be 39.5 mg/kg DM (equivalent to 1.4 and 1.7 mg/kg bw for dairy and beef cattle, respectively). Residues of 5-OH-dicamba not expected to be present in animal matrices since residues <0.01 mg/kg in all animal products (<0.005 mg/kg in milk) in a feeding study conducted with 5-OH-dicamba and for the dose rate of 60 mg/kg DM (c.a. 1.5N)."

**Conclusion on feeding studies**

The requested uses do not modify the theoretical maximum daily intake for animals, while the new mode of calculation does, but regarding available feeding studies, there is no risk for animal MRL to be exceeded.

### 7.4.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) (KCA 6.5.2-6.5.3)

Data/information on processing studies was reviewed during the approval of active substance(s) and considered acceptable. Additional studies have been performed and are summarised in the MRL compilation dossier and are reported below.

As quantifiable residues of dicamba are not expected in the treated crops and the TMDI is <10% (see section 7.4.8), there is no need to investigate the effect of industrial and/or household processing. However, processing studies are required to cover industrial and domestic processes commonly applied to cereal grains. Representative crop processing studies have been carried out to cover industrial and domestic processes commonly applied to cereal grains.

#### 7.4.5.1 Available data for all crops under consideration

New processing studies have been submitted by the applicant in the framework of this application. These studies are summarized in the table below. The results are also presented in Appendix 2.

**Table 7.4-15: Overview of the available processing studies**

| Processed commodity | Number of studies | Median PF (a) | Median CF (b) | Comments | Report reference | Source |
|---|---|---|---|---|---|---|
| **New data** | | | | | | |
| **Enforcement residue definition:** Dicamba and its salts (free and conjugated) | | | | | | |
| Barley, beer | | <0.42 (mean) | | - | 03-7017<br>03-7018<br>G/01/SG/1/97<br>G/01/SG/2/97 | Richards S., MacKenzie R., 2004,<br>Richards S., 2004<br>Wesche H., 1998, a |
| Barley, pearl barley | | 0.53 (mean) | | - | | |
| Oats, flakes (rolled oats) | | 1.32 (mean) | | - | gr 05298<br>gr 06498<br>gr 04398<br>gr 07598 | Stolze K., 2000, a, b, c |

(a): The median processing factor is obtained by calculating the median of the individual processing factors of each processing study.
(b): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors of each processing study.

#### 7.4.5.2 Conclusion on processing studies

Processing factors were derived for barley and oat processed products.

### 7.4.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

Considering available data dealing with nature of residues in rotational crops (see section 7.4.2.2), no study dealing with magnitude of residues in succeeding crops is needed.

### 7.4.6.1 Field rotational crop studies (KCA 6.6.2)

**Available data**

Studies investigating the magnitude of residues in succeeding crops were not conducted. No new data submitted in the framework of this application.

**Conclusion on rotational crops studies**

Based on the rotational confined rotational crop studies and considering that the application rate of dicamba within the EU ranges between 0.150-0.288 kg a.s./ha and the fact that dicamba was applied to a bare soil (interception of dicamba by the plants is expected in practice), it can be concluded that dicamba residue levels in rotational commodities are not expected to exceed 0.01 mg/kg, provided that dicamba is applied in compliance with the GAPs supported for this submission.

### 7.4.7 Other / special studies (KCA6.10, 6.10.1)

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of A18385B. According to SANTE/11956/2016 rev.9, maize is a crop with no melliferous capacity. Therefore, other special studies are not needed.

### 7.4.8 Estimation of exposure through diet and other means (KCA 6.9)

Toxicological reference values relevant for dietary risk assessment are reported in the summary of the evaluation (see section 7.1.2).

### 7.4.8.1 Input values for the consumer risk assessment

Syngenta uses, values corresponding to actual EU MRLs and several animal matrices were considered for IEDI calculation.

**Table 7.4-16: Input values for the consumer risk assessment**

| Commodity | Chronic risk assessment | | Acute risk assessment | |
|---|---|---|---|---|
| | Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
| **Risk assessment residue definition:** Dicamba and 5-OH-dicamba (free and conjugated) | | | | |
| Maize | 0.02 | Median residue (this application) | 0.1 | Highest residue (this application) |
| Sweet corn | 0.023 | Median residue (MRL Compilation dossier, 2011) | Not relevant, the acute risk assessment only corresponds to crops on the formulation's GAP table, i.e. maize. | |
| Herbs | 0.84 | Median residue (EFSA, 2013) | | |

| Commodity | Chronic risk assessment | | Acute risk assessment | |
|---|---|---|---|---|
| | **Input value (mg/kg)** | **Comment** | **Input value (mg/kg)** | **Comment** |
| Barley | 1.6 | Median residue (EFSA, 2011b) | | |
| Millet | 0.02 | Median residue (MRL Compilation dossier, 2011) | | |
| Oats | 0.13 | Median residue (MRL Compilation dossier, 2011) | | |
| Rye | 0.04 | Median residue (MRL Compilation dossier, 2011) | | |
| Sorghum | 1.0 | Median residue (EFSA, 2011b) | | |
| Wheat | 0.22 | Median residue (EFSA, 2011b) | | |
| Herbal infusions (dried): Flowers | 0.84 | Median residue (EFSA, 2013) | | |
| Herbal infusions (dried): Leaves | 0.84 | Median residue (EFSA, 2013) | | |
| **Risk assessment residue definition:** Dicamba (free and conjugated) | | | | |
| Ruminant muscle | 0.01 | Median residue (MRL Compilation dossier, 2011) | 0.01 | Highest residue (MRL Compilation dossier, 2011) |
| Ruminant fat | 0.02 | Median residue (MRL Compilation dossier, 2011) | 0.05 | Highest residue (MRL Compilation dossier, 2011) |
| Ruminant liver | 0.02 | Median residue (MRL Compilation dossier, 2011) | 0.05 | Highest residue (MRL Compilation dossier, 2011) |
| Ruminant kidney | 0.12 | Median residue (MRL Compilation dossier, 2011) | 0.23 | Highest residue (MRL Compilation dossier, 2011) |
| Ruminant edible offals | 0.12 | Median residue (MRL Compilation dossier, 2011) | 0.23 | Highest residue (MRL Compilation dossier, 2011) |
| Ruminant others | 0.01 | Median residue (MRL Compilation dossier, 2011) | 0.01 | Highest residue (MRL Compilation dossier, 2011) |
| Pig muscle | 0.01 | Median residue (MRL Compilation dossier, 2011) | 0.01 | Highest residue (MRL Compilation dossier, 2011) |
| Pig fat | 0.02 | Median residue (MRL Compilation dossier, 2011) | 0.05 | Highest residue (MRL Compilation dossier, 2011) |

| Commodity | Chronic risk assessment | | Acute risk assessment | |
|---|---|---|---|---|
| | Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
| Pig liver | 0.02 | Median residue (MRL Compilation dossier, 2011) | 0.05 | Highest residue (MRL Compilation dossier, 2011) |
| Pig kidney | 0.12 | Median residue (MRL Compilation dossier, 2011) | 0.23 | Highest residue (MRL Compilation dossier, 2011) |
| Pig edible offals | 0.12 | Median residue (MRL Compilation dossier, 2011) | 0.23 | Highest residue (MRL Compilation dossier, 2011) |
| Pig others | 0.01 | Median residue (MRL Compilation dossier, 2011) | 0.01 | Highest residue (MRL Compilation dossier, 2011) |
| Poultry muscle | 0.01 | Median residue (MRL Compilation dossier, 2011) | 0.01 | Highest residue (MRL Compilation dossier, 2011) |
| Poultry fat | 0.01 | Median residue (MRL Compilation dossier, 2011) | 0.01 | Highest residue (MRL Compilation dossier, 2011) |
| Poultry liver | 0.01 | Median residue (MRL Compilation dossier, 2011) | 0.01 | Highest residue (MRL Compilation dossier, 2011) |
| Poultry kidney | 0.01 | Median residue (MRL Compilation dossier, 2011) | 0.01 | Highest residue (MRL Compilation dossier, 2011) |
| Poultry edible offals | 0.01 | Median residue (MRL Compilation dossier, 2011) | 0.01 | Highest residue (MRL Compilation dossier, 2011) |
| Poultry others | 0.01 | Median residue (MRL Compilation dossier, 2011) | 0.01 | Highest residue (MRL Compilation dossier, 2011) |
| Milk | 0.01 | Median residue (MRL Compilation dossier, 2011) | 0.01 | Median residue (MRL Compilation dossier, 2011) |
| Eggs | 0.01 | Median residue (MRL Compilation dossier, 2011) | 0.01 | Highest residue (MRL Compilation dossier, 2011) |

### 7.4.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

**Table 7.4-17: Consumer risk assessment**

| | |
|---|---|
| TMDI (% ADI) according to EFSA PRIMo rev. 3.1 | Not conducted as the proposed EU MRL values for dicamba are based on the residues of the parent compound only. |
| IEDI (% ADI) according to EFSA PRIMo rev. 3.1 | 0.8% (based on GEMS/Food G08) |
| IESTI (% ARfD) according to EFSA PRIMo rev. 3.1 | Maize/oil: 0.2% (based on NL toddler)<br>Bovine edible offals: 0.6% (based on UK infant)<br>Other animal matrices: ≤0.4% |

The proposed uses of dicamba in A18385B do not represent unacceptable acute and chronic risks for the consumer.

## 7.5 Combined exposure and risk assessment

From a scientific point of view it is regarded necessary to take into account potential combination effects. However, the evaluation of cumulative or synergistic effects as requested by Art. 4 (3b) of Regulation (EC) No. 1107/2009 should only be performed when harmonised “scientific methods accepted by the Authority to assess such effects are available.”

Currently, no EU-harmonized guidance is available on the risk assessment of combined exposure to multiple active substances; this approach is not mandatory at EU level.

The following paragraphs are to be considered as proposals, based on “standard” criteria.

The product is a mixture of three active substances and for two of them an acute reference dose has been allocated. Therefore, combined acute exposure can be considered.

### 7.5.1 Acute consumer risk assessment from combined exposure

In a first step, dose-addition of residues of the individual active substances is assumed by making use of the Hazard Index (HI) concept. The Hazard Quotient (HQ) is calculated for all active substances in the PPP that are acutely toxic by performing deterministic IESTI/NESTI calculations with the calculation models EFSA PRIMo (rev.2) and appropriate national models, if required, and dividing the individual exposure levels by the respective ARfD. Addition of the individual HQs irrespective of any considerations on phenomenological effects or mode(s)/mechanisms of action results in the HI. The results of the HQ/HI calculations are summarized in the following table.

For animal matrices, only the commodity with the highest ARfD utilisation per compound is shown; all other animal products will have lower HQ values.

**Table 7.5-1: Acute consumer risk assessment from combined exposure**

| Crop | Active Ingredient | HQ (based on IESTI according to EFSA PRIMo) | |
|---|---|---|---|
| | | **Children** | **Adults** |
| Maize | Prosulfuron | 0.002 | 0.001 |
| | Dicamba | 0.002 | 0.001 |
| | **Cumulative risk maize (HI)** | **0.004** | **0.002** |
| Bovine edible offal | Prosulfuron | 0.004 | 0.002 |
| | Dicamba | 0.006 | 0.003 |
| | **Cumulative risk bovine edible offal (HI)** | **0.010** | **0.005** |

| Crop | Active Ingredient | HQ (based on IESTI according to EFSA PRIMo) | |
|---|---|---|---|
| | | **Children** | **Adults** |
| Milk | Prosulfuron | 0.025 | 0.008 |
| | Dicamba | 0.004 | 0.001 |
| | **Cumulative risk bovine meat (HI)** | **0.029** | **0.009** |

The Hazard Index is <1. Thus combined exposure to all active substances in A18385B is not expected to present a consumer risk. No further refinement of the assessment is required.

### 7.5.2 Chronic consumer risk assessment from combined exposure

The uses under consideration provide only a minor contribution to the overall chronic exposure of consumers to pesticide residues. The issue requires a more universal consideration and possibly the generic usage of monitoring data. A harmonised approach is not yet available, and currently no specific consideration is warranted in the scope of this evaluation.

## 7.6 References


Prosulfuron

EC (European Commission), 2002. Review report for the active substance prosulfuron. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 26 February 2002 in view of the inclusion of prosulfuron in Annex I of Council Directive 91/414/EEC. SANCO/3055/99-Final, 2 July 2002.

EFSA (European Food Safety Authority), 2012. Review of the existing maximum residue levels (MRLs) for prosulfuron according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2012;10(12):3013, [31 pp.] doi:10.2903/j.efsa.2012.3013.

EFSA (European Food Safety Authority), 2014. Conclusion on the peer review of the pesticide risk assessment of the active substance prosulfuron. EFSA Journal 2014; 12(9):3815. [94 pp.]. doi:10.2903/j.efsa.2014.3815.

EFSA (European Food Safety Authority), 2020. Conclusion on the peer review of the pesticide risk assessment of the active substance prosulfuron. EFSA Journal 2020;18(7):6181, 20 pp.

France, 1998. Draft assessment report on the active substance prosulfuron prepared by the rapporteur Member State France in the framework of Council Directive 91/414/EEC, December 1998.

France, 2001. Addendum to the draft assessment report on the active substance prosulfuron prepared by the rapporteur Member State France in the framework of Council Directive 91/414/EEC, (date unspecified) 2001.

France, 2013. Draft renewal assessment report on the active substance prosulfuron prepared by the rapporteur Member State France in the framework of Council Regulation (EU) No 1141/2010, May 2013.

France, 2014. Final addendum to the renewal assessment report on the active substance prosulfuron prepared by the rapporteur Member State France in the framework of Council Regulation (EU) No 1141/2010, June 2014.

Nicosulfuron

EC (European Commission), 2008. Review report for the active substance nicosulfuron. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 22 January 2008 in view of the inclusion of nicosulfuron in Annex I of Council Directive 91/414/EEC. SANCO/3780/07-rev.1, 22 January 2008.

EFSA (European Food Safety Authority), 2007. Conclusion on the peer review of the pesticide risk assessment of the active substance nicosulfuron. EFSA Scientific Report (2007) 120, 1-91.

EFSA (European Food Safety Authority), 2012. Review of the existing maximum residue levels (MRLs) for nicosulfuron according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2012;10(12):3048, [27 pp.] doi:10.2903/j.efsa.2012.3048.

United Kingdom, 2006. Draft assessment report on the active substance nicosulfuron prepared by the rapporteur Member State United Kingdom in the framework of Council Directive 91/414/EEC, June 2006.

United Kingdom, 2007. Final addendum to the draft assessment report on the active substance nicosulfuron prepared by the rapporteur Member State United Kingdom in the framework of Council Directive 91/414/EEC, compiled by EFSA, July 2007.

Dicamba

Denmark, 2007. Draft assessment report on the active substance dicamba prepared by the rapporteur Member State Denmark in the framework of Council Directive 91/414/EEC, February 2007.

Denmark, 2010. Final addendum to the draft assessment report on the active substance dicamba prepared by the rapporteur Member State Denmark in the framework of Council Directive 91/414/EEC, compiled by EFSA, November 2010.

EC (European Commission), 2008. Review report for the active substance dicamba. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 14 March 2008 in view of the inclusion of dicamba in Annex I of Council Directive 91/414/EEC. SANCO/829/08-rev.2, 07 March 2008.

EC (European Commission), 2016. Review report for the active substance dicamba. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 14 March 2008 in view of the inclusion of dicamba in Annex I of Council Directive 91/414/EEC. SANCO/829/08-final rev.2, 12 July 2016.

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FAO (Food and Agriculture Organisation of the United Nations), 2011b. Dicamba. In: Pesticide residues in food – 2011. Evaluations. Part I. Residues. FAO Plant Production and Protection Paper 212.

FAO (Food and Agriculture Organisation of the United Nations), 2011c. Dicamba. In: Pesticide residues in food – 2010. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 200.

FAO (Food and Agriculture Organisation of the United Nations), 2011d. Dicamba. In: Pesticide residues in food – 2011. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 211.

MRL Compilation Dossier, 2011. Dicamba – Document M-II, Section 4. Metabolism and Residues Data. MRL Compilation Dossier Core. SAN837_11409.

# 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<br>Y/N | Owner |
|---|---|---|---|---|---|
| KCA1<br>6.3.1 / 01 | Kaethner M. | 1995 | Determination of Residues of Dicamba and 5-OH Dicamba in Corn (whole plant , cobs and grain) after Application of SAN 845 H 70 WG under Field Conditions in Italy, 1994 (DC).<br>Novartis Crop Protection AG, Basel, Switzerland<br>Sandoz Agro Ltd., Huningue, France, R10305<br>GLP<br>not published<br>Syngenta File No SAN837/5588; VV-381298 | N | SYN |
| KCA1<br>6.3.1 / 02 | Gasser A. | 1998 | Determination of Residues of Dicamba and 5-OH Dicamba in Corn (Zea mays) matrices after application of Cadence or Mondak 21 S under field conditions in Italy, 1996<br>Novartis Crop Protection AG, Basel, Switzerland<br>Novartis Crop Protection AG, Basel, Switzerland, R96-032<br>GLP<br>not published<br>Syngenta File No SAN837/0416; VV-381309 | N | SYN |
| KCA1<br>6.5.3 / 01 | Richards S., Mac-Kenzie R. | 2004 | Residue Study with Dicamba (SAN837) in or on Winter Barley and Brewing Fractions in the United Kingdom<br>Syngenta Crop Protection AG, Basel, Switzerland<br>Syngenta - Jealott's Hill, Bracknell, United Kingdom, 03-7017<br>GLP<br>not published<br>Syngenta File No SAN837/6359; VV-331997 | N | SYN |
| KCA1<br>6.5.3 / 02 | Richards S. | 2004 | Residue Study with Dicamba (SAN837) in or on Winter Barley and Brewing Fractions in The United Kingdom<br>Syngenta Crop Protection AG, Basel, Switzerland<br>Syngenta - Jealott's Hill, Bracknell, United Kingdom, 03-7018<br>GLP<br>not published | N | SYN |

| 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 |
|---|---|---|---|---|---|
| | | | Syngenta File No SAN837/6360; VV-332134 | | |
| KCA1 6.5.3 / 03 | Stolze K. | 2000 | Determination of SAN 837, 5-OH-Dicamba and CGA 131036 in Oats and Determination of SAN 837 and 5-OH-Dicamba in Processing Products after Application of NAD 11010 H<br>Novartis Crop Protection AG, Basel, Switzerland<br>Novartis Agro GmbH, Frankfurt, Germany, gr 05298<br>GLP<br>not published<br>Syngenta File No CGA131036/1037; VV-312430 | N | SYN |
| KCA1 6.5.3 / 04 | Stolze K. | 2000a | Determination of SAN 837, 5-OH-Dicamba and CGA 131036 in Oats and Determination of SAN 837 and 5-OH-Dicamba in Processing Products after Application of NAD 11010 H<br>Syngenta Crop Protection AG, Basel, Switzerland<br>Novartis Agro GmbH, Frankfurt, Germany, gr 06498<br>GLP<br>not published<br>Syngenta File No CGA131036/1070; VV-324009 | N | SYN |
| KCA1 6.5.3 / 05 | Stolze K. | 2000b | Determination of SAN 837, 5-OH-Dicamba and CGA 131036 in Oats and Determination of SAN 837 and 5-OH-Dicamba in Processing Products after Application of NAD 11010 H<br>Syngenta Crop Protection AG, Basel, Switzerland<br>Novartis Agro GmbH, Frankfurt, Germany, gr 04398<br>GLP<br>not published<br>Syngenta File No CGA131036/1069; VV-323997 | N | SYN |
| KCA1 6.5.3 / 06 | Stolze K. | 2000c | Determination of SAN 837, 5-OH-Dicamba and CGA 131036 in Oats and Determination of SAN 837 and 5-OH-Dicamba in Processing Products after Application of NAD 11010 H<br>Syngenta Crop Protection AG, Basel, Switzerland<br>Novartis Agro GmbH, Frankfurt, Germany, gr 07598<br>GLP<br>not published<br>Syngenta File No CGA131036/1068; VV-323902 | N | SYN |
| KCA1 | Wesche H. | 1998 | Determination of Dicamba residues in spring wheat after application of NAD 11000 H under field condi- | N | SYN |

| 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 |
|---|---|---|---|---|---|
| 6.5.3 / 07 | | | tions in Germany 1997<br>Syngenta<br>Agrostat GmbH, Herrentierbach, Germany, G/01/SW/1/97<br>GLP<br>not published<br>Syngenta File No SAN837/0297; VV-365805 | | |
| KCA1 6.5.3 / 08 | Wesche H. | 1998a | Determination of Dicamba residues in spring wheat after application of NAD 11000 H under field conditions in Germany 1997<br>Syngenta<br>Agrostat GmbH, Herrentierbach, Germany, G/01/SW/2/97<br>GLP<br>not published<br>Syngenta File No SAN837/0298; VV-365807 | N | SYN |

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

Prosulfuron

| 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 |
|---|---|---|---|---|---|
| KCA 6.1 | Eudy L.W. | 1994a | Title: Stability of CGA-152005 fortified into corn substrates under freezer storage conditions.<br>Company Report No.: ABR-93051<br>Source: Ciba-Geigy Corp., Greensboro, NC, USA<br>GLP<br>Unpublished | N | SYN |

| 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 |
|---|---|---|---|---|---|
| KCA 6.1 | Eudy L.W. | 1994b | Title: Stability of CGA 152005 fortified into meat, milk, and eggs under freezer storage conditions.<br>Company Report No.: ABR-93055<br>Source: Ciba-Geigy Corp., Greensboro, NC, USA<br>GLP<br>Unpublished | N | SYN |
| KCA 6.1 | Eudy L.W. | 1997 | Title: Stability of CGA-152005 fortified into meat, milk and eggs under freezer storage conditions.<br>Company Report No.: ABR-97044<br>Source: Ciba-Geigy Corp., Greensboro, NC, USA<br>GLP<br>Unpublished | N | SYN |
| KCA 6.1 | Hayworth C. | 1994 | Title: Storage stability of in field- incurred residues of CGA-152005 in corn (whole plant) under freezer storage conditions.<br>Company Report No.: ABR-94046<br>Source: Ciba-Geigy Corp., Greensboro, NC, USA<br>GLP<br>Unpublished | N | SYN |
| KCA 6.2.1 | Rezaaiyan R. | 1994a | Title: Uptake and metabolism of CGA 152005 in field grown corn after spray treatment with [phenyl-$^{14}$C]-CGA-152005 and [triazine-$^{14}$C]-CGA-152005.<br>Company Report No.: ABR-93047<br>Source: Ciba-Geigy Corp., Greensboro, NC, USA<br>GLP<br>Unpublished | N | SYN |

| 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 |
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| KCA 6.2.1 | Rezaaiyan R. | 1994b | Title: Uptake and metabolism of CGA 152005 in greenhouse grown corn after spray treatment or stem injection with [phenyl-$^{14}$C]-CGA-152005 and [triazine-$^{14}$C]-CGA-152005.<br>Company Report No.: ABR-93048<br>Source: Ciba-Geigy Corp., Greensboro, NC, USA<br>GLP<br>Unpublished | N | SYN |
| KCA 6.2.1 | Rezaaiyan R. | 1994c | Title: Stability of CGA-152005 metabolites in greenhouse grown corn after spray treatment with [phenyl-$^{14}$C]-CGA-152005 and [triazine-$^{14}$C]-CGA-152005.<br>Company Report No.: ABR-93050<br>Source: Ciba-Geigy Corp., Greensboro, NC, USA<br>GLP<br>Unpublished | N | SYN |
| KCA 6.2.2 | xxxxxxxx | 1994 | Title: Metabolism of [triazine-$^{14}$C]-CGA 152005 in the chicken – Addendum 1.<br>Company Report No.: F-00115<br>xxxxxxxxxxxxxxxxxxxxx<br>GLP<br>Unpublished | Y | SYN |
| KCA 6.2.2 | xxxxxxxxxxxxxxxx | 1993a | Title: Metabolism of [triazine-$^{14}$C]-CGA 152005 in the chicken.<br>Company Report No.: F-00115<br>xxxxxxxxxxxxxxxxx<br>GLP<br>Unpublished | Y | SYN |

| 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 |
|---|---|---|---|---|---|
| KCA 6.2.2 | xxxxxxxxxxxxxx | 1993b | Title: Metabolism of [phenyl-$^{14}$C]-CGA 152005 in the chicken.<br>Company Report No.: F-00116<br>Source: xxxxxxxxxxxxxxxxxxxxx<br>GLP<br>Unpublished | Y | SYN |
| KCA 6.2.3 | xxxxxxxxxx | 1994a | Title: Metabolism of [triazine-$^{14}$C]-CGA-152005 in lactating goats after multiple oral administrations.<br>Company Report No.: ABR-93041<br>Source: xxxxxxxxxxxxxxxxxxx<br>GLP<br>Unpublished | Y | SYN |
| KCA 6.2.3 | xxxxxxxxxxxx | 1994b | Title: Metabolism of [phenyl-$^{14}$C]-CGA-152005 after multiple oral administrations to lactating goat.<br>Company Report No.: ABR-93042<br>Source: xxxxxxxxxxxxxxxxxxxxxxxxxx<br>GLP<br>Unpublished | Y | SYN |
| KCA 6.3 | Gasser A. | 1999a | Title: Residue Study with Prosulfuron (CGA 152005) and Pyridate (SAN 319) in or on Maize in France (North).<br>Company Report No.: 3096/98<br>Source: Novartis Crop Protection AG, Basel, Switzerland<br>GLP<br>Unpublished | N | SYN |

| 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 |
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| KCA 6.3 | Gasser A. | 1999b | Title: Residue Study with Prosulfuron (CGA 152005) and Pyridate (SAN 319) in or on Maize in France (North).<br>Company Report No.: 3097/98<br>Source: Novartis Crop Protection AG, Basel, Switzerland<br>GLP<br>Unpublished | N | SYN |
| KCA 6.3 | Gasser A. | 1999c | Title: Residue Study with Prosulfuron (CGA 152005) and Pyridate (SAN 319) in or on Maize in France (North).<br>Company Report No.: 3098/98<br>Source: Novartis Crop Protection AG, Basel, Switzerland<br>GLP<br>Unpublished | N | SYN |
| KCA 6.3 | Gasser A. | 1999d | Title: Residue Study with Prosulfuron (CGA 152005) and Pyridate (SAN 319) in or on Maize in France (South).<br>Company Report No.: 3099/98<br>Source: Novartis Crop Protection AG, Basel, Switzerland<br>GLP<br>Unpublished | N | SYN |
| KCA 6.3 | Gasser A. | 1999e | Title: Residue Study with Prosulfuron (CGA 152005) and Pyridate (SAN 319) in or on Maize in France (South).<br>Company Report No.: 3100/98<br>Source: Novartis Crop Protection AG, Basel, Switzerland<br>GLP<br>Unpublished | N | SYN |

| 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 |
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| KCA 6.3 | Gasser A. | 1999f | Title: Residue Study with Prosulfuron (CGA 152005) and Pyridate (SAN 319) in or on Maize in France (South).<br>Company Report No.: 3101/98<br>Source: Novartis Crop Protection AG, Basel, Switzerland<br>GLP<br>Unpublished | N | SYN |
| KCA 6.3 | Gasser A. | 1999g | Title: Residue Study with Prosulfuron (CGA 152005) and Pyridate (SAN 319) in or on Maize in France (South).<br>Company Report No.: 3102/98<br>Source: Novartis Crop Protection AG, Basel, Switzerland<br>GLP<br>Unpublished | N | SYN |
| KCA 6.3 | Hofherr W. | 1997a | Title: Magnitude of Residues after Application of Prosulfuron (CGA 152005) and Primisulfuron-Methyl (CGA 136872) as Formulation WG 80 (A-8988 A) in Maize.<br>Company Report No.: 3024/96<br>Source: Novartis Crop Protection AG, Basel, Switzerland<br>GLP<br>Unpublished | N | SYN |
| KCA 6.3 | Hofherr W. | 1997b | Title: Magnitude of Residues after Application of Prosulfuron (CGA 152005) and Primisulfuron-Methyl (CGA 136872) as Formulation WG 80 (A-8988 A) in Maize.<br>Company Report No.: 3025/96<br>Source: Novartis Crop Protection AG, Basel, Switzerland<br>GLP<br>Unpublished | N | SYN |

| 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 |
|---|---|---|---|---|---|
| KCA 6.3 | Kwiatkowski A., Mound L. | 2006 | Title: Prosulfuron (CGA152005) and Dicamba (SAN837): Residue study on Maize in Italy.<br>Company Report No.: 04-7015<br>Source: Syngenta – Jealott's Hill International, Bracknell, Berkshire, United Kingdom<br>GLP<br>Unpublished | N | SYN |
| KCA 6.3 | Maffezzoni M. | 1994 | Title: CGA 152005 and Bromoxynil-Phenol (C 9217), WG 63, Maize, France.<br>Company Report No.: OH93209<br>Source: Ciba-Geigy SA, France<br>GLP<br>Unpublished | N | SYN |
| KCA 6.3 | Mostert I. | 1994a | Title: CGA 152005, PEAK 75 WG, Maize, Germany.<br>Company Report No.: 3134/93<br>Source: Ciba-Geigy Ltd., Basle, Switzerland<br>GLP<br>Unpublished | N | SYN |
| KCA 6.3 | Mostert I. | 1994b | Title: CGA 152005, PEAK 75 WG, Maize, Germany.<br>Company Report No.: 3133/93<br>Source: Ciba-Geigy Ltd., Basle, Switzerland<br>GLP<br>Unpublished | N | SYN |
| KCA 6.3 | Mostert I. | 1994c | Title: CGA 152005, PEAK 75 WG, Maize, Germany.<br>Company Report No.: 3132/93<br>Source: Ciba-Geigy Ltd., Basle, Switzerland<br>GLP<br>Unpublished | N | SYN |

| 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 |
|---|---|---|---|---|---|
| KCA 6.3 | Mostert I. | 1994d | Title: CGA 152005, PEAK 75 WG, Maize, Greece.<br>Company Report No.: 3089/93<br>Source: Ciba-Geigy Ltd., Basle, Switzerland<br>GLP<br>Unpublished | N | SYN |
| KCA 6.3 | Mostert I. | 1994e | Title: CGA 152005, PEAK 75 WG, Maize, Greece.<br>Company Report No.: 3088/93<br>Source: Ciba-Geigy Ltd., Basle, Switzerland<br>GLP<br>Unpublished | N | SYN |
| KCA 6.3 | Mostert I. | 1994f | Title: CGA 152005, PEAK 75 WG, Maize, Greece.<br>Company Report No.: 3087/93<br>Source: Ciba-Geigy Ltd., Basle, Switzerland<br>GLP<br>Unpublished | N | SYN |
| KCA 6.3 | Mostert I. | 1993a | Title: CGA 152005 and Bromoxynil-Phenol, WG 63, Residue, Maize, Switzerland.<br>Company Report No.: 3003-92<br>Source: Ciba-Geigy Ltd., Basle, Switzerland<br>GLP<br>Unpublished | N | SYN |
| KCA 6.3 | Mostert I. | 1993b | Title: CGA 152005 and Bromoxynil-Phenol, WG 63, Residue, Maize, Switzerland.<br>Company Report No.: 3004-92<br>Source: Ciba-Geigy Ltd., Basle, Switzerland<br>GLP<br>Unpublished | N | SYN |

| 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<br>Y/N | Owner |
|---|---|---|---|---|---|
| KCA 6.3 | Mostert I. | 1994g | Title: CGA 152005 and Bromoxynil-Phenol (C 9217), WG 63, Maize, Switzerland.<br>Company Report No.: 3018/94<br>Source: Ciba-Geigy Ltd., Basle, Switzerland<br>GLP<br>Unpublished | N | SYN |
| KCA 6.3 | Mostert I. | 1994h | Title: CGA 152005 and Bromoxynil-Phenol (C 9217), WG 63, Maize, Switzerland.<br>Company Report No.: 3019/94<br>Source: Ciba-Geigy Ltd., Basle, Switzerland<br>GLP<br>Unpublished | N | SYN |
| KCA 6.3 | Mostert I. | 1993c | Title: CGA 152005 and Bromoxynil-Phenol (C 9217), WG 63, Maize, France.<br>Company Report No.: 3046-92<br>Source: Ciba-Geigy Ltd., Basle, Switzerland<br>GLP<br>Unpublished | N | SYN |
| KCA 6.3 | Mostert I. | 1993d | Title: CGA 152005 and Bromoxynil-Phenol (C 9217), WG 63, Maize, France.<br>Company Report No.: 3045-92<br>Source: Ciba-Geigy Ltd., Basle, Switzerland<br>GLP<br>Unpublished | N | SYN |
| KCA 6.3 | Mostert I. | 1993e | Title: CGA 152005 and Bromoxynil-Phenol (C 9217), WG 63, Maize, France.<br>Company Report No.: 3044-92<br>Source: Ciba-Geigy Ltd., Basle, Switzerland<br>GLP<br>Unpublished | N | SYN |

| 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<br>Y/N | Owner |
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| KCA 6.3 | Mostert I. | 1993f | Title: CGA 152005 + CGA 136872, WG 80, Residue, Maize, Switzerland.<br>Company Report No.: 3006-92<br>Source: Ciba-Geigy Ltd., Basle, Switzerland<br>GLP<br>Unpublished | N | SYN |
| KCA 6.3 | Mostert I. | 1993g | Title: CGA 152005 + CGA 136872, WG 80, Residue, Maize, Switzerland.<br>Company Report No.: 3005-92<br>Source: Ciba-Geigy Ltd., Basle, Switzerland<br>GLP<br>Unpublished | N | SYN |
| KCA 6.3 | Mound L., Gardinal P., Kwiatkowski A. | 2006 | Title: Prosulfuron (CGA152005) and Dicamba (SAN837): Residue Study in or on Maize In Switzerland.<br>Company Report No.: 04-7016<br>Source: Syngenta – Jealott's Hill International, Bracknell, Berkshire, United Kingdom<br>GLP<br>Unpublished | N | SYN |
| KCA 6.3 | Mound L., Kwiat-kowski A. | 2007 | Title: Prosulfuron (CGA152005) and Dicamba (SAN837): Residue study on Maize in Italy.<br>Company Report No.: 05-7010<br>Source: Syngenta – Jealott's Hill International, Bracknell, Berkshire, United Kingdom<br>GLP<br>Unpublished | N | SYN |

| 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 |
|---|---|---|---|---|---|
| KCA 6.3 | Oppilliart S. | 2009a | Title: Dicamba (CGA57706) and Prosulfuron (CGA152005) – Residue study on Corn in France (north) in 2007.<br>Company Report No.: T001033-07-REG<br>Source: Eurofins – ADME Bioanalyses, Vergeze, France<br>GLP<br>Unpublished | N | SYN |
| KCA 6.3 | Oppilliart S. | 2009b | Title: Dicamba (CGA57706) and Prosulfuron (CGA152005) – Residue study on Corn in France (north) in 2007.<br>Company Report No.: T001034-07-REG<br>Source: Eurofins – ADME Bioanalyses, Vergeze, France<br>GLP<br>Unpublished | N | SYN |
| KCA 6.3 | Pointurier R. | 1998a | Title: Magnitude of Residues of CGA 152005 and Bromoxynil in Maize after Application of Formulations A 8714 C WG 75 and F 70568 WP 20.<br>Company Report No.: 9720401<br>Source: Novartis Agro S.A., Aigues-Vives, France<br>GLP<br>Unpublished | N | SYN |
| KCA 6.3 | Pointurier R. | 1992 | Title: CGA 152005, WG 63, Maize (Grains, Cobs and Fodder), France.<br>Company Report No.: OH92007<br>Source: Ciba-Geigy SA, France<br>GLP<br>Unpublished | N | SYN |

| 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 |
|---|---|---|---|---|---|
| KCA 6.3 | Pointurier R. | 1998b | Title: Magnitude of Residues of CGA 152005 and Bromoxynil in Maize after Application of Formulations A 8714 C WG 75 and F 70568 WP 20.<br>Company Report No.: 9720402<br>Source: Novartis Agro S.A., Aigues-Vives, France<br>GLP<br>Unpublished | N | SYN |
| KCA 6.3 | Salvi M. | 2002a | Title: Residue Study with Primisulfuron-Methyl (CGA 136872) and Prosulfuron (CGA 152005) in or on Maize in Switzerland.<br>Company Report No.: 3005/00<br>Source: ADME – Bioanalyses, Vergeze, France<br>GLP<br>Unpublished | N | SYN |
| KCA 6.3 | Salvi M. | 2002b | Title: Residue Study with Primisulfuron-Methyl (CGA 136872) and Prosulfuron (CGA 152005) in or on Maize in Switzerland.<br>Company Report No.: 3004/00<br>Source: ADME – Bioanalyses, Vergeze, France<br>GLP<br>Unpublished | N | SYN |
| KCA 6.3 | Schulz H. | 2011a | Title: Dicamba and Prosulfuron – Residue Study on Maize in France (North) in 2008.<br>Company Report No.: T009437-07-REG<br>Source: SGS Institut Fresenius GmbH, Taunusstein, Germany<br>GLP<br>Unpublished | N | SYN |

| 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 |
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| KCA 6.3 | Schulz H. | 2011b | Title: Dicamba and Prosulfuron – Residue Study on Maize in France (South) in 2008.<br>Company Report No.: T009438-07-REG<br>Source: SGS Institut Fresenius GmbH, Taunusstein, Germany<br>GLP<br>Unpublished | N | SYN |
| KCA 6.3 | Simon P. | 2002a | Title: Residues of Primisulfuron-Methyl (CGA 136872) and Prosulfuron (CGA 152005) in Maize after Post-emergence Application of A8988A, Germany 2000.<br>Company Report No.: gr03200<br>Source: Syngenta Agro GmbH, Maintal, Germany<br>GLP<br>Unpublished | N | SYN |
| KCA 6.3 | Simon P. | 2002b | Title: Residues of Primisulfuron-Methyl (CGA 136872) and Prosulfuron (CGA 152005) in Maize after Post-emergence Application of A8988A, Germany 2000.<br>Company Report No.: gr02100<br>Source: Syngenta Agro GmbH, Maintal, Germany<br>GLP<br>Unpublished | N | SYN |
| KCA 6.3 | Simon P. | 2002c | Title: Residues of Primisulfuron-Methyl (CGA 136872) and Prosulfuron (CGA 152005) in Maize after Post-emergence Application of A8988A, Germany 2000.<br>Company Report No.: gr04300<br>Source: Syngenta Agro GmbH, Maintal, Germany<br>GLP<br>Unpublished | N | SYN |

| 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 |
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| KCA 6.3 | Simon P. | 2002d | Title: Residues of Primisulfuron-Methyl (CGA 136872) and Prosulfuron (CGA 152005) in Maize after Post-emergence Application of A8988A, Germany 2000.<br>Company Report No.: gr05400<br>Source: Syngenta Agro GmbH, Maintal, Germany<br>GLP<br>Unpublished | N | SYN |
| KCA 6.3 | Simon P. | 2006 | Title: Prosulfuron and Dicamba: Residue Study in or on Maize in Germany 2004 (Test Product: A14031B).<br>Company Report No.:.gmz043004<br>Source: Syngenta Agro GmbH, Maintal, Germany<br>GLP<br>Unpublished | N | SYN |
| KCA 6.5.3 | Oakes T.L. | 1994a | Title: Analytical determination of CGA 152005 in samples of whole corn and the corresponding processed fractions, USA.<br>Company Report No.: MW-HR-103-92, no. 2<br>Source: Ciba-Geigy Corp., Greensboro, NC, USA<br>GLP<br>Unpublished | N | SYN |
| KCA 6.5.3 | Oakes T.L. | 1994b | Title: Analytical determination of CGA 152005 in samples of whole corn and the corresponding processed fractions, USA.<br>Company Report No.: MW-HR-702-92, no. 2<br>Source: Ciba-Geigy Corp., Greensboro, NC, USA<br>GLP<br>Unpublished | N | SYN |

| 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 |
|---|---|---|---|---|---|
| KCA 6.6.1 | Daun R.J. | 1994 | Title: Uptake and metabolism of CGA 152005 in field rotational crops following a 1X bare ground treatment with [phenyl-$^{14}$C]-CGA 152005 and triazine-$^{14}$C-CGA-152005.<br>Company Report No.: HWI 6117-219<br>Source: Hazelton Wisconsin Inc., Madison WI, USA<br>GLP<br>Unpublished | N | SYN |

Nicosulfuron

| 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 |
|---|---|---|---|---|---|
| KCA 6.1 | Schulz M., Ullrich-Mitzel A. | 1995 | Title: Storage stability of SL-950 and its metabolites ASDM and ADMP in corn plants and ears<br>Company Report No.: 304762<br>Source: ISK<br>GLP<br>Unpublished | N | ISK |
| KCA 6.2.1 | Mamouni A. | 1995 | Title: $^{14}$C-SL-950 (P) Plant metabolism study with corn in the greenhouse<br>Company Report No.: 272158<br>Source: ISK<br>GLP<br>Unpublished | N | ISK |
| KCA 6.2.1 | Schanné C. | 1991 | Title: $^{14}$C-SL-950 (Pm): Plant metabolism study with corn in the greenhouse<br>Company Report No.: 274173<br>Source: ISK | N | ISK |

| 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 |
|---|---|---|---|---|---|
| | | | GLP<br>Unpublished | | |
| KCA 6.2.3 | xxxxxxxxxxxxxx. | 1995a | Title: $^{14}$C-SL-950 (P): Distribution, degradation, metabolism and excretion after repeated oral administration to a lactating goat<br>Company Report No.: 358323<br>Source: ISK<br>GLP<br>Unpublished | Y | ISK |
| KCA 6.2.3 | xxxxxxxxxxxxxxx | 1995b | Title: $^{14}$C-SL-950 (Pm): Distribution, degradation, metabolism and excretion after repeated oral administration to a lactating goat<br>Company Report No.: 358312<br>Source: ISK<br>GLP<br>Unpublished | Y | ISK |
| KCA 6.2.3 | xxxxxxxxxxxxxxxxxxxxxxxxx | 1995c | Title: $^{14}$C-SL-950 (Pm): Absorption, distribution and excretion after repeated oral administration to a lactating goat, based on an assumed daily intake of 0.15 mg/kg diet<br>Company Report No.: 367356<br>Source: ISK<br>GLP<br>Unpublished | Y | ISK |
| KCA 6.3 | Bonfanti F. | 1995 | Title: SL-950: Determination of residues in maize. Italy 1992<br>Company Report No.: F-005-H<br>Source: ISK<br>GLP<br>Unpublished | N | ISK |

| 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 |
|---|---|---|---|---|---|
| KCA 6.3 | Schulz H. | 1993 | Title: Determination of the residues of SL-950 and its metabolites in corn (Germany, 1991)<br>Company Report No.: 310656<br>Source: ISK<br>GLP<br>Unpublished | N | ISK |
| KCA 6.3 | Schulz H. | 1994a | Title: Determination of the residues of SL-950 and its metabolites in corn (Exp.No. S009KP, France 1991); Field part attached<br>Company Report No.: 313964<br>Source: ISK<br>GLP<br>Unpublished | N | ISK |
| KCA 6.3 | Schulz H. | 1994b | Title: Determination of the residues of SL-950 and its metabolites in corn (Exp.No. 30536, France 1991); Field part attached<br>Company Report No.: 313975<br>Source: ISK<br>GLP<br>Unpublished | N | ISK |
| KCA 6.3 | Schulz H., Ullrich A. | 1991a | Title: Determination of the residues of SL-950 and its metabolites in corn. Report to: Determination of residues of SL-950 in corn; Field part attached<br>Company Report No.: 272114<br>Source: ISK<br>GLP<br>Unpublished | N | ISK |
| KCA 6.3 | Schulz H., Ullrich A. | 1991b | Title: Determination of the residues of SL-950 and its metabolites in corn. Report to: Determination of residues of SL-950 in corn (dissipation study); Field part attached<br>Company Report No.: 272125 | N | ISK |

| 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 |
|---|---|---|---|---|---|
| | | | Source: ISK<br>GLP<br>Unpublished | | |
| KCA 6.3 | Schulz M. | 1994 | Title: Re-analysis of SL-950 in corn samples (France, 1991) by GC/MS<br>Company Report No.: F-005-H<br>Source: ISK<br>GLP<br>Unpublished | N | ISK |
| KCA 6.3 | Schulz M. | 1994b | Title: SL-950 4% SC: Residue analysis in corn – Greece 1993; Field part attached<br>Company Report No.: 363666<br>Source: ISK<br>GLP<br>Unpublished | N | ISK |
| KCA 6.3 | Schulz M. | 1995a | Title: Determination of the residues of SL-950 and its metabolites in fresh corn samples (Germany, 1992)<br>Company Report No.: 343528<br>Source: ISK<br>GLP<br>Unpublished | N | ISK |
| KCA 6.3 | Schulz M. | 1995b | Title: SL-950: Residue in maize-Italy 1992<br>Company Report No.: 330693<br>Source: ISK<br>GLP<br>Unpublished | N | ISK |
| KCA 6.3 | Ulrich C. | 1994a | Title: Nicosulfuron (4% w/v) – water miscible suspension. Field trials to generate samples for residue | N | ISK |

| 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 |
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| | | | analysis following one application in maize<br>Company Report No.: ER 91 DEU 501<br>Source: ISK<br>GLP<br>Unpublished | | |
| KCA 6.3 | Ulrich C. | 1994b | Title: Nicosulfuron (4% w/v) – water miscible suspension. Field trials to generate samples for residue analysis following one application in maize<br>Company Report No.: ER 92 DEU 501<br>Source: ISK<br>GLP<br>Unpublished | N | ISK |
| KCA 6.3 | Wyss-Benz M. | 1994 | Title: SL-950 4% SC: Residue analysis in corn – Spain 1992; Field part attached<br>Company Report No.: 330715<br>Source: ISK<br>GLP<br>Unpublished | N | ISK |
| KCA 6.6.1 | Becker F.A., Raunft E. | 1996 | Title: Phytotoxicity test of nicosulfuron on rotational crops under field conditions in Germany (trial period 1993/94)<br>Company Report No.: DE/HN/035/93<br>Source: ISK<br>GLP<br>Unpublished | N | ISK |
| KCA 6.6.1 | Schulz M. | 1995 | Title: Analysis of soil residue samples; Analytical report to: evaluation of the phytotoxicity of nicosulfu-ron on subsequent crops under field conditions in Germany<br>Company Report No.: 350267<br>Source: ISK | N | ISK |

| 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 |
|---|---|---|---|---|---|
| | | | GLP<br>Unpublished | | |
| KCA 6.6.1 | Hesse B., Becker F.A. | 1995 | Title: Investigation into the dissipation behabiour of nicosulfuron and its influence on rotation crops under field conditions in the Federal Republic of Germany<br>Company Report No.: DE/HN/01/91<br>Source: ISK<br>GLP<br>Unpublished | N | ISK |
| KCA 6.6.1 | Wyss-Benz M. | 1993a | Title: Determination of the residues of SL-950 and its metabolites in soil (field study II, Germany)<br>Company Report No.: 310678<br>Source: ISK<br>GLP<br>Unpublished | N | ISK |
| KCA 6.6.1 | Wyss-Benz M. | 1993b | Title: Analysis of soil residue samples; Analytical report to: evaluation of the phytotoxicity of nicosulfu-ron on subsequent crops under field conditions in Germany<br>Company Report No.: 310680<br>Source: ISK<br>GLP<br>Unpublished | N | ISK |

Dicamba

| 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 |
|---|---|---|---|---|---|
| KCA 6.1 | Formanski L.J. | 1996 | Title: Stability of dicamba and 3,6-dichlorosalicylic acid in stored frozen beef tissues and milk<br>Company Report No.: 151<br>Source: Novartis Crop Protection AG, Basel, Switzerland; Sandoz Agro Inc., Des Plaines, USA<br>GLP<br>Unpublished | N | SYN |
| KCA 6.1 | Jimenez N.C. | 1995 | Title: Stability of Dicamba and 5-Hydroxy Dicamba in Stored Frozen Field Corn<br>Company Report No.: 127<br>Source: Novartis Crop Protection AG, Basel, Switzerland; Sandoz Agro Inc., Des Plaines, USA<br>GLP<br>Unpublished | N | SYN |
| KCA 6.2.1 | Butz R., Atallah Y. | 1981a | Title: Metabolic Fate of Dicamba in Sugarcane Plants<br>Company Report No.: 24<br>Source: Novartis Crop Protection AG, Basel, Switzerland; Velsicol Environmental Science, Chicago, USA<br>Non-GLP<br>Unpublished | N | SYN |
| KCA 6.2.1 | Butz R., Atallah Y. | 1981b | Title: Extractability of Dicamba Residues from Sugarcane Leaves<br>Company Report No.: 13<br>Source: Novartis Crop Protection AG, Basel, Switzerland; Velsicol Environmental Science, Chicago, USA<br>Non-GLP<br>Unpublished | N | SYN |

| 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 |
|---|---|---|---|---|---|
| KCA 6.2.1 | Butz R., Atallah Y. | 1982 | Title: Foliar Absorption, Metabolism and Translocation of Dicamba by Soybeans at Early Pod fill and Late Senescent Stages<br>Company Report No.: 39<br>Source: Novartis Crop Protection AG, Basel, Switzerland; Velsicol Environmental Science, Chicago, USA<br>Non-GLP<br>Unpublished | N | SYN |
| KCA 6.2.1 | Butz R. | 1982 | Title: Foliar Absorption, Metabolism and Translocation of Dicamba by Cotton Plants<br>Company Report No.: 44<br>Source: Novartis Crop Protection AG, Basel, Switzerland; Velsicol Environmental Science, Chicago, USA<br>GLP<br>Unpublished | N | SYN |
| KCA 6.2.1 | Butz R. | 1984 | Title: Characterization of Radiocarbon from Seeds of 14C-Dicamba Treated Cotton Plants after Acid Hydrolysis<br>Company Report No.: 70<br>Source: Novartis Crop Protection AG, Basel, Switzerland; Velsicol Environmental Science, Chicago, USA<br>GLP<br>Unpublished | N | SYN |
| KCA 6.2.1 | Völlmin S. | 1999 | Title: Metabolism and Behaviour of Dicamba in Field grown Spring Wheat after Application of [Phenyl-(U)-14C] Material<br>Company Report No.: 97SV01<br>Source: Novartis Crop Protection AG, Basel, Switzerland<br>GLP<br>Unpublished | N | SYN |

| 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 |
|---|---|---|---|---|---|
| KCA 6.2.2 | xxxxxxxxxxx | 1983 | Title: Pharmacokinetics and Metabolism of 14C-dicamba in Hens<br>Company Report No.: 65<br>Source: xxxxxxxxxxxxx<br>Non-GLP<br>Unpublished | Y | SYN |
| KCA 6.2.2 | xxxxxxxxxxxxx | 1994 | Title: Dicamba: Metabolism in Laying Hens<br>Company Report No.: 25<br>Source: xxxxxxxxxxxxxxxxxxxxxx<br>GLP<br>Unpublished | Y | SYN |
| KCA 6.2.3 | xxxxxxxxxxxxxxxxx | 1994 | Title: Metabolism of Dicambain Lactating Goats<br>Company Report No.: 28<br>Source: xxxxxxxxxxxxxxxxxxxxxxxxx<br>GLP<br>Unpublished | Y | SYN |
| KCA 6.2.3 | xxxxxxxxxxxxxxxxxxxx | 1980 | Title: Metabolic Fate of the Herbicide Dicamba in a Lactating Cow<br>J.xxxxxxxxxxxxxxx. Vol. 28, No. 4, 1980<br>Published | Y | |
| KCA 6.3 | Gasser A. | 1998 | Title: SAN 837 H, Cadence 70 WG, A-9781 A (SAN 845 H 70 WG) or Banvel D, 480 SL, A-7254 B (SAN 1214 H 480 SL), Corn (zea mays), Spain, 1996<br>Company Report No.: R96-008<br>Source: Novartis Crop Protection AG, Basel, Switzerland<br>GLP<br>Unpublished | N | SYN |

| 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 |
|---|---|---|---|---|---|
| KCA 6.3 | Hertl P. | 1995 | Title: Determination of residues of DICAMBA in Corn (Zea mais) after application of BANVEL 4S or SAN 845 H 70 WG under field conditions in the Federal Republic of Germany, 1993.<br>Company Report No.: R10280<br>Source: Novartis Crop Protection AG, Basel, Switzerland; Sandoz Agro Ltd., Huningue, France<br>GLP<br>Unpublished | N | SYN |
| KCA 6.3 | Kaethner M. | 1993 | Title: Determination of residues of Dicamba and 5-OH Dicamba on corn after application of two different formulations, SAN 845 H 70 WG 001 SP and BANVEL 4S, and one mixture of SAN 845 H + SAN 1287 H at 6 leaf stage under field conditions in France<br>Company Report No.: BS3941<br>Source: Novartis Crop Protection AG, Basel, Switzerland; Sandoz Agro Ltd., Huningue, France<br>GLP<br>Unpublished | N | SYN |
| KCA 6.3 | Kaethner M. | 1996a | Title: Determination of Residues of Dicamba and 5-OH Dicamba in Corn after Application of BANVEL D under Field conditions in Spain, 1993 (RAH)<br>Company Report No.: R93041E<br>Source: Novartis Crop Protection AG, Basel, Switzerland; Sandoz Agro Ltd., Huningue, France<br>GLP<br>Unpublished | N | SYN |
| KCA 6.3 | Kaethner M. | 1996b | Title: Determination of Residues of Dicamba and 5-OH Dicamba in Corn after Application of SAN 845 H under Field conditions in Spain, 1993 (RAH)<br>Company Report No.: R93042E<br>Source: Novartis Crop Protection AG, Basel, Switzerland; Sandoz Agro Ltd., Huningue, France<br>GLP<br>Unpublished | N | SYN |

| 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 |
|---|---|---|---|---|---|
| KCA 6.3 | Kaethner M. | 1996c | Title: Determination of Residues of Dicamba and 5-OH Dicamba in Corn after Application of SAN 845 H 70 WG under Field Conditions in France (N/S), 1993 (RAH)<br>Company Report No.: R93041F<br>Source: Novartis Crop Protection AG, Basel, Switzerland; Sandoz Agro Ltd., Huningue, France<br>GLP<br>Unpublished | N | SYN |
| KCA 6.3 | Taylor D.T. et al. | 1984 | Title: Determination of Dicamba and 5-Hydroxy Dicamba, A-7254 B, in Autrian Maize Grain and Straw<br>Company Report No.: 206/4<br>Source: Novartis Crop Protection AG, Basel, Switzerland; Hazleton Europe Ltd., Harrogate, North Yorkshire, United Kingdom<br>GLP<br>Unpublished | N | SYN |
| KCA 6.4.1 | xxxxxxxxxxxxxxxx | 1984 | Title: Determination of Dicamba Residues in Laying Hen Tissues and Eggs After a 28 Day Feeding Study<br>Company Report No.: 74<br>Source: xxxxxxxxxxxxxxxxxxx, USA<br>Non-GLP<br>Unpublished | Y | SYN |
| KCA 6.4.1 | xxxxxxxxxxxxxxxxxxxxx | 1984 | Title: Transfer of dicamba residues to tissues and eggs of laying hens<br>Company Report No.: 107-203<br>Source: xxxxxxxxxxxxxxxxxxx<br>Non-GLP<br>Unpublished | Y | SYN |

| 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 |
|---|---|---|---|---|---|
| KCA 6.4.2 | xxxxxxxxxxxxxx | 1979 | Title: Effect of feeding Dicamba to dairy cattle (Residues in Liver, Kidney, Muscle, and Fat)<br>Company Report No.: 379<br>Source: xxxxxxxxxxx<br>GLP<br>Unpublished | Y | SYN |
| KCA 6.4.2 | xxxxxxxxxxxxxxxx | 1979 | Title: EFFECT OF FEEDING DICAMBA TO DAIRY CATTLE (Residues in Milk)<br>Company Report No.: 379<br>Source: xxxxxxxxxxxxx<br>GLP<br>Unpublished | Y | SYN |
| KCA 6.5.1 | Grout S.J. | 2003 | Title: Aqueous Hydrolysis at 90°, 100 & 120 °C<br>Company Report No.: RJ3333B<br>Source:<br>GLP<br>Unpublished | N | SYN |
| KCA 6.6.1 | Moore P. | 1989 | Title: Confined Accumulation Studies of Dicamba on Rotational Crops After Spring Application<br>Company Report No.: 16<br>Source: Novartis Crop Protection AG, Basel, Switzerland; Sandoz Agro Inc., Des Plaines, USA<br>Non-GLP<br>Unpublished | N | SYN |
| KCA 6.6.1 | Pierotti M.V. | 1995 | Title: Confined Accumulation Studies of Dicamba on Rotational Crops<br>Company Report No.: 22<br>Source: Novartis Crop Protection AG, Basel, Switzerland; Sandoz Agro Inc., Des Plaines, USA<br>GLP<br>Unpublished | N | SYN |

# Appendix 2 Detailed evaluation of the additional studies relied upon

## A 2.1 Prosulfuron

### A 2.1.1 Stability of residues

No new or additional studies have been submitted.

### A 2.1.2 Nature of residues in plants, livestock and processed commodities

No new or additional studies have been submitted.

### A 2.1.3 Magnitude of residues in plants

#### A 2.1.3.1 Maize

**Table A 1: Comparison of intended and critical EU GAPs**

| Type of GAP | Number of applications | Application rate per treatment (precise unit) | Interval between application | Growth stage at last application | PHI (days) |
|---|---|---|---|---|---|
| cGAP EU (Conclusion, EFSA, 2014) | 1 | 0.020 kg a.s./ha | -- | BBCH 12-18 | 90 (grain)<br>60 (silage) |
| cGAP EU (Art. 12, EFSA, 2012) | 1 | 0.015 kg a.s./ha (NEU)<br>0.025 kg a.s./ha (SEU) | -- | BBCH 12-18 (NEU)<br>BBCH 09-17 (SEU) | Some MSs have a defined PHI of 60 or 90 days (NEU)<br>n.s. (SEU) |
| Intended cGAP (number 1*) | 1 | 0.020 kg a.s./ha[(a)] | -- | BBCH 12-18 | n.s. |

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0
(a) 0.020 kg/ha prosulfuron, 0.050 kg/ha nicosulfuron and 0.200 kg/ha dicamba
n.s. not specified

No new or additional studies have been submitted.

### A 2.1.4 Magnitude of residues in livestock

No new or additional studies have been submitted.

### A 2.1.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

No new or additional studies have been submitted.

### A 2.1.6 Magnitude of residues in representative succeeding crops

No new or additional studies have been submitted.

### A 2.1.7 Other/Special Studies

No new or additional studies have been submitted.

## A 2.2 Nicosulfuron

### A 2.2.1 Stability of residues

No new or additional studies have been submitted.

### A 2.2.2 Nature of residues in plants, livestock and processed commodities

No new or additional studies have been submitted.

### A 2.2.3 Magnitude of residues in plants

#### A 2.2.3.1 Maize

**Table A 2: Comparison of intended and critical EU GAPs**

| Type of GAP | Number of applications | Application rate per treatment (precise unit) | Interval between application | Growth stage at last application | PHI (days) |
|---|---|---|---|---|---|
| cGAP EU (Conclusion, EFSA, 2007) | 1 | 0.060 kg a.s./ha | -- | BBCH 12-18 | n.s. |
| cGAP EU (Art. 12, EFSA, 2012) | 1 | 0.060 kg a.s./ha | -- | BBCH 12-20 | n.s. |
| Intended cGAP (number 1*) | 1 | 0.050 kg a.s./ha[(a)] | -- | BBCH 12-18 | n.s. |

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0
(a) 0.050 kg/ha nicosulfuron, 0.020 kg/ha prosulfuron and 0.200 kg/ha dicamba
n.s. not specified

No new or additional studies have been submitted.

### A 2.2.4 Magnitude of residues in livestock

No new or additional studies have been submitted.

### A 2.2.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

No new or additional studies have been submitted.

### A 2.2.6 Magnitude of residues in representative succeeding crops

No new or additional studies have been submitted.

### A 2.2.7 Other/Special Studies

No new or additional studies have been submitted.

## A 2.3 Dicamba

### A 2.3.1 Stability of residues

No new or additional studies have been submitted.

### A 2.3.2 Nature of residues in plants, livestock and processed commodities

No new or additional studies have been submitted.

### A 2.3.3 Magnitude of residues in plants

#### A 2.3.3.1 Maize

**Table A 3: Comparison of intended and critical EU GAPs**

| Type of GAP | Number of applications | Application rate per treatment (precise unit) | Interval between application | Growth stage at last application | PHI (days) |
|---|---|---|---|---|---|
| cGAP EU (Conclusion, EFSA, 2011a) | 1 | 0.360 kg a.s./ha | -- | Post-emergence until BBCH 16 | n.s. |
| Most recent overall | 1 | 0.288 kg a.s./ha | -- | BBCH 12-19 | n.s. |

| Type of GAP | Number of applications | Application rate per treatment (precise unit) | Interval between application | Growth stage at last application | PHI (days) |
|---|---|---|---|---|---|
| cGAP | | | | | |
| Intended cGAP (number 1*) | 1 | 0.200 kg a.s./ha(a) | -- | BBCH 12-18 | n.s. |

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0
(a) 0.200 kg/ha dicamba, 0.020 kg/ha prosulfuron and 0.050 kg/ha nicosulfuron
n.s. not specified

### A 2.3.3.1.1 Study 1

| | |
|---|---|
| Comments of zRMS: | The study is acceptable.<br>The samples from these 2 decline trials were analysed for residues of dicamba and its metabolite S-OH dicamba according to the method no. P-14.063.02 (source: Dr. Specht & Partner) by GC using a MSD for the determination. The LOQ was set at 0.01 mg/kg for dicamba and its metabolite 5-OH dicamba. No residues of dicamba and 5-OH dicamba were found in any of the untreated corn control samples.<br>The rates within the study and the residue details can be seen in the applicant’s tables below.<br>However, the trials from Italy are not relevant for CEU (NEU). |

The following residue study on maize has not previously been reviewed and is provided in support of this assessment.

Reference: KCA1 6.3/01

Report: Determination of Residues of Dicamba and 5-OH Dicamba in Corn (whole plant, cobs and grain) after Application of SAN 845 H 70 WG under Field Conditions in Italy, 1994 (DC), Kaethner M., 1995, Report No. R10305, Syngenta File No. SAN837/5588; VV-381298

Guideline(s): Yes (7029/VI/95 rev. 5)

Deviations: No

GLP: Yes

Acceptability: Yes

**Table A 4: Summary of the study 1 trials**

| GLP and Trial Details | Crop (Variety) | Country (Region) | Application Rate<br>(g as/ha)<br>(Formulation Number) | Growth Stage at Application | PHI (days) | Crop Part | Residue Found (mg/kg Uncorrected) | | | Recovery Data |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Dicamba | Dicamba-5-OH | Total Residue | |
| Report: R10305<br>Study: R10305<br>Trial: Site 1 (WG 70)<br>- Study to GLP<br>- Study carried out in 1994 | Maize (Luana) | ITALY (Europe South) | 275<br><br>(A9781A) | 7 leaves | 0 | Forage | 11.00 | 0.04 | 11.04 | Dicamba<br>Cob: Mean = 90% RSD = 21% (n = 4 in 0.01 - 0.10 mg/kg spiking range)<br>Forage: Mean = 92% RSD = 12% (n = 3 in 0.01 - 11.90 mg/kg spiking range)<br>Grain: Mean = 88% RSD = 24% (n = 4 in 0.01 - 0.10 mg/kg spiking range)<br>NOA405873<br>Cob: Mean = 83% RSD = 15% (n = 4 in 0.01 - 0.10 mg/kg spiking range)<br>Forage: Mean = 83% RSD = 7% (n = 3 in 0.01 - 0.10 mg/kg spiking range)<br>Grain: Mean = 76% RSD = 5% (n = 3 in 0.01 - 0.10 mg/kg spiking range) |
| | | | | | 30 | Forage | < 0.01 | 0.01 | 0.02 | |
| | | | | | 60 | Cob | <0.01 | <0.01 | <0.02 | |
| | | | | | 60 | Forage | < 0.01, < 0.01 (Mean = 0.01) | < 0.01, < 0.01 (Mean = 0.01) | 0.02 | |
| | | | | | 91 | Grain | <0.01 | <0.01 | <0.02 | |
| | | | | | 91 | Stover (fodder) | < 0.01, < 0.01 (Mean = <0.01) | < 0.01, < 0.01 (Mean = <0.01) | <0.02 | |
| Report: R10305<br>Study: R10305<br>Trial: Site 2 (WG 70)<br>- Study to GLP<br>- Study carried out in 1994 | Maize (Elena) | ITALY (Europe South) | 286<br><br>(A9781A) | 6 leaves | 0 | Forage | 13.00 | < 0.01 | 13.01 | Dicamba<br>Cob: Mean = 90% RSD = 21% (n = 4 in 0.01 - 0.10 mg/kg spiking range)<br>Forage: Mean = 92% RSD = 12% (n = 3 in 0.01 - 11.90 mg/kg spiking range)<br>Grain: Mean = 88% RSD = 24% (n = 4 in 0.01 - 0.10 mg/kg spiking range)<br>NOA405873<br>Cob: Mean = 83% RSD = 15% (n = 4 in 0.01 - 0.10 mg/kg spiking range)<br>Forage: Mean = 83% RSD = 7% (n = 3 in 0.01 - 0.10 mg/kg spiking range)<br>Grain: Mean = 76% RSD = 5% (n = 3 in 0.01 - 0.10 mg/kg spiking range) |
| | | | | | 30 | Forage | 0.01 | 0.01 | 0.02 | |
| | | | | | 60 | Cob | <0.01 | <0.01 | <0.02 | |
| | | | | | 60 | Forage | < 0.01, < 0.01 (Mean = <0.01) | < 0.01, 0.02 (Mean = 0.02) | 0.03 | |
| | | | | | 91 | Grain | <0.01 | <0.01 | <0.02 | |
| | | | | | 91 | Stover (fodder) | < 0.01, < 0.01 (Mean = <0.01) | < 0.01, < 0.01 (Mean = <0.01) | <0.02 | |

N/A – not applicable (n ≤ 3)
NOA405873 = 5-OH-dicamba

### A 2.3.3.1.2 Study 2

| | |
|---|---|
| Comments of zRMS: | The study is acceptable.<br>The samples from the trials were analysed for residues of dicamba and its metabolite S-OH dicamba by GC using a MSD for the determination. The method used is acceptable. This method was validated in the study R97-003. The LOQ was set at 0.01 mg/kg for dicamba and its metabolite 5-OH dicamba. No residues of dicamba and 5-OH dicamba were found in any of the untreated corn control samples.<br>The rates within the study and the residue details can be seen in the applicant's tables below.<br>However, the trials from Italy are not relevant for CEU (NEU). |

The following residue study on maize has not previously been reviewed and is provided in support of this assessment.

Reference: KCA1 6.3/02

Report: Determination of Residues of Dicamba and 5-OH Dicamba in Corn (Zea mays) matrices after application of Cadence or Mondak 21 S under field conditions in Italy, 1996, Gasser A., 1998, Report No. R96-032, Syngenta File No. SAN837/0416; VV-381309

Guideline(s): Yes (7029/VI/95 rev. 5)

Deviations: No

GLP: Yes

Acceptability: Yes

**Table A 5: Summary of the study 2 trials**

| GLP and Trial Details | Crop (Variety) | Country (Region) | Application Rate (g as/ha) (Formulation Number) | Growth Stage at Application | PHI (days) | Crop Part | Residue Found (mg/kg Uncorrected) | | | Recovery Data |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Dicamba | Dicamba-5-OH | Total Residue | |
| Report: R96-032<br>Study: R96-032<br>Trial: T11 (WG 70)<br>- Study to GLP<br>- Study carried out in 1996 | Maize (Alicia) | ITALY (Europe South) | 280<br><br>(A9781A) | BBCH 18 | 0 | Whole plant | 14.00 | 0.06 | 14.06 | Dicamba<br>Cob: Mean = 107% RSD = N/A (n = 2 in 0.01 - 0.01 mg/kg spiking range)<br>Grain: Mean = 99% RSD = N/A (n = 2 in 0.01 - 0.05 mg/kg spiking range)<br>Stover (fodder): Mean = 80% RSD = 19% (n = 6 in 0.01 - 0.10 mg/kg spiking range)<br>Whole plant: Mean = 83% RSD = 29% (n = 6 in 0.05 - 25.00 mg/kg spiking range)<br>NOA405873<br>Cob: Mean = 103% RSD = N/A (n = 2 in 0.01 - 0.10 mg/kg spiking range)<br>Grain: Mean = 92% RSD = N/A (n = 2 in 0.01 - 0.05 mg/kg spiking range)<br>Stover (fodder): Mean = 100% RSD = 22% (n = 7 in 0.01 - 0.50 mg/kg spiking range)<br>Whole plant: Mean = 77% RSD = 7% (n = 6 in 0.05 - 25.00 mg/kg spiking range) |
| | | | | | 0 | Whole plant | 15.50 | 0.09 | 15.59 | |
| | | | | | 30 | Whole plant | 0.02 | 0.05 | 0.07 | |
| | | | | | 30 | Whole plant | 0.03 | 0.02 | 0.05 | |
| | | | | | 57 | Whole plant | 0.01 | 0.03 | 0.04 | |
| | | | | | 57 | Whole plant | 0.01 | 0.04 | 0.05 | |
| | | | | | 78 | Cobs | < 0.01 | < 0.01 | <0.02 | |
| | | | | | 78 | Cobs | < 0.01 | < 0.01 | <0.02 | |
| | | | | | 78 | Remaining plant part | 0.03 | 0.06 | 0.09 | |
| | | | | | 78 | Remaining plant part | 0.01 | 0.05 | 0.06 | |
| | | | | | 113 | Grains | < 0.01 | < 0.01 | <0.02 | |
| | | | | | 113 | Grains | < 0.01 | < 0.01 | <0.02 | |
| | | | | | 113 | Straw | 0.08 | 0.02 | 0.10 | |
| Report: R96-032<br>Study: R96-032<br>Trial: T12 (SL 240)<br>- Study to GLP<br>- Study carried out in 1996 | Maize (Alicia) | ITALY (Europe South) | 292<br><br>(A10037A) | BBCH 18 | 0 | Whole plant | 29.20 | 0.04 | 29.24 | Dicamba<br>Cob: Mean = 107% RSD = N/A (n = 2 in 0.01 - 0.01 mg/kg spiking range)<br>Grain: Mean = 99% RSD = N/A (n = 2 in 0.01 - 0.05 mg/kg spiking range)<br>Stover (fodder): Mean = 80% RSD = 19% (n = 6 in 0.01 - 0.10 mg/kg spiking range)<br>Whole plant: Mean = 83% RSD = 29% (n = 6 in 0.05 - 25.00 mg/kg spiking range)<br>NOA405873<br>Cob: Mean = 103% RSD = N/A (n = 2 in 0.01 - 0.10 mg/kg spiking range)<br>Grain: Mean = 92% RSD = N/A (n = 2 in 0.01 - 0.05 mg/kg spiking range)<br>Stover (fodder): Mean = 100% RSD = 22% (n = 7 in 0.01 - 0.50 mg/kg spiking range)<br>Whole plant: Mean = 77% RSD = 7% (n = 6 in 0.05 - 25.00 mg/kg spiking range) |
| | | | | | 0 | Whole plant | 23.10 | 0.05 | 23.15 | |
| | | | | | 30 | Whole plant | 0.02 | 0.04 | 0.06 | |
| | | | | | 30 | Whole plant | < 0.01 | 0.02 | 0.03 | |
| | | | | | 57 | Whole plant | < 0.01 | 0.03 | 0.04 | |
| | | | | | 57 | Whole plant | < 0.01 | 0.03 | 0.04 | |
| | | | | | 78 | Cobs | < 0.01 | < 0.01 | <0.02 | |
| | | | | | 78 | Cobs | < 0.01 | < 0.01 | <0.02 | |
| | | | | | 78 | Remaining plant part | < 0.01 | 0.03 | 0.04 | |
| | | | | | 78 | Remaining plant part | < 0.01 | 0.03 | 0.04 | |
| | | | | | 113 | Grains | < 0.01 | < 0.01 | <0.02 | |
| | | | | | 113 | Grains | < 0.01 | < 0.01 | <0.02 | |
| | | | | | 113 | Straw | 0.01 | 0.08 | 0.09 | |

| GLP and Trial Details | Crop (Variety) | Country (Region) | Application Rate (g as/ha) (Formulation Number) | Growth Stage at Application | PHI (days) | Crop Part | Residue Found (mg/kg Uncorrected) | | | Recovery Data |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Dicamba | Dicamba-5-OH | Total Residue | |
| Report: R96-032<br>Study: R96-032<br>Trial: T21 (WG 70)<br>- Study to GLP<br>- Study carried out in 1996 | Maize (Lorena) | ITALY (Europe South) | 284<br><br>(A9781A) | BBCH 18 | 0 | Whole plant | 17.30 | 0.23 | 17.53 | Dicamba<br>Cob: Mean = 107% RSD = N/A (n = 2 in 0.01 - 0.01 mg/kg spiking range)<br>Grain: Mean = 99% RSD = N/A (n = 2 in 0.01 - 0.05 mg/kg spiking range)<br>Stover (fodder): Mean = 80% RSD = 19% (n = 6 in 0.01 - 0.10 mg/kg spiking range)<br>Whole plant: Mean = 83% RSD = 29% (n = 6 in 0.05 - 25.00 mg/kg spiking range)<br>NOA405873<br>Cob: Mean = 103% RSD = N/A (n = 2 in 0.01 - 0.10 mg/kg spiking range)<br>Grain: Mean = 92% RSD = N/A (n = 2 in 0.01 - 0.05 mg/kg spiking range)<br>Stover (fodder): Mean = 100% RSD = 22% (n = 7 in 0.01 - 0.50 mg/kg spiking range)<br>Whole plant: Mean = 77% RSD = 7% (n = 6 in 0.05 - 25.00 mg/kg spiking range) |
| | | | | | 0 | Whole plant | 19.30 | 0.26 | 19.56 | |
| | | | | | 30 | Whole plant | 0.02 | 0.04 | 0.06 | |
| | | | | | 30 | Whole plant | < 0.01 | 0.03 | 0.04 | |
| | | | | | 57 | Whole plant | 0.03 | 0.01 | 0.04 | |
| | | | | | 57 | Whole plant | < 0.01 | 0.01 | 0.02 | |
| | | | | | 83 | Cobs | < 0.01 | < 0.01 | <0.02 | |
| | | | | | 83 | Cobs | < 0.01 | < 0.01 | <0.02 | |
| | | | | | 83 | Remaining plant part | 0.02 | 0.03 | 0.05 | |
| | | | | | 83 | Remaining plant part | 0.02 | 0.02 | 0.04 | |
| | | | | | 107 | Grains | < 0.01 | < 0.01 | <0.02 | |
| | | | | | 107 | Grains | < 0.01 | < 0.01 | <0.02 | |
| | | | | | 107 | Straw | 0.02 | 0.01 | 0.03 | |
| Report: R96-032<br>Study: R96-032<br>Trial: T21 (SL 240)<br>- Study to GLP<br>- Study carried out in 1996 | Maize (Lorena) | ITALY (Europe South) | 288<br><br>(A10037A) | BBCH 18 | 0 | Whole plant | 14.10 | 0.11 | 14.21 | Dicamba<br>Cob: Mean = 107% RSD = N/A (n = 2 in 0.01 - 0.01 mg/kg spiking range)<br>Grain: Mean = 99% RSD = N/A (n = 2 in 0.01 - 0.05 mg/kg spiking range)<br>Stover (fodder): Mean = 80% RSD = 19% (n = 6 in 0.01 - 0.10 mg/kg spiking range)<br>Whole plant: Mean = 83% RSD = 29% (n = 6 in 0.05 - 25.00 mg/kg spiking range)<br>NOA405873<br>Cob: Mean = 103% RSD = N/A (n = 2 in 0.01 - 0.10 mg/kg spiking range)<br>Grain: Mean = 92% RSD = N/A (n = 2 in 0.01 - 0.05 mg/kg spiking range)<br>Stover (fodder): Mean = 100% RSD = 22% (n = 7 in 0.01 - 0.50 mg/kg spiking range)<br>Whole plant: Mean = 77% RSD = 7% (n = 6 in 0.05 - 25.00 mg/kg spiking range) |
| | | | | | 0 | Whole plant | 16.60 | 0.21 | 16.81 | |
| | | | | | 30 | Whole plant | < 0.01 | 0.02 | 0.03 | |
| | | | | | 30 | Whole plant | < 0.01 | 0.02 | 0.03 | |
| | | | | | 57 | Whole plant | < 0.01 | 0.01 | 0.02 | |
| | | | | | 57 | Whole plant | < 0.01 | 0.04 | 0.05 | |
| | | | | | 83 | Cobs | < 0.01 | < 0.01 | <0.02 | |
| | | | | | 83 | Cobs | < 0.01 | < 0.01 | <0.02 | |
| | | | | | 83 | Remaining plant part | < 0.01 | 0.02 | 0.03 | |
| | | | | | 83 | Remaining plant part | < 0.01 | < 0.01 | <0.02 | |
| | | | | | 107 | Grains | < 0.01 | < 0.01 | <0.02 | |
| | | | | | 107 | Grains | < 0.01 | < 0.01 | <0.02 | |
| | | | | | 107 | Straw | 0.01 | 0.07 | 0.08 | |

N/A – not applicable (n ≤ 3)
NOA405873 = 5-OH-dicamba

## A 2.3.4 Magnitude of residues in livestock

No new or additional studies have been submitted.

## A 2.3.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

### A 2.3.5.1 Distribution of the residue in peel/pulp

There are no crops in this submission for which distribution of the residues in peel/pulp is relevant. No new or additional studies have been submitted.

### A 2.3.5.2 Processing studies on a core set of representative processes

Processing studies have previously been summarised and submitted for evaluation. Thus, they are not summarised here again.

Representative crop processing studies have been carried out to cover industrial and domestic processes commonly applied to cereal grains. These processes are summarised in the table below.

**Table A 6: Crops and commodities obtained from industrial or domestic processing**

| Crop | Crop group | Industrial or household commodity |
|---|---|---|
| Barley | Cereals | Beer, pearl barley |
| Oats | Cereals | Oat flakes |

Processing studies have previously been summarised and submitted for evaluation.

| **Study** | **Author/s** | **Date** | **Report No.** |
|---|---|---|---|
| *Barley* | *Richards S et al.* | *2004* | *03-7017* |
| *Barley* | *Richards S et al.* | *2004* | *03-7018* |
| *Barley* | *Wesche H* | *1998* | *G/01/SG/1/97* |
| *Barley* | *Wesche H* | *1998* | *G/01/SG/2/97* |
| *Oats* | *Stolze K* | *2000* | *gr 05298* |
| *Oats* | *Stolze K* | *2000* | *gr 06498* |
| *Oats* | *Stolze K* | *2000* | *gr 04398* |
| *Oats* | *Stolze K* | *2000* | *gr 07598* |

**Summary – Processing**

Processing studies (balance and follow-up) have been conducted on barley (beer, pearl barley) and oats (oat flakes). Mean transfer factors for parent dicamba from these processing studies are summarised in Table A7.

**Table A 7: Dicamba transfer factors obtained during processing**

| Crop | Commodity | Mean Transfer Factor |
|---|---|---|
| Barley | Beer | <0.42 |
| | Pearl Barley | 0.53 |
| Oats | Flakes (rolled oats) | 1.32 |

## A 2.3.6 Magnitude of residues in representative succeeding crops

No new or additional studies have been submitted.

## A 2.3.7 Other/Special Studies

No new or additional studies have been submitted.

# Appendix 3 Pesticide Residue Intake Model (PRIMo)

## A 3.1 TMDI calculations

Prosulfuron

Not shown, please refer to IEDI calculations.

Nicosulfuron

Not shown, please refer to IEDI calculations.

Dicamba

Not conducted as the proposed EU MRL values for dicamba are based on the residues of the parent compound only.

## A 3.2 IEDI calculations

### Prosulfuron

European Food Safety Authority
EFSA PRIMo revision 3.1; 2019/03/19

**Prosulfuron**

| | | | |
|---|---|---|---|
| LOQs (mg/kg) range from: | 0.01 | to: | 0.05 |
| **Toxicological reference values** | | | |
| ADI (mg/kg bw/day): | 0.02 | ARfD (mg/kg bw): | 0.1 |
| Source of ADI: | EFSA | Source of ARfD: | EFSA |
| Year of evaluation: | 2014 | Year of evaluation: | 2014 |

Input values
Details - chronic risk assessment
Supplementary results - chronic risk assessment
Details - acute risk assessment/children
Details - acute risk assessment/adults

Comments:

**Refined calculation mode**

**Chronic risk assessment: JMPR methodology (IEDI/TMDI)**

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

| Calculated exposure (% of ADI) | MS Diet | Expsoure (µg/kg bw per day) | Highest contributor to MS diet (in % of ADI) | Commodity / group of commodities | 2nd contributor to MS diet (in % of ADI) | Commodity / group of commodities | 3rd contributor to MS diet (in % of ADI) | Commodity / group of commodities | Exposure resulting from MRLs set at the LOQ (in % of ADI) | Exposure resulting from commodities not under assessment (in % of ADI) |
|---|---|---|---|---|---|---|---|---|---|---|
| 7% | NL toddler | 1.34 | 6% | Milk: Cattle | 0.4% | Maize/corn | 0.1% | Bovine: Muscle/meat | 7% | 7% |
| 4% | UK infant | 0.86 | 4% | Milk: Cattle | 0.1% | Eggs: Chicken | 0.1% | Bovine: Muscle/meat | 4% | 4% |
| 3% | FR toddler 2 3 yr | 0.67 | 3% | Milk: Cattle | 0.1% | Bovine: Muscle/meat | 0.1% | Swine: Muscle/meat | 3% | 3% |
| 3% | FR child 3 15 yr | 0.58 | 2% | Milk: Cattle | 0.1% | Bovine: Muscle/meat | 0.1% | Swine: Muscle/meat | 3% | 3% |
| 3% | NL child | 0.56 | 2% | Milk: Cattle | 0.1% | Swine: Muscle/meat | 0.1% | Bovine: Muscle/meat | 3% | 3% |
| 2% | UK toddler | 0.47 | 2% | Milk: Cattle | 0.1% | Bovine: Muscle/meat | 0.1% | Eggs: Chicken | 2% | 2% |
| 2% | DE child | 0.45 | 2% | Milk: Cattle | 0.1% | Eggs: Chicken | 0.1% | Poultry: Muscle/meat | 2% | 2% |
| 2% | DK child | 0.36 | 1% | Milk: Cattle | 0.2% | Swine: Muscle/meat | 0.1% | Bovine: Muscle/meat | 2% | 2% |
| 2% | FR infant | 0.36 | 2% | Milk: Cattle | 0.0% | Swine: Muscle/meat | 0.0% | Bovine: Muscle/meat | 2% | 2% |
| 2% | ES child | 0.36 | 1% | Milk: Cattle | 0.1% | Bovine: Muscle/meat | 0.1% | Poultry: Muscle/meat | 2% | 2% |
| 2% | SE general | 0.35 | 1% | Milk: Cattle | 0.4% | Bovine: Muscle/meat | 0.1% | Eggs: Chicken | 2% | 2% |
| 2% | RO general | 0.30 | 1% | Milk: Cattle | 0.1% | Swine: Muscle/meat | 0.1% | Poultry: Muscle/meat | 2% | 2% |
| 1% | DE general | 0.30 | 1% | Milk: Cattle | 0.1% | Swine: Muscle/meat | 0.0% | Bovine: Muscle/meat | 1% | 1% |
| 1% | DE women 14-50 yr | 0.29 | 1% | Milk: Cattle | 0.1% | Swine: Muscle/meat | 0.0% | Bovine: Muscle/meat | 1% | 1% |
| 1% | GEMS/Food G15 | 0.23 | 0.7% | Milk: Cattle | 0.1% | Swine: Muscle/meat | 0.1% | Poultry: Muscle/meat | 1% | 1% |
| 1% | GEMS/Food G11 | 0.22 | 0.8% | Milk: Cattle | 0.1% | Swine: Muscle/meat | 0.1% | Poultry: Muscle/meat | 1% | 1% |
| 1% | NL general | 0.22 | 0.8% | Milk: Cattle | 0.1% | Swine: Muscle/meat | 0.1% | Bovine: Muscle/meat | 1% | 1% |
| 1% | GEMS/Food G07 | 0.22 | 0.6% | Milk: Cattle | 0.1% | Poultry: Muscle/meat | 0.1% | Swine: Muscle/meat | 1% | 1% |
| 1.0% | GEMS/Food G08 | 0.19 | 0.6% | Milk: Cattle | 0.2% | Swine: Muscle/meat | 0.1% | Poultry: Muscle/meat | 1.0% | 1.0% |
| 1.0% | GEMS/Food G10 | 0.19 | 0.5% | Milk: Cattle | 0.1% | Poultry: Muscle/meat | 0.1% | Bovine: Muscle/meat | 1.0% | 1.0% |
| 0.8% | ES adult | 0.16 | 0.5% | Milk: Cattle | 0.1% | Bovine: Muscle/meat | 0.1% | Swine: Muscle/meat | 0.8% | 0.8% |
| 0.8% | DK adult | 0.16 | 0.5% | Milk: Cattle | 0.1% | Swine: Muscle/meat | 0.1% | Bovine: Muscle/meat | 0.8% | 0.8% |
| 0.7% | IE adult | 0.14 | 0.4% | Milk: Cattle | 0.1% | Sheep: Liver | 0.0% | Bovine: Muscle/meat | 0.7% | 0.7% |
| 0.7% | FR adult | 0.14 | 0.4% | Milk: Cattle | 0.1% | Swine: Muscle/meat | 0.1% | Bovine: Muscle/meat | 0.7% | 0.7% |
| 0.6% | LT adult | 0.12 | 0.4% | Milk: Cattle | 0.1% | Swine: Muscle/meat | 0.0% | Eggs: Chicken | 0.6% | 0.6% |
| 0.5% | GEMS/Food G06 | 0.10 | 0.2% | Milk: Cattle | 0.1% | Maize/corn | 0.1% | Poultry: Muscle/meat | 0.5% | 0.5% |
| 0.5% | UK adult | 0.09 | 0.3% | Milk: Cattle | 0.1% | Bovine: Muscle/meat | 0.0% | Poultry: Muscle/meat | 0.5% | 0.5% |
| 0.4% | IE child | 0.09 | 0.4% | Milk: Cattle | 0.0% | Swine: Muscle/meat | 0.0% | Eggs: Chicken | 0.4% | 0.4% |
| 0.4% | UK vegetarian | 0.07 | 0.3% | Milk: Cattle | 0.0% | Eggs: Chicken | 0.0% | Poultry: Muscle/meat | 0.4% | 0.4% |
| 0.0% | PT general | 0.00 | 0.0% | Maize/corn | | FRUIT AND TREE NUTS | | | 0.0% | 0.0% |
| 0.0% | FI 3 yr | 0.00 | 0.0% | Sweet corn | 0.0% | Maize/corn | | | 0.0% | 0.0% |
| 0.0% | IT toddler | 0.00 | 0.0% | Maize/corn | 0.0% | Sweet corn | | | 0.0% | 0.0% |
| 0.0% | FI 6 yr | 0.00 | 0.0% | Maize/corn | 0.0% | Sweet corn | | | 0.0% | 0.0% |
| 0.0% | IT adult | 0.00 | 0.0% | Maize/corn | 0.0% | Sweet corn | | | 0.0% | 0.0% |
| 0.0% | FI adult | 0.00 | 0.0% | Sweet corn | 0.0% | Maize/corn | | | 0.0% | 0.0% |
| 0.0% | PL general | 0.00 | 0.0% | Maize/corn | | FRUIT AND TREE NUTS | | | 0.0% | 0.0% |

**Conclusion:**
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Prosulfuron is unlikely to present a public health concern.

## Nicosulfuron

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

### Nicosulfuron

| | | | |
|---|---|---|---|
| LOQs (mg/kg) range from: | 0.01 | to: | 0.05 |
| **Toxicological reference values** | | | |
| ADI (mg/kg bw/day): | 2 | ARfD (mg/kg bw): | not necessary |
| Source of ADI: | EFSA | Source of ARfD: | EFSA |
| Year of evaluation: | 2007 | Year of evaluation: | 2007 |

Input values

Details - chronic risk assessment

Supplementary results - chronic risk assessment

Details - acute risk assessment/children

Details - acute risk assessment/adults

Comments:

**Normal mode**

**Chronic risk assessment: JMPR methodology (IEDI/TMDI)**

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

| Calculated exposure (% of ADI) | MS Diet | Expsoure (µg/kg bw per day) | Highest contributor to MS diet (in % of ADI) | Commodity / group of commodities | 2nd contributor to MS diet (in % of ADI) | Commodity / group of commodities | 3rd contributor to MS diet (in % of ADI) | Commodity / group of commodities | Exposure resulting from MRLs set at the LOQ (in % of ADI) | Exposure resulting from commodities not under assessment (in % of ADI) |
|---|---|---|---|---|---|---|---|---|---|---|
| 0.1% | NL toddler | 1.34 | 0.1% | Milk: Cattle | 0.0% | Maize/corn | 0.0% | Bovine: Muscle/meat | 0.1% | |
| 0.0% | UK infant | 0.86 | 0.0% | Milk: Cattle | 0.0% | Eggs: Chicken | 0.0% | Bovine: Muscle/meat | 0.0% | |
| 0.0% | FR toddler 2 3 yr | 0.68 | 0.0% | Milk: Cattle | 0.0% | Bovine: Muscle/meat | 0.0% | Swine: Muscle/meat | 0.0% | |
| 0.0% | FR child 3 15 yr | 0.58 | 0.0% | Milk: Cattle | 0.0% | Bovine: Muscle/meat | 0.0% | Swine: Muscle/meat | 0.0% | |
| 0.0% | NL child | 0.57 | 0.0% | Milk: Cattle | 0.0% | Swine: Muscle/meat | 0.0% | Bovine: Muscle/meat | 0.0% | |
| 0.0% | UK toddler | 0.47 | 0.0% | Milk: Cattle | 0.0% | Bovine: Muscle/meat | 0.0% | Eggs: Chicken | 0.0% | |
| 0.0% | DE child | 0.46 | 0.0% | Milk: Cattle | 0.0% | Eggs: Chicken | 0.0% | Poultry: Muscle/meat | 0.0% | |
| 0.0% | DK child | 0.36 | 0.0% | Milk: Cattle | 0.0% | Swine: Muscle/meat | 0.0% | Bovine: Muscle/meat | 0.0% | |
| 0.0% | FR infant | 0.36 | 0.0% | Milk: Cattle | 0.0% | Swine: Muscle/meat | 0.0% | Bovine: Muscle/meat | 0.0% | |
| 0.0% | ES child | 0.36 | 0.0% | Milk: Cattle | 0.0% | Bovine: Muscle/meat | 0.0% | Poultry: Muscle/meat | 0.0% | |
| 0.0% | SE general | 0.36 | 0.0% | Milk: Cattle | 0.0% | Bovine: Muscle/meat | 0.0% | Eggs: Chicken | 0.0% | |
| 0.0% | RO general | 0.30 | 0.0% | Milk: Cattle | 0.0% | Swine: Muscle/meat | 0.0% | Poultry: Muscle/meat | 0.0% | |
| 0.0% | DE general | 0.30 | 0.0% | Milk: Cattle | 0.0% | Swine: Muscle/meat | 0.0% | Bovine: Muscle/meat | 0.0% | |
| 0.0% | DE women 14-50 yr | 0.29 | 0.0% | Milk: Cattle | 0.0% | Swine: Muscle/meat | 0.0% | Bovine: Muscle/meat | 0.0% | |
| 0.0% | GEMS/Food G15 | 0.23 | 0.0% | Milk: Cattle | 0.0% | Swine: Muscle/meat | 0.0% | Poultry: Muscle/meat | 0.0% | |
| 0.0% | GEMS/Food G11 | 0.22 | 0.0% | Milk: Cattle | 0.0% | Swine: Muscle/meat | 0.0% | Poultry: Muscle/meat | 0.0% | |
| 0.0% | NL general | 0.22 | 0.0% | Milk: Cattle | 0.0% | Swine: Muscle/meat | 0.0% | Bovine: Muscle/meat | 0.0% | |
| 0.0% | GEMS/Food G07 | 0.22 | 0.0% | Milk: Cattle | 0.0% | Poultry: Muscle/meat | 0.0% | Swine: Muscle/meat | 0.0% | |
| 0.0% | GEMS/Food G08 | 0.19 | 0.0% | Milk: Cattle | 0.0% | Swine: Muscle/meat | 0.0% | Poultry: Muscle/meat | 0.0% | |
| 0.0% | GEMS/Food G10 | 0.19 | 0.0% | Milk: Cattle | 0.0% | Poultry: Muscle/meat | 0.0% | Bovine: Muscle/meat | 0.0% | |
| 0.0% | ES adult | 0.16 | 0.0% | Milk: Cattle | 0.0% | Bovine: Muscle/meat | 0.0% | Swine: Muscle/meat | 0.0% | |
| 0.0% | DK adult | 0.16 | 0.0% | Milk: Cattle | 0.0% | Swine: Muscle/meat | 0.0% | Bovine: Muscle/meat | 0.0% | |
| 0.0% | IE adult | 0.14 | 0.0% | Milk: Cattle | 0.0% | Sheep: Liver | 0.0% | Bovine: Muscle/meat | 0.0% | |
| 0.0% | FR adult | 0.14 | 0.0% | Milk: Cattle | 0.0% | Swine: Muscle/meat | 0.0% | Bovine: Muscle/meat | 0.0% | |
| 0.0% | LT adult | 0.12 | 0.0% | Milk: Cattle | 0.0% | Swine: Muscle/meat | 0.0% | Eggs: Chicken | 0.0% | |
| 0.0% | GEMS/Food G06 | 0.10 | 0.0% | Milk: Cattle | 0.0% | Maize/corn | 0.0% | Poultry: Muscle/meat | 0.0% | |
| 0.0% | UK adult | 0.09 | 0.0% | Milk: Cattle | 0.0% | Bovine: Muscle/meat | 0.0% | Poultry: Muscle/meat | 0.0% | |
| 0.0% | IE child | 0.09 | 0.0% | Milk: Cattle | 0.0% | Swine: Muscle/meat | 0.0% | Eggs: Chicken | 0.0% | |
| 0.0% | UK vegetarian | 0.07 | 0.0% | Milk: Cattle | 0.0% | Eggs: Chicken | 0.0% | Poultry: Muscle/meat | 0.0% | |
| 0.0% | PT general | 0.00 | 0.0% | Maize/corn | | FRUIT AND TREE NUTS | | | 0.0% | |
| 0.0% | FI 3 yr | 0.00 | 0.0% | Sweet corn | 0.0% | Honey and other apiculture products | 0.0% | Maize/corn | 0.0% | |
| 0.0% | FI 6 yr | 0.00 | 0.0% | Honey and other apiculture products | 0.0% | Maize/corn | 0.0% | Sweet corn | 0.0% | |
| 0.0% | IT toddler | 0.00 | 0.0% | Maize/corn | 0.0% | Sweet corn | | | 0.0% | |
| 0.0% | IT adult | 0.00 | 0.0% | Maize/corn | 0.0% | Sweet corn | | | 0.0% | |
| 0.0% | FI adult | 0.00 | 0.0% | Sweet corn | 0.0% | Maize/corn | | | 0.0% | |
| 0.0% | PL general | 0.00 | 0.0% | Maize/corn | | FRUIT AND TREE NUTS | | | 0.0% | |

**Conclusion:**
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Nicosulfuron is unlikely to present a public health concern.

Dicamba

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

# Dicamba

| LOQs (mg/kg) range from: | | to: | |
|---|---|---|---|
| **Toxicological reference values** | | | |
| ADI (mg/kg bw/day): | **0.3** | ARfD (mg/kg bw): | **0.3** |
| Source of ADI: | **EFSA** | Source of ARfD: | **EFSA** |
| Year of evaluation: | **2011** | Year of evaluation: | **2011** |

Input values

Details - chronic risk assessment

Supplementary results - chronic risk assessment

Details - acute risk assessment/children

Details - acute risk assessment/adults

Comments:

**Normal mode**

**Chronic risk assessment: JMPR methodology (IEDI/TMDI)**

No of diets exceeding the ADI : ---

**TMDI/NEDI/IEDI calculation (based on average food consumption)**

| Calculated exposure (% of ADI) | MS Diet | Exposure (µg/kg bw per day) | Highest contributor to MS diet (in % of ADI) | Commodity / group of commodities | 2nd contributor to MS diet (in % of ADI) | Commodity / group of commodities | 3rd contributor to MS diet (in % of ADI) | Commodity / group of commodities | Exposure resulting from MRLs set at the LOQ (in % of ADI) | Exposure resulting from commodities not under assessment (in % of ADI) |
|---|---|---|---|---|---|---|---|---|---|---|
| 0.8% | GEMS/Food G08 | 2.50 | 0.5% | Barley | 0.3% | Wheat | 0.0% | Milk: Cattle | | 0.0% |
| 0.8% | GEMS/Food G15 | 2.42 | 0.4% | Barley | 0.3% | Wheat | 0.0% | Milk: Cattle | | 0.0% |
| 0.7% | GEMS/Food G11 | 2.18 | 0.4% | Barley | 0.3% | Wheat | 0.0% | Milk: Cattle | | 0.0% |
| 0.7% | GEMS/Food G07 | 2.07 | 0.3% | Barley | 0.3% | Wheat | 0.0% | Milk: Cattle | | 0.0% |
| 0.7% | GEMS/Food G10 | 1.99 | 0.3% | Barley | 0.3% | Wheat | 0.0% | Milk: Cattle | | 0.0% |
| 0.7% | NL toddler | 1.96 | 0.3% | Wheat | 0.2% | Milk: Cattle | 0.1% | Barley | | 0.3% |
| 0.6% | GEMS/Food G06 | 1.85 | 0.5% | Wheat | 0.0% | Barley | 0.0% | Sorghum | | 0.0% |
| 0.5% | IT toddler | 1.50 | 0.5% | Wheat | 0.0% | Barley | 0.0% | Other herbs | | 0.0% |
| 0.5% | DE general | 1.44 | 0.3% | Barley | 0.1% | Wheat | 0.0% | Milk: Cattle | | 0.0% |
| 0.5% | DK child | 1.42 | 0.3% | Wheat | 0.1% | Rye | 0.0% | Milk: Cattle | | 0.1% |
| 0.5% | ES adult | 1.39 | 0.3% | Barley | 0.2% | Wheat | 0.0% | Milk: Cattle | | 0.0% |
| 0.5% | FR child 3 15 yr | 1.35 | 0.3% | Wheat | 0.1% | Milk: Cattle | 0.0% | Bovine: Muscle/meat | | 0.1% |
| 0.4% | DE child | 1.35 | 0.3% | Wheat | 0.1% | Milk: Cattle | 0.0% | Rye | | 0.1% |
| 0.4% | RO general | 1.28 | 0.4% | Wheat | 0.0% | Milk: Cattle | 0.0% | Maize/corn | | 0.1% |
| 0.4% | NL child | 1.23 | 0.3% | Wheat | 0.1% | Milk: Cattle | 0.0% | Barley | | 0.1% |
| 0.4% | ES child | 1.16 | 0.3% | Wheat | 0.0% | Milk: Cattle | 0.0% | Bovine: Muscle/meat | | 0.1% |
| 0.4% | UK toddler | 1.13 | 0.3% | Wheat | 0.1% | Milk: Cattle | 0.0% | Barley | | 0.1% |
| 0.4% | UK infant | 1.07 | 0.2% | Wheat | 0.1% | Milk: Cattle | 0.0% | Oat | | 0.2% |
| 0.3% | FR toddler 2 3 yr | 1.05 | 0.2% | Wheat | 0.1% | Milk: Cattle | 0.0% | Bovine: Muscle/meat | | 0.1% |
| 0.3% | NL general | 1.02 | 0.2% | Barley | 0.1% | Wheat | 0.0% | Milk: Cattle | | 0.0% |
| 0.3% | DE women 14-50 yr | 0.98 | 0.2% | Wheat | 0.1% | Barley | 0.0% | Milk: Cattle | | 0.0% |
| 0.3% | IT adult | 0.95 | 0.3% | Wheat | 0.0% | Barley | 0.0% | Other herbs | | 0.0% |
| 0.3% | PT general | 0.93 | 0.3% | Wheat | 0.0% | Barley | 0.0% | Maize/corn | | 0.0% |
| 0.3% | SE general | 0.91 | 0.2% | Wheat | 0.0% | Milk: Cattle | 0.0% | Bovine: Muscle/meat | | 0.1% |
| 0.2% | IE adult | 0.68 | 0.2% | Wheat | 0.0% | Milk: Cattle | 0.0% | Basil and edible flowers | | 0.0% |
| 0.2% | FR adult | 0.58 | 0.2% | Wheat | 0.0% | Milk: Cattle | 0.0% | Swine: Muscle/meat | | 0.0% |
| 0.2% | UK vegetarian | 0.53 | 0.2% | Wheat | 0.0% | Milk: Cattle | 0.0% | Barley | | 0.0% |
| 0.2% | FI 3 yr | 0.47 | 0.1% | Wheat | 0.0% | Barley | 0.0% | Oat | | 0.0% |
| 0.2% | UK adult | 0.46 | 0.1% | Wheat | 0.0% | Barley | 0.0% | Milk: Cattle | | 0.0% |
| 0.1% | LT adult | 0.44 | 0.1% | Wheat | 0.0% | Barley | 0.0% | Rye | | 0.0% |
| 0.1% | FI 6 yr | 0.38 | 0.1% | Wheat | 0.0% | Barley | 0.0% | Oat | | 0.0% |
| 0.1% | FR infant | 0.37 | 0.1% | Wheat | 0.1% | Milk: Cattle | 0.0% | Parsley | | 0.1% |
| 0.1% | DK adult | 0.35 | 0.1% | Wheat | 0.0% | Milk: Cattle | 0.0% | Rye | | 0.0% |
| 0.1% | IE child | 0.31 | 0.1% | Wheat | 0.0% | Milk: Cattle | 0.0% | Barley | | 0.0% |
| 0.0% | FI adult | 0.15 | 0.0% | Wheat | 0.0% | Barley | 0.0% | Rye | | 0.0% |
| 0.0% | PL general | 0.01 | 0.0% | Celery leaves | 0.0% | Parsley | 0.0% | Chives | | 0.0% |

**Conclusion:**
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Dicamba is unlikely to present a public health concern.

## A 3.3 IESTI calculations - Raw commodities

Prosulfuron

| Acute risk assessment /children | Acute risk assessment / adults / general population |
|---|---|
| Details - acute risk assessment /children | Details - acute risk assessment/adults |

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

**Show results for all crops**

Unprocessed commodities

**Results for children**
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

**Results for adults**
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

**IESTI**

| Highest % of ARfD/ADI | Commodities | MRL / input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI | Commodities | MRL / input for RA (mg/kg) | Exposure (µg/kg bw) |
|---|---|---|---|---|---|---|---|
| 2% | Milk: Cattle | 0.02 / 0.02 | 2.5 | 0.8% | Milk: Cattle | 0.02 / 0.02 | 0.77 |
| 0.5% | Milk: Goat | 0.02 / 0.02 | 0.48 | 0.4% | Milk: Goat | 0.02 / 0.02 | 0.37 |
| 0.4% | Bovine: Liver | 0.05 / 0.05 | 0.40 | 0.3% | Milk: Sheep | 0.02 / 0.02 | 0.30 |
| 0.4% | Bovine: Edible offals (other | 0.05 / 0.05 | 0.36 | 0.2% | Poultry: Liver | 0.05 / 0.05 | 0.24 |
| 0.3% | Poultry: Muscle/meat | 0.02 / 0.02 | 0.34 | 0.2% | Poultry: Muscle | 0.02 / 0.02 | 0.23 |
| 0.2% | Eggs: Chicken | 0.02 / 0.02 | 0.25 | 0.2% | Bovine: Liver | 0.05 / 0.05 | 0.20 |
| 0.2% | Swine: Muscle/meat | 0.02 / 0.02 | 0.24 | 0.2% | Bovine: Edible offals (other | 0.05 / 0.05 | 0.17 |
| 0.2% | Swine: Edible offals (other | 0.05 / 0.05 | 0.15 | 0.2% | Swine: Other products | 0.05 / 0.05 | 0.16 |
| 0.1% | Bovine: Muscle/meat | 0.02 / 0.02 | 0.14 | 0.1% | Sheep: Liver | 0.05 / 0.05 | 0.14 |
| 0.1% | Sheep: Muscle/meat | 0.02 / 0.02 | 0.11 | 0.1% | Swine: Edible offals (other | 0.05 / 0.05 | 0.13 |
| 0.08% | Bovine: Kidney | 0.02 / 0.02 | 0.08 | 0.1% | Bovine: Muscle | 0.02 / 0.02 | 0.11 |
| 0.07% | Milk: Sheep | 0.02 / 0.02 | 0.07 | 0.1% | Bovine: Other products | 0.05 / 0.05 | 0.10 |
| 0.07% | Maize/corn | 0.01 / 0.01 | 0.07 | 0.10% | Swine: Muscle/meat | 0.02 / 0.02 | 0.10 |
| 0.06% | Swine: Liver | 0.05 / 0.05 | 0.06 | 0.09% | Sheep: Muscle/meat | 0.02 / 0.02 | 0.09 |
| 0.06% | Poultry: Liver | 0.05 / 0.05 | 0.06 | 0.09% | Eggs: Chicken | 0.02 / 0.02 | 0.09 |

Expand/collapse list

**Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)**

Nicosulfuron

As ARfD was not deemed necessary, acute risk assessment is not relevant.

Dicamba

**Acute risk assessment /children**

**Acute risk assessment / adults / general population**

Details - acute risk assessment /children

Details - acute risk assessment/adults

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

**Show results for all crops**

Unprocessed commodities

**Results for children**
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

**Results for adults**
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

**IESTI**

| Highest % of ARfD/ADI | Commodities | MRL / input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI | Commodities | MRL / input for RA (mg/kg) | Exposure (µg/kg bw) |
|---|---|---|---|---|---|---|---|
| 0.6% | Bovine: Edible offals (other | 0 / 0.23 | 1.7 | 0.3% | Bovine: Edible offals (other | 0 / 0.23 | 0.76 |
| 0.4% | Milk: Cattle | 0 / 0.01 | 1.2 | 0.2% | Swine: Edible offals (other | 0 / 0.23 | 0.60 |
| 0.3% | Bovine: Kidney | 0 / 0.23 | 0.87 | 0.2% | Swine: Kidney | 0 / 0.23 | 0.51 |
| 0.2% | Swine: Edible offals (other | 0 / 0.23 | 0.69 | 0.2% | Bovine: Kidney | 0 / 0.23 | 0.48 |
| 0.1% | Bovine: Liver | 0 / 0.05 | 0.40 | 0.1% | Milk: Cattle | 0 / 0.01 | 0.39 |
| 0.10% | Swine: Kidney | 0 / 0.23 | 0.29 | 0.07% | Bovine: Liver | 0 / 0.05 | 0.20 |
| 0.08% | Milk: Goat | 0 / 0.01 | 0.24 | 0.06% | Milk: Goat | 0 / 0.01 | 0.18 |
| 0.06% | Poultry: Muscle/meat | 0 / 0.01 | 0.17 | 0.05% | Sheep: Edible offals (other | 0 / 0.23 | 0.16 |
| 0.04% | Maize/corn | 0 / 0.02 | 0.13 | 0.05% | Milk: Sheep | 0 / 0.01 | 0.15 |
| 0.04% | Swine: Muscle/meat | 0 / 0.01 | 0.12 | 0.05% | Sheep: Liver | 0 / 0.05 | 0.14 |
| 0.03% | Bovine: Fat tissue | 0 / 0.05 | 0.10 | 0.04% | Poultry: Muscle | 0 / 0.01 | 0.12 |
| 0.03% | Swine: Fat tissue | 0 / 0.05 | 0.09 | 0.03% | Swine: Fat tissue | 0 / 0.05 | 0.10 |
| 0.02% | Bovine: Muscle/meat | 0 / 0.01 | 0.07 | 0.02% | Swine: Liver | 0 / 0.05 | 0.07 |
| 0.02% | Swine: Liver | 0 / 0.05 | 0.06 | 0.02% | Bovine: Muscle | 0 / 0.01 | 0.06 |
| 0.02% | Sheep: Muscle/meat | 0 / 0.01 | 0.05 | 0.02% | Bovine: Fat tissue | 0 / 0.05 | 0.05 |

Expand/collapse list

**Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)**

## A 3.4 IESTI calculations - Processed commodities

Prosulfuron

| Processed commodities | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | **Results for children** | | | | **Results for adults** | | | |
| | No of processed commodities for which ARfD/ADI is exceeded (IESTI): | | | --- | No of processed commodities for which ARfD/ADI is exceeded (IESTI): | | | --- |
| | **IESTI** | | | | **IESTI** | | | |
| | Highest % of ARfD/ADI | Processed commodities | MRL / input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI | Processed commodities | MRL / input for RA (mg/kg) | Exposure (µg/kg bw) |
| | 0.2% | Maize / oil | 0.01 / 0.25 | 0.23 | 0.1% | Maize / oil | 0.01 / 0.25 | 0.13 |
| | 0.0% | Maize / processed (not speci | 0.01 / 0.01 | 0.02 | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! |
| | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! |
| | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! |
| | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! |
| | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! |
| | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! |
| | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! |
| | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! |
| | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! |
| | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! |
| | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! |
| | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! |
| | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! |
| | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! |
| | Expand/collapse list | | | | | | | |

**Conclusion:**
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of Prosulfuron is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

Nicosulfuron

As ARfD was not deemed necessary, acute risk assessment is not relevant.

## Dicamba

| Processed commodities | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | **Results for children**<br>No of processed commodities for which ARfD/ADI is exceeded (IESTI): | | | --- | **Results for adults**<br>No of processed commodities for which ARfD/ADI is exceeded (IESTI): | | | --- |
| | **IESTI** | | | | **IESTI** | | | |
| | Highest % of ARfD/ADI | Processed commodities | MRL / input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI | Processed commodities | MRL / input for RA (mg/kg) | Exposure (µg/kg bw) |
| | 0.2% | Maize / oil | 0 / 0.5 | 0.47 | 0.1% | Maize / oil | 0 / 0.5 | 0.25 |
| | 0.0% | Maize / processed (not speci | 0 / 0.02 | 0.04 | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! |
| | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! |
| | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! |
| | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! |
| | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! |
| | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! |
| | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! |
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| | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! | #ZAHL! |
| | Expand/collapse list | | | | | | | |

**Conclusion:**

No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of Dicamba is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.