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| --- |
| FINAL REGISTRATION REPORT  Part B  Section 7  Metabolism and Residues  Detailed summary of the risk assessment |
| CHR/RW/PROH 100 WG: **CHR/RW/PROH 100 WG**  Product name(s): **Heksal 100 WG, Jamur 100 WG**  Chemical Prohexadione calcium:  **Prohexadione calcium, 100 g/kg** |
| Central zone  Zonal Rapporteur Member State: Poland |
| Core Assessment |
| Applicant: Innvigo Sp. z o.o.  Submission date: November 2021  MS Finalisation date: 27/09/2022 |

Version history

|  |  |
| --- | --- |
| When | What |
| September 2021 | Dossier sent for evaluation to Merit Mark (PL) |
| December 2021 | zRMS finalised evaluation |
| April 2022 | Final version prepared by zRMS after Commenting period |
| September 2022 | zRMS updated finalised evaluation |

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# Metabolism and residue data (KCA section 6)

New and additional applicant information provided in 09/2022 is highlighted in blue.

## Summary and zRMS Conclusion

The applicant’s dRR was not rewritten. zRMS text is on grey background.

### 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 CHR/RW/PROH 100 WG are presented in Table 7.1‑1. They have been selected from the individual GAPs in the zone for apples and winter wheat. A list of all intended uses within the zone is given in Part B, Section 0.

The representative uses supported during the EU pesticides peer review for the renewal of prohexadione authorisation were foliar spraying on apples and cereals. The additional report to the DAR has been peer reviewed by EFSA (EJ 2010; 8(3):1555). The approval of prohexadione under Regulation (EC) No 1107/20094 was renewed for a restricted use as plant growth regulator.

Critical GAPs for prohexadione-calcium in Northern Europe are on apple: 2 applications at the rate dose of 0.125 kg prohexadione-calcium/ha, before the growth stage BBCH 75, with an interval between application of 21-35 days and a PHI of 55 days. On cereals the critical GAPs is 0.060 kg prohexadione-calcium/ha, 1 application before BBCH 39 growth stage (see the source GAP table – Appendix II of SANCO/11023/2011 Rev 2).

Overall conclusion

No new data were submitted in the framework of this application. Sufficient unprotected residue trials on cereals and apples in accordance with the representative uses are available and are supported by freezer storage stability studies. From these an exceedance of the current MRL for cereals and apples of 0,1 mg/kg for prohexadione calcium as laid down in Reg. (EU) 396/2005 (prohexadione and its salts expressed as prohexadione-calcium) is not expected.

According to the MRLs compliance within pome fruits group (0,1) the representative apple uses could be extrapolated to pears, crab apples, quinces and medlars.

Tobacco, in the context of the residues assessment as not edible crop can be authorized.

However, there was no possibility of extrapolating any residues data to walnuts. Therefore, walnuts cannot be authorized.

Processing studies are not required because the TMDI was <10%. Prohexadione-calcium is rapidly degraded in soil; therefore, no quantifiable residues of prohexadione-calcium are expected in rotational crops. This was confirmed by a confined rotational crop study.

Based on the applicant’s dietary burden, there is no exceedance for intakes above 0.004 mg/kg bw/d, therefore the risk from feeding to animals is acceptable. Based on DAR no data from livestock feeding studies with poultry and/or cattle are required to support the use of prohexadione-Ca on apples and cereals.

Thus, the data available are considered sufficient for risk assessment.

The chronic and the short-term intakes of Prohexadione calcium 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 uses, except the use in walnuts.

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

Data gaps

Noticed data gaps are:

None, in the context of the present authorisation request.

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

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 15 | 11 | 12 | 13 | 15 |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Use-No. (e)** | **Member state(s)** | **Crop and/ or situation  (crop destination / purpose of crop)** | **F, Fn, Fpn G, Gn, Gpn or I** | **Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group) | **Application** | | | | **Application rate** | | | **PHI** (days) | ZRMs Conclusion |
| Method / Kind | Timing / Growth stage of crop & season | Max. number  a) per use  b) per crop/ season | Min. interval between applications (days) | kg or L product / ha  a) max. rate per appl.  b) max. total rate per crop/season | g or kg as/ha  a) max. rate per appl.  b) max. total rate per crop/season | Water L/ha  min / max |
| **Zonal uses (field or outdoor uses, certain types of protected crops)** | | | | | | | | | | | | |  |
| 1 | PL | Apple  (MABSD) | F | Plant Growth Regulator PGR | Spray, medium sprayer | Spring  BBCH 31-75 | a) 2  b) 2 | 21-35 | a) 1.25 kg/ha  b) 2.50 kg/ha | a) 0.125 kg a.s./ha  b) 0.25 kg a.s./ha | 500-2000 | 55 |  |
| 2 | PL | Winter wheat (TRZAW) | F | Plant Growth Regulator PGR | Spray, medium sprayer | Spring  BBCH 30 | a)1  b)1 | n/a | a) 0.4-0.6 kg/ha  b) 0.4-0.6 kg/ha | a) 0.04-0.06 kg a.s./ha  b) 0.04-0.06 kg a.s./ha | 100-400 |  |  |
| 3 | PL | Winter wheat (TRZAW) | F | Plant Growth Regulator PGR | Spray, medium sprayer | Spring  BBCH 39 | a)1  b)1 | n/a | a) 0.4-0.6 kg/ha  b) 0.4-0.6 kg/ha | a) 0.04-0.06 kg a.s./ha  b) 0.04-0.06 kg a.s./ha | 100-400 |  |  |
| **Minor uses according to Article 51 (zonal uses)** | | | | | | | | | | | | |  |
| 4 | PL | Pear  (PYUCO)  Oriental Pear | F | Plant Growth Regulator PGR | Spray, medium sprayer | Spring  BBCH 31-75 | a) 2  b) 2 | 21-35 | a) 1.25 kg/ha  b) 1.25 kg/ha | a) 0.125 kg a.s./ha  b) 0.25 kg a.s./ha | 500-2000 | 55 |  |
| 5 | PL | Crab Apple  (MABSY) | F | Plant Growth Regulator PGR | Spray, medium sprayer | Spring  BBCH 31-75 | a) 2  b) 2 | 21-35 | a) 1.25 kg/ha  b) 1.25 kg/ha | a) 0.125 kg a.s./ha  b) 0.25 kg a.s./ha | 500-2000 | 55 |  |
| 6 | PL | Medlar  (MSPGE) | F | Plant Growth Regulator PGR | Spray, medium sprayer | Spring  BBCH 31-75 | a) 2  b) 2 | 21-35 | a) 1.25 kg/ha  b) 1.25 kg/ha | a) 0.125 kg a.s./ha  b) 0.25 kg a.s./ha | 500-2000 | 55 |  |
| 7 | PL | Quince  (CYDOB) | F | Plant Growth Regulator PGR | Spray, medium sprayer | Spring  BBCH 31-75 | a) 2  b) 2 | 21-35 | a) 1.25 kg/ha  b) 1.25 kg/ha | a) 0.125 kg a.s./ha  b) 0.25 kg a.s./ha | 500-2000 | 55 |  |
| ~~8~~ | ~~PL~~ | ~~Walnut~~  ~~(IUGRE)~~ | ~~F~~ | ~~Plant Growth Regulator PGR~~ | ~~Spray, medium sprayer~~ | ~~Spring~~  ~~BBCH 31-75~~ | ~~a) 2~~  ~~b) 2~~ | ~~21-35~~ | ~~a) 1.25 kg/ha~~  ~~b) 1.25 kg/ha~~ | ~~a) 0.125 kg a.s./ha~~  ~~b) 0.25 kg a.s./ha~~ | ~~500-2000~~ |  | No data submitted. |
| 9 | PL | Spring Rye  (SECCS) | F | Plant Growth Regulator PGR | Spray, medium sprayer | Spring  BBCH 30-39 | a)1  b)1 | n/a | a) 0.4-0.6 kg/ha  b) 0.4-0.6 kg/ha | a) 0.04-0.06 kg a.s./ha  b) 0.04-0.06 kg a.s./ha | 100-400 |  |  |
| 10 | PL | Tobacco  (NIOTA) | F | Plant Growth Regulator PGR | Spray, medium sprayer | BBCH 20-49 | a) 2  b) 2 | 21-35 | a) 1.25 kg/ha  b) 1.25 kg/ha | a) 0.125 kg a.s./ha  b) 0.25 kg a.s./ha | 500-2000 |  |  |

Explanation for Column 15 “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 |

### Summary of the evaluation

The preparation CHR/RW/PROH 100 WG is composed of Prohexadione calcium.

Table 7.1‑2: Toxicological reference values for the dietary risk assessment of Prohexadione calcium.

| Reference value | Source | Year | Value | Study relied upon | Safety factor |
| --- | --- | --- | --- | --- | --- |
| Prohexadione calcium - Parent compound (if applicable) | | | | | |
| ADI | *EFSA Journal 2010; 8(3):1555* | 2010 | 0.2 | Dog, 1 year study | 100 |
| ARfD | - | - | Not applicable | - | - |

#### Summary for Prohexadione calcium

Table 7.1‑3: Summary for Prohexadione calcium

| 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 | Apples | Yes | Yes  (9 trials) | Yes | Yes | Yes | No | No |
| 2 | Winter wheat | Yes | Yes  (11 trials) | Yes | Yes | Yes | No |

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

**Conclusions**

**Studies on apples**

Five apple trials were conducted in 1999 in Italy (3 trials) and Northern France (2 trials) in the first study

(N°2000/1000252), four trials were conducted in 2000 in Italy (2 trials) and Northern France (2 trials) in the study two (N°2000/10000253), five trials conducted in 1999 Germany (3 trials) and France (2 trials) in the third study (N°2000/1014844) and four apple trials were conducted in 2000 in Germany (2 trials) and Southern France (2 trials) in the fourth study (N° 2000/1014845).

Each trial consists of two plots: a control (untreated) plot and a treated plot which received two sequential

applications of Prohexadione-calcium (WG formulation) applied at a **41 to 60 day interval** between

applications. The target rate for each application was 1.25 kg/ha of BAS 125 10 W and a target spray volume of 600 L/ha.

**Studies on cereals**

Residues trials were performed in France in 1991 and 1992 on cereals (winter barley and winter wheat) in

northern European region (9 trials in barley and 7 trials in wheat) and in southern European region (2 trials in barely and 9 in wheat). Supervised residues trials were also performed in other country (Germany and United Kingdom) in 1991 and 1992 on barley and wheat also, but only one trial (1 of the 8 trials from UK study, 1992) allows to support the intended GAP.

Reference: *Draft Assessment report, 2009, Volume 3, B7*

#### Summary for CHR/RW/PROH 100 WG

Table 7.1‑4: Information on CHR/RW/PROH 100 WG (KCA 6.8)

| Crop | PHI for CHR/RW/PROH 100 WG  proposed by applicant | PHI/ Withholding period\* sufficiently supported for | PHI for CHR/RW/PROH 100 WG  proposed by zRMS | zRMS Comments  (if different PHI proposed) |
| --- | --- | --- | --- | --- |
| Prohexadione calcium |  |  |
| Apples | 55 days | Yes | 55 days |  |
| Winter wheat | NR | Yes | F |  |

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).

NR: not relevant

## Prohexadione calcium

General data on Prohexadione calcium are summarized in the table below (last updated 2018/06/5)

**Table 7.2‑1: General information on Prohexadione calcium**

|  |  |
| --- | --- |
| Prohexadione calcium (ISO Common Name) | Prohexadione calcium |
| IUPAC | Calcium 3-oxido-5-oxo-  4-propionylcyclohex-3-enecarboxylate |
| Chemical structure |  |
| Molecular formula | C10H10O5Ca |
| Molar mass | 250.26 g/mol |
| Chemical group | Calcium salt |
| Mode of action (if available) | Plant growth regulator |
| Systemic | Yes |
| Company | BASF |
| Rapporteur Member State (RMS) | Poland |
| Approval status | Approved  Date of approval (01/01/2012)  (COMMISSION DIRECTIVE 2010/56/eu - REGULATION (EU) No 540/2011) |
| Restriction | Only uses as plant growth regulator may be authorised. |
| Review Report | *SANCO/11023/2011*– rev. 2  17/06/2011 |
| Current MRL regulation | Regulation (EC) No 2018/70 |
| Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed | Yes |
| EFSA Journal : Conclusion on the peer review | *EFSA Journal 2010; 8(3):1555* |
| EFSA Journal: conclusion on article 12 | No |
| Current MRL applications on intended uses | N/A – MRL already set |

\* Notifier in the EU process to whom the a.s. belong(s)

\*\* If yes: EFSA, YYYY - see list of references

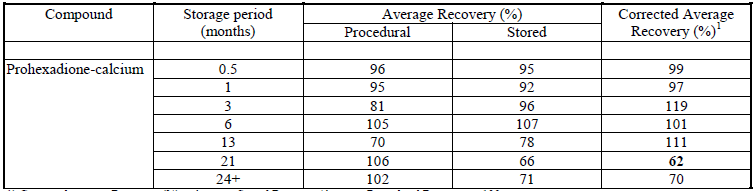
### Stability of Residues (KCA 6.1)

#### Stability of residues during storage of samples

Available data

No new data submitted in the framework of this application.

Table 7.2‑2: Summary of stability data achieved at ≤ ‑ 5 °C in apples

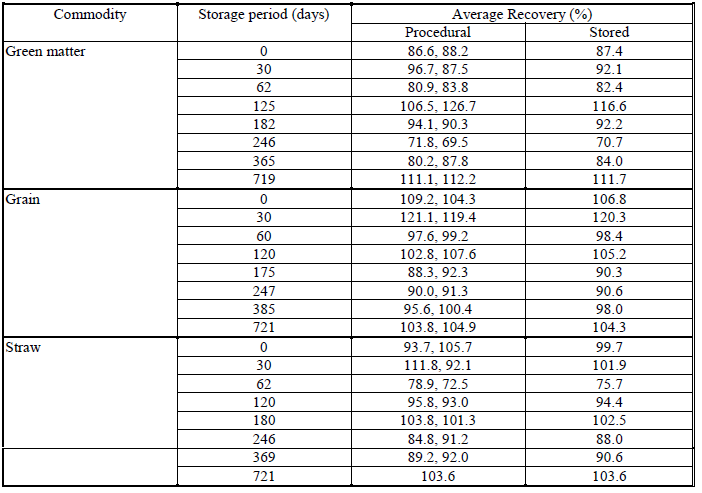


Reference: Stewart, J. M., 2002, *Storage stability of BAS 125 W and metabolite BW 125 31F in apples*

Conclusion on stability of residues during storage in apples

The results of these analyses indicate that residues of prohexadione-calcium are stable (recoveries >70%) in apple matrices for at least 24 months under freezer conditions (< -5°C). Corrected recoveries are below 70% at the 21 month analysis point but above 70% at the 24 month analysis point suggesting that although there is a drop in recovery, it can be considered acceptable up to 24 months storage.

Table 7.2‑3: Summary of stability data achieved at ≤ ‑ 20 °C in wheat



Reference: Mackenrot, H., C., 1995, *Investigation of the storage stability of prohexadione-Ca in wheat: Test of storage stability in green matter, grain and straw*

Conclusion on stability of residues during storage in wheat

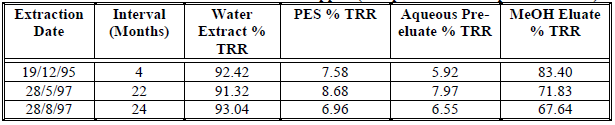
Prohexadione-calcium was stable in cereal matrices for at least 24 months (721 days) under freezer conditions (< -20°C).

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

Available data

No new data submitted in the framework of this application.

Table 7.2‑4: Summary of stability in sample extracts in apples



Conclusion on stability of residues in sample extracts in Apples

The extraction results obtained for harvest apples processed over a period of 20 months (4 months to 24 months from field collection) is given in the table above. These results indicate that the extractability of radioactive residues from harvest apples remain stable throughout the period of 20 months. The radioactivity in the organosoluble (methanol) eluate and aqueous pre-eluate also remain stable. The HPLC chromatographic metabolite profiles in the organosoluble fractions obtained from samples extracted after 4 months and 24 months were compared. These chromatographic profiles were similar with key individual metabolite peaks remaining stable. It can be concluded that prohexadione and its metabolites were stable in plant tissue for at least 20 months (equivalent to 24 months from collection date).

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

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

Available data

No new data submitted in the framework of this application.

Summary of plant metabolism studies reported in the EU

Table 7.2‑5: Summary of plant metabolism studies

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Crop Group | Crop | Label position | Application and sampling details | | | | Reference |
| Method,  F or G (a) | Rate  (kg a.s./ha) | No | Sampling (DAT) |  |
| **EU data** | | | | | | |  |
| Fruits and fruiting vegetable | Apples | 14C-labelled  Prohexadione-calcium- 3 and 5 carbon atom in cyclohexenone ring | foliar treatment, F | 1.97 | 2 | 0, 34, 0(35)\*, 45 (80)\*\* days | Patel, J. R., et al., 1998, *Metabolism of 14C-BAS 125 W in apples*, 1997/5005 |
| Tree nuts | Peanuts | 13C and 14C-labelled Prohexadione- calcium- 3 and 5 carbon atom in cyclohexenone ring | foliar treatment, F | 1.12 | 1 | 0, 13, 22 | Steginsky, C., et al., 1997, *Metabolism of 14 C BAS 125 W (Prohexadione Calcium) in peanut,* 1997/5341 |
| Cereals | Barley | 14C-labelled  Prohexadione-calcium- 3 and 5 carbon atom in cyclohexenone ring | foliar treatment, F | 0.14 | 1 | 66 | *EFSA Journal 2009; 7(11):1378* |
| Rice | 0.336 | 1 | 25,50 |

\*0 days after the second application, 35 days after the first application

\*\*45 days after the second application, 80 days after the first application

Conclusion on metabolism in primary crops

Prohexadione-calcium is supported by two metabolism studies on barley and rice (cereals group) and two newer metabolism studies on peanut (pulse and oilseed group) and apple (fruit group). The studies show a highly comparable metabolic pathway based on α-, β- or ring oxidation. Only three metabolites were greater than 10% of TRR – prohexadione acid, tricarballylic acid (peanut hay and hull) and BX 112-15 (apples). In the study on barley, component 1 was unidentified and slightly exceeded 10% TRR in stalks and leaves (16.8 and 11.8% TRR, respectively). However, the retention times shows the component to remain at the origin of the TLC plate confirming the highly polar nature of this component. Neither cereal stalks or leaves are used as a human feeding stuff and only form a small part of animal diets. Therefore, taking all metabolism studies available, it can be demonstrated that metabolism of Prohexadionecalcium is well understood in plants and would not be expected to show additional metabolites beyond those identified regardless of crop group.

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

Available data

No new data submitted in the framework of this application.

Summary of plant metabolism studies reported in the EU

Table 7.2‑6: Summary of metabolism studies in rotational crops

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Crop group | Crop | Label position | Application and sampling details | | | Reference |
| Method,  F or G \* | Rate  (kg a.s./ha) | Sowing intervals  (DAT) |
| **EU data** | | | | | | |
| Fruits and fruiting vegetable | Apples | Not relevant to apples since these are crops which are not considered to be grown in rotation (refer to OECD guidline – metabolism in rotational crops). | | | | |
| Cereals | Wheat | 14C-prohexadione-calcium | F | 0.38 | 121 | Steginsky, C. A., et al., 1996, *Confined rotational crop study with 14C-BAS 9054 W (Prohexadione-Calcium)* |
| Leafy vegetables | Lettuce | 14C-prohexadione-calcium | F | 0.38 | 121 | Steginsky, C. A., et al., 1996, *Confined rotational crop study with 14C-BAS 9054 W (Prohexadione-Calcium)* |
| Root vegetables | Turnip | 14C-prohexadione-calcium | F | 0.38 | 31 | Steginsky, C. A., et al., 1996, *Confined rotational crop study with 14C-BAS 9054 W (Prohexadione-Calcium)* |

\* Outdoor/field application (F) or glasshouse/protected/indoor application (G)

Conclusion on metabolism in rotational crops

Prohexadione-calcium is rapidly degraded in soil, therefore no quantifiable residues of prohexadione-calcium are expected in rotational crops.

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

Processing studies are not required because the TMDI was <10% and residues do not exceed the trigger value of 0.1 mg/kg.

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

Table 7.2‑7: Summary of the nature of residues in commodities of plant origin

|  |  |
| --- | --- |
| **Endpoints** | |
| Plant groups covered | Fruits and fruiting vegetable (Apples)  Cereals (Wheat) |
| Rotational crops covered | Cereals (Wheat)  Leafy vegetables (Lettuce)  Root vegetables (Turnip) |
| Metabolism in rotational crops similar to metabolism in primary crops? | Yes |
| Processed commodities | None |
| Residue pattern in processed commodities similar to pattern in raw commodities? | N/A |
| Plant residue definition for monitoring | Prohexadione and its salts expressed as  Prohexadione-calcium |
| Plant residue definition for risk assessment | Prohexadione and its salts expressed as  Prohexadione-calcium |
| Conversion factor from enforcement to RA | No conversion factor |

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

Available data

No new data submitted in the framework of this application.

Metabolism of the active substance was reviewed during the Annex I inclusion process and was summarised in the *EFSA Journal 2010; 8(3):1555 as follows:*

*The residue definition for livestock is based on metabolism studies in lactating goats and laying hens.*

*Radioactive residues were very low, with prohexadione being a main component. Therefore, the*

*following residue definition for animal matrices for monitoring and risk assessment was proposed:*

*prohexadione and its salts expressed as prohexadione-calcium. The dietary burden calculation showed levels of 0.23 mg/kg DM and 0.12 mg/kg DM for beef and dairy cattle respectively. Residue levels below*

*the LOQ of 0.01 mg/kg for all other matrices are expected. The chronic risk assessment using the EFSA*

*PRIMo model rev.2 results in a TMDI of 0.9% of the ADI. An acute risk assessment is not required as no*

*ARfD was set.*

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

Table 7.2‑8: 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 | Not applicable |
| Animal residue definition for monitoring | Prohexadione and its salts expressed as  Prohexadione-calcium |
| Animal residue definition for risk assessment | Prohexadione and its salts expressed as  Prohexadione-calcium |
| Conversion factor | No conversion factor |
| Metabolism in rat and ruminant similar | Yes |
| Fat soluble residue | No |

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

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

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 CHR/RW/PROH 100 WG and conformity to existing MRL

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Commodity | Source | Residue zone (N-EU, S-EU, EU, outside EU) | Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition | STMR (mg/kg) | HR (mg/kg) | Unrounded OECD calculator MRL (mg/kg) | Current EU MRL  (mg/kg)  \* | MRL compliance |
| Wheat grain | *EFSA Journal 2010; 8(3):1555* | N-EU | 10 × <0.05, 0.07 | 0.05 | 0.07 | 0.158 | 0.1 | Yes |
| Spring Rye | Extrapolated from residue studies in wheat grain. | | | | | | 0.1 | Yes |
| Apples | *EFSA Journal 2010; 8(3):1555* | N-EU | 8 × <0.05; 0.052 | 0.05 | 0.052 | 0.151 | 0.1 | Yes |
| Pears | Extrapolated from residue studies in apples. | | | | | | 0.1 | Yes |
| Crab Apples |
| Medlar |
| Quince |
| ~~Walnut~~ |

\* Source of EU MRL: EFSA Journal 2009; 7(11):1378, COMMISSION REGULATION (EU) 2018/70

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

According to the available data, the intended uses on Winter wheat and apples are considered acceptable. The data submitted show that no exceedance of the MRL will occur. The uses are considered acceptable.

According to appendix D of EU guidelines, extrapolation to Pome fruits (Pear, Oriental Pear, Crab Apple, Medlar, Quince) ~~and Walnuts~~ is possible with trials on apples, which is the case here.

According to appendix D of EU guidelines, extrapolation to Winter Rye is possible with trials on winter wheat, which is the case here.

The data submitted show that no exceedance of the MRL will occur.

The uses are considered acceptable.

### Magnitude of residues in livestock

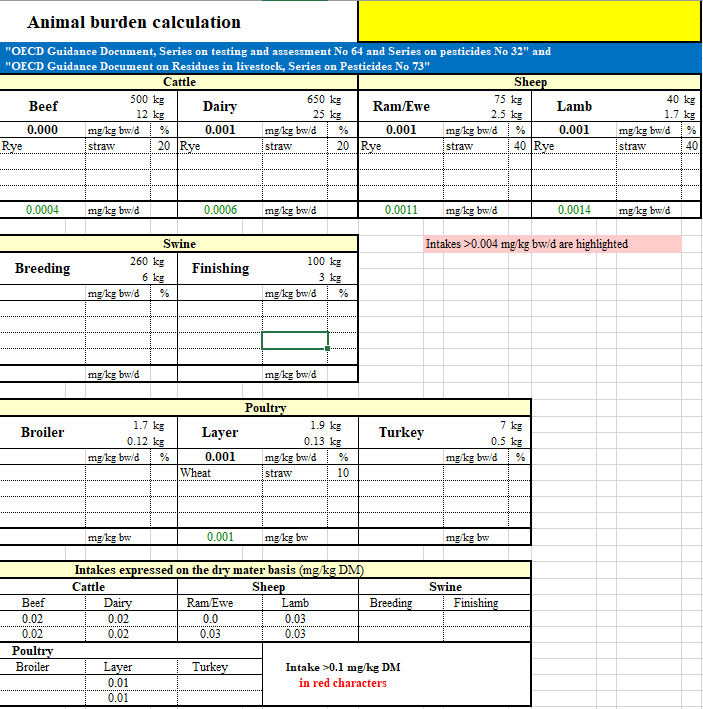
#### Dietary burden calculation

Table 7.2‑10: 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 (mg/kg) | Comment | Input value (mg/kg) | Comment |
| Prohexadione (prohexadione (acid) and its salts expressed as prohexadione-calcium) | | | | |
| Apple pomace | 0.05\* | *EFSA Journal 2010; 8(3):1555* | 0.052 | *EFSA Journal 2010; 8(3):1555* |
| Wheat grain | 0.05\* | *EFSA Journal 2010; 8(3):1555* | 0.07 | *EFSA Journal 2010; 8(3):1555* |
| Wheat straw | 0.05\* | *EFSA Journal 2010; 8(3):1555* | 0.07 | *EFSA Journal 2010; 8(3):1555* |
| Wheat gluten | 0.05\* | *EFSA Journal 2010; 8(3):1555* | 0.07 | *EFSA Journal 2010; 8(3):1555* |
| Wheat milled by-pdts | 0.05\* | *EFSA Journal 2010; 8(3):1555* | 0.07 | *EFSA Journal 2010; 8(3):1555* |

New Dietary Burden calculations were performed, taking into account STMR and HR values from residues trials on CHR/F/PF. New calculations were presented below with MRL-Calculator.

Table 7.2‑11: Results of the dietary burden calculation



**Conclusions**

Based on dietary burden calculator, there is no exceedance for intakes above 0.004 mg/kg bw/d or 0.1 mg/kg DM, therefore no additional livestock feeding studies are required.

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

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

Conclusion on feeding studies

Based on dietary burden calculator, there is no exceedance for intakes above 0.004 mg/kg bw/d or 0.1 mg/kg DM, therefore the risk from feeding to animals is acceptable.

DAR 2009 vol.3 3.15: Dietary burden calculation

Considering the low residues anticipated in animal feed, and the concentrations in tissues milk and eggs observed in the livestock metabolism studies, it can be concluded that there is no significant exposure of consumer via food from animal origin. By extrapolating the results obtained from the livestock metabolism studies performed at exaggerated rates to the 1x feeding level of prohexadione-Ca, it can be confidently stated that “total residues” would be around or below the LOQ of the livestock analytical enforcement method (0.01 mg/kg), and most certainly, parent prohexadione residues would be well below the limit of quantification (~). No data from livestock feeding studies with poultry and/or cattle are required to support the use of prohexadione-Ca on apples and cereals.

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

No further studies have been performed.

#### Available data for all crops under consideration

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

#### Conclusion on processing studies

Processing studies are not required because the TMDI was <10% and residues do not exceed the trigger value of 0.1 mg/kg.

### Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation, but according to *EFSA Journal 2010; 8(3):1555* Prohexadione-calcium is rapidly degraded in soil, therefore no quantifiable residues of prohexadione-calcium are expected in rotational crops. This was confirmed by a rotational crop study.

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

Available data

No new data submitted in the framework of this application.

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

The available data for the Prohexadione calcium sufficiently address aspects of the residue situation that might arise from the use of CHR/RW/PROH 100 WG. Therefore, other special studies are not needed.

### 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 7.1.2).

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

#### Input values for the consumer risk assessment

Table 7.2‑12: Input values for the consumer risk assessment

| Commodity | Chronic risk assessment | |
| --- | --- | --- |
| Input value (mg/kg) | Comment |
| Prohexadione (prohexadione (acid) and its salts expressed as prohexadione-calcium) | | |
| Apples | 0.10 | *Commission Regulation (EU) 2018/70* |
| Pears | 0.10 | *Commission Regulation (EU) 2018/70* |
| Quinces | 0.10 | *Commission Regulation (EU) 2018/70* |
| Medlar | 0.10 | *Commission Regulation (EU) 2018/70* |
| Walnuts | 0.01 | *Commission Regulation (EU) 2018/70* |
| Rye | 0.10 | *Commission Regulation (EU) 2018/70* |
| Wheat | 0.10 | *Commission Regulation (EU) 2018/70* |
| Apples/ juice | 0.10 | PRIMo ver. 3.1 |
| Pears/ juice | 0.10 | PRIMo ver. 3.1 |
| Quinces/ jam | 0.10 | PRIMo ver. 3.1 |
| Rye / milling (wholemeal)-baking | 0.10 | PRIMo ver. 3.1 |
| Rye / boiled | 0.10 | PRIMo ver. 3.1 |
| Wheat / bread (wholemeal) | 0.10 | PRIMo ver. 3.1 |
| Wheat / bread/pizza | 0.10 | PRIMo ver. 3.1 |
| Wheat / pasta | 0.10 | PRIMo ver. 3.1 |
| Wheat / milling (wholemeal)-baking | 0.10 | PRIMo ver. 3.1 |
| Wheat / milling (flour) | 0.10 | PRIMo ver. 3.1 |

#### Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.2‑16: Consumer risk assessment

|  |  |
| --- | --- |
| TMDI (% ADI) according to EFSA PRIMo | 1.0 % (based on NL toddler) |
| ~~IESTI (% ARfD) according to EFSA PRIMo (unprocessed)~~ | ~~7.0 % (based on children) - Pears~~ |
| ~~IESTI (% ARfD) according to EFSA PRIMo (processed)~~ | ~~3.0 % (based on children) – Apple juice~~ |

The proposed uses of Prohexadione calcium in the CHR/RW/PROH 100 WG do not represent unacceptable chronic risks for the consumer.

The Consumer risk assessment needs correction because it is unclear what was happened here. The TMDI is 1% based on NL toddler, and it looks correct, but although ARfD is not allocated, the applicant shows also IESTI results – based on what? Also, the insertions in Appendix 3 are not acceptable.

Please correct the issue pasting the entire page of the relevant PRIMo 3 report where the name of the active and ADI/ARfD values are visible.

The unclear issues were corrected by the applicant. The risk assessment performed is correct.

## References

- EFSA Journal 2010; 8(3):1555

- Assessment report, Volume 3, Part B7, June 2009

1. Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

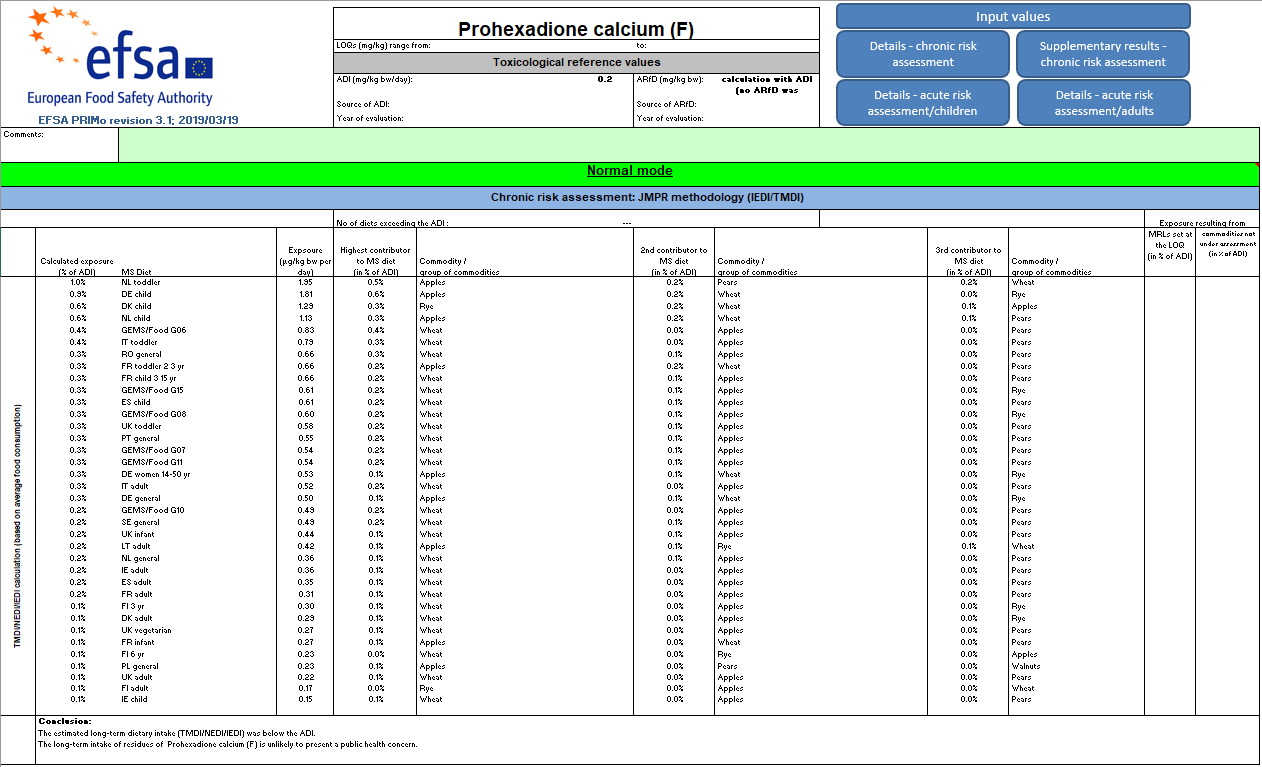
List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

| Data point | Author(s) | Year | Title Company Report No.  Source (where different from company) GLP or GEP status Published or not | Vertebrate study  Y/N | Owner |
| --- | --- | --- | --- | --- | --- |
| KCA 6.1/01 | Stewart, J. M. | 2002 | *Storage stability of BAS 125 W and metabolite BW 125 31 F in apples*  2001/5002487  GLP  Unpublished | N | BASF |
| KCA 6.1/02 | Mackenrot, H. C. | 1995 | *Investigation of the storage stability of prohexadione-Ca in wheat: Test of storage stability in green matter, grain and straw*  95/10624  GLP  Unpublished | N | BASF |
| KCA 6.2.1/01 | Patel, J. R., et. Al. | 1998 | *Metabolism of 14C-BAS 125 W in apples*,  1997/5005  GLP  Unpublished | N | BASF |
| KCA 6.2.1/02 | Steginsky, C. A., et al. | 1997 | *Metabolism of 14 C BAS 125 W (Prohexadione Calcium) in peanut*  1997/5341  GLP  Unpublished | N | BASF |
| KCA 6.6.1 | Steginsky, C. A., et al. | 1996 | *Confined rotational crop study with 14C-BAS 9054 W (Prohexadione-Calcium*  1996/5005  GLP  Unpublished | N | BASF |

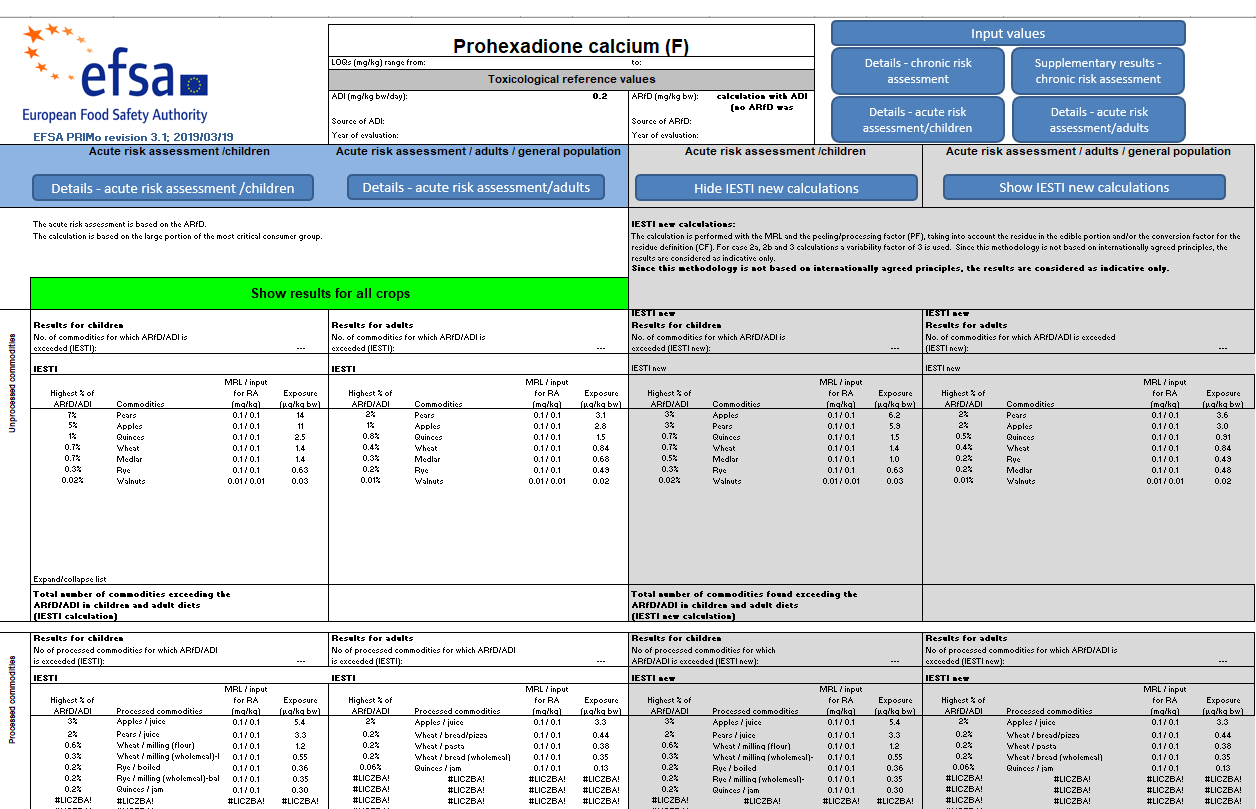
1. Detailed evaluation of the additional studies relied upon

No additional studies was carried.

1. Pesticide Residue Intake Model (PRIMo)
   1. TMDI calculations



* 1. IESTI calculations



1. Additional information provided by the applicant