Modification of the existing maximum residue levels for prochloraz in various commodities

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant ADAMA Agriculture BV submitted an application to the competent national authority in Belgium (evaluating Member State (EMS)) to modify the existing maximum residue levels (MRLs) for the active substance prochloraz in sugar beet root and in liver and kidney of swine and ruminant. The data submitted in support of the request were found to be sufficient to derive an MRL proposal for sugar beet root. Residues in sugar beet tops from the new use were found to contribute significantly to the livestock exposure. As the dietary burden needs to be calculated including all feed items and since not all information is available at the moment, EFSA proposes to assess the magnitude of prochloraz residues in animal commodities under the currently ongoing review of prochloraz MRLs according to Article 12 of Regulation (EC) No 396/2005. Adequate analytical methods are available to control the residues of prochloraz residues in plant and animal matrices. The risk assessment performed by EFSA gave an indication that residues of prochloraz may lead to an exceedance of the acceptable daily intake (ADI). Thus, before the MRL for sugar beet is amended, it is necessary that a comprehensive, refined risk assessment is performed, taking into account all existing uses of prochloraz and the intended new use on sugar beet. Considering that the MRL review for prochloraz is currently ongoing, the results of the comprehensive risk assessment will be available in due time.

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, ADAMA Agriculture BV submitted an application to the competent national authority in Belgium (evaluating Member State (EMS)) to modify the existing maximum residue levels (MRLs) for the active substance prochloraz in sugar beet root and in liver and kidney of swine and ruminant. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 2 October 2017. To accommodate for the intended uses of prochloraz on sugar beet and fodder beet, the EMS proposed to raise the existing MRLs from 0.1 mg/kg to 0.3 mg/kg in sugar beet root, and to 0.7 mg/kg in ruminant kidney, to 3 mg/kg in ruminant liver, to 0.6 mg/kg in swine kidney and to 2 mg/kg in swine liver. The EMS also submitted new data and derived MRL proposals for prochloraz according to the residue definition which was proposed during the peer review but so far has not been enforced.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC and the additional data provided by the EMS in the framework of this application, the following conclusions are derived.

The metabolism of prochloraz following foliar, seed treatment and local application was investigated in fruit crops, cereals and pulses/oilseeds and in mushrooms. Due to a similar metabolic pattern observed in three crop groups, the peer review concluded that the metabolism of prochloraz in plant commodities is addressed.

Studies investigating the effect of processing on the nature of prochloraz (hydrolysis studies) demonstrated that the active substance is stable.

The peer review also concluded that the metabolic profile observed in rotational crops was similar to that in primary crops.

Based on the metabolic pattern identified in metabolism studies, hydrolysis studies and the toxicological significance of metabolites, the residue definitions for plant products were proposed by the peer review as 'the sum of prochloraz, BTS 44595 and BTS 44596, expressed as prochloraz' for enforcement and for risk assessment as 'the sum of prochloraz and its metabolites containing the 2,4,6-TCP moiety, expressed as prochloraz'. These residue definitions are applicable to primary crops, rotational crops and processed products. It is noted that the current enforcement residue definition in Regulation (EC) No 396/2005 is established as 'sum of prochloraz and its metabolites containing the 2,4,6-TCP moiety, expressed as prochloraz' and all conclusions derived under this assessment will be based on the currently applicable enforcement residue definition, pending the outcome of the MRL review for prochloraz according to Article 12 of Regulation (EC) No 396/2005.

EFSA concluded that for the sugar beets assessed in this application, metabolism of prochloraz in primary and rotational crops and the possible degradation in processed products has been sufficiently addressed. Sufficiently validated analytical methods are available to quantify prochloraz residues in sugar beet roots and leaves.

The available residue trials are sufficient to derive an MRL proposal of 0.2 mg/kg for sugar beet root for the existing enforcement residue definition. Additionally, an MRL proposal of 0.15 mg/kg was derived for sugar beet root anticipating the residue definition proposed by the peer review.

Specific studies investigating the magnitude of prochloraz residues in processed sugar beet root have not been submitted and would be required.

Based on the confined rotational crop study, EFSA concluded that significant residues of prochloraz and its metabolites will not be present in rotational crops if the active substance is used according to the intended use pattern.

Sugar and fodder beet root and leaves can be fed to livestock. An indicative livestock dietary burden was calculated for the current enforcement residue definition, considering existing MRLs in Regulation (EC) No 396/2005 and the residues in sugar/fodder beet from the intended uses. The livestock exposure was above the trigger value of 0.1 mg/kg dry matter (DM) for all relevant animal species with citrus dried pulp and sugar beet tops being the main contributors. EFSA is of the opinion that the calculated dietary burden is not reliable since it was calculated using the existing MRLs and lacking residue data in the relevant feed items/by-products. It is therefore proposed that MRLs for prochloraz in animal commodities are revised under the currently ongoing Article 12 MRL review considering the new use on sugar/fodder beet and all authorised European uses of prochloraz and taking into account the different enforcement residue definition proposed by the peer review.
The toxicological profile of prochloraz was assessed in the framework of the EU pesticides peer review and the data were sufficient to derive an acceptable daily intake (ADI) of 0.01 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 0.025 mg/kg bw.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). The estimated long-term dietary intake accounted for a maximum of 106% of the ADI (WHO Cluster diet B), indicating that a long term consumer intake concern cannot be excluded. The contribution of residues in the sugar beet root to the overall long-term exposure accounted for a maximum of 14% of the ADI (UK toddler diet). No short-term intake concerns were identified for prochloraz residues in sugar beet.

The results of the long-term dietary risk assessment give an indication for a potential chronic risk related to prochloraz residues. Further refinements of the dietary intake calculations would be necessary, taking into account all existing uses of prochloraz and the intended use on sugar beet and the supporting residue data, before a decision on the amendment of the existing MRL for sugar beet root is taken. Considering that the MRL review for prochloraz is currently ongoing, the results of the comprehensive risk assessment will be available in due time.

EFSA proposes to amend the existing MRLs as reported in the summary table below.

Full details of all endpoints and the consumer risk assessment can be found in Appendices B to D.

| Code(a) | Commodity       | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification                                      |
|---------|-----------------|-------------------------|-------------------------|------------------------------------------------------------|
| 0900010 | Sugar beet roots| 0.1                     | No proposal             | Based on the submitted residue data, a MRL of 0.2 mg/kg is calculated for the NEU use. For the new residue definition derived in the peer review, a MRL of 0.15 mg/kg would be appropriate. A long-term consumer health concern was identified for the existing prochloraz MRLs. Lacking specific processing studies and detailed information on the existing uses of prochloraz, the risk assessment could not be further refined. |
| 1011030 | Swine liver     | 0.1*                    | No proposal             | The MRL proposals in swine and ruminant kidney and liver will be considered in the framework of the Article 12 MRL review. |
| 1011040 | Swine kidney    | 0.1*                    |                         |                                                            |
| 1012030 | Bovine liver    | 2.0                     |                         |                                                            |
| 1013030 | Sheep liver     | 0.1*                    |                         |                                                            |
| 1014030 | Goat liver      | 0.1*                    |                         |                                                            |
| 1012040 | Bovine kidney   | 0.5                     |                         |                                                            |
| 1013040 | Sheep kidney    | 0.1*                    |                         |                                                            |
| 1014040 | Goat kidney     | 0.1*                    |                         |                                                            |

MRL: maximum residue level; NEU: northern Europe.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
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Assessment

The detailed description of the intended uses of prochloraz which are the basis for the current MRL application is reported in Appendix A.

Prochloraz is the ISO common name for N-propyl-N-[2-(2,4,6-trichlorophenoxy)ethyl]imidazole-1-carboxamide (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix E.

Prochloraz was evaluated in the framework of Regulation (EC) No 1107/2009 with Ireland designated as rapporteur Member State (RMS) for the representative uses as a fungicide on cereals (foliar spray and seed treatment) and mushrooms. The Additional Report to the draft assessment report (AR) prepared by the RMS has been peer reviewed by EFSA (2011).

Prochloraz was approved for the use as a fungicide. A restriction is set for the outdoor uses regarding the application rate which shall not exceed 450 g/ha per application.

The EU MRLs for prochloraz (sum of prochloraz and its metabolites containing the 2,4,6-trichlorophenol moiety expressed as prochloraz) are established in Annexes II and III B of Regulation (EC) No 396/2005. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) is currently ongoing and is expected to be finalised by mid 2018.

EFSA based its assessment on the evaluation report submitted by the EMS Belgium (Belgium, 2017), the Draft Assessment Report (DAR) and Additional Report to the Draft Assessment Report (Ireland, 2007, 2010, 2011) prepared under Commission Regulation (EC) No 33/2008 and the conclusion on the peer review of the pesticide risk assessment of the active substance prochloraz (EFSA, 2011).

For this application, the data requirements established in Regulation (EU) No 544/2011 and the guidance documents applicable at the date of submission of the MRL application to the EMS are applicable (European Commission, 1997a-g, 2000, 2010a,b, 2017; OECD, 2011, 2013). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011.

A selected list of end points of the studies assessed by the European Food Safety Authority (EFSA) in the framework of the this MRL application, including the end points of relevant studies assessed previously, submitted in support of the current MRL application, are presented in Appendix B.

The evaluation report submitted by the EMS (Belgium, 2017) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available as background documents to this reasoned opinion.

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

The nature of prochloraz in primary plants was investigated in the framework of the EU pesticides peer review in cereals/grass crop group (wheat and barley) following foliar and seed treatment and in oilseeds/pulses (rapeseed) and fruit crops (apple) following foliar treatment or local application. The

1 Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009 p. 1–50.

2 Commission Implementing Regulation (EU) No 1143/2011 approving the active substance prochloraz, in accordance with Regulation (EC) No 1107/2009 of the European parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 and Commission Decision 2008/934/EC. OJ L 293, 11.11.2011, p. 26–30.

3 Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.03.2005, p. 1–16.

4 Commission Regulation (EC) No 33/2008 of 17 January 2008 laying down detailed rules for the application of Council Directive 91/414/EEC as regards a regular and an accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of that Directive but have not been included into its Annex I. OJ L 15, 18.1.2008, p. 5–12.

5 Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.
fate of prochloraz was also investigated in mushroom after application to the surface of the compost bed (Ireland, 2007; EFSA, 2011).

Following foliar applications, prochloraz is rapidly and extensively metabolised. The parent molecule is only detected at significant levels in the samples collected just after the treatment, but with a fast decrease and proportions typically below 10% total radioactive residue (TRR) in the days following the application. In all plant groups, the metabolism proceeds first by the cleavage of the imidazole ring, leading to the metabolite BTS 44596 which is further degraded to the amide metabolite BTS 44595. In contrast, metabolism observed in mushroom was low with prochloraz remaining by far the most abundant compound, representing 70% TRR 30 days after application. The peer review concluded that sufficient studies are available to conclude on a similar metabolism of prochloraz in all plant commodities (EFSA, 2011).

For the sugar and fodder beet under consideration, metabolism of prochloraz is considered sufficiently addressed and new studies are not necessary.

### 1.1.2. Nature of residues in rotational crops

Sugar and fodder beet can be grown in a crop rotation. According to the soil degradation studies which were investigated in the framework of the EU pesticides peer review, in laboratory studies prochloraz exhibited moderate to very high persistence, forming major (> 10% applied radioactivity (AR)) metabolites BTS 44596 (max. 12.8% AR) and BTS 40348 (max. 13.9% AR), which exhibited low to moderate and low to high persistence, respectively. The field studies indicate that most critical DT$_{50}$ value for prochloraz is 244 days, 35.8 days for metabolite BTS 44596 and 266 days for metabolite BTS 44595. The DT$_{90}$ value of metabolite BTS 40348 according to soil degradation studies accounts for a maximum of 402 days (EFSA, 2011).

Consequently, the nature and magnitude of prochloraz and its metabolites in rotational crops has to be further investigated.

The nature of prochloraz in rotational crops has been investigated in cereals/grass, leafy and root crops after bare soil treatment (EFSA, 2011). In study I, soil was treated with 1.1 kg prochloraz and 30, 120 and 365 days later wheat, lettuce and radish were planted/sown (Ireland, 2007). In study II, prochloraz was applied on the soil at a rate of 1.08 kg/ha and 29 days later spring barley, cabbage and potato were planted/sown (Ireland, 2010). Additionally, there are two studies available where wheat and potato were sown/planted as rotational crops following the harvest of cereal which have been treated with labelled prochloraz at application rates of 1.0–0.94 kg/ha (Study III).

**Study I:** Parent prochloraz and metabolite BTS 44596 in edible plant matrices were below 10% TRR (< 0.01 mg/kg) at all plant-back intervals (PBIs). Metabolite BTS 44595 accounted for a maximum of 19% TRR (< 0.01 mg/kg) in lettuce (120-day PBI) and was still present in radish roots at PBI of 365 days (40% TRR, 0.011 mg/kg). Metabolite BTS 45186 was at low levels identified in lettuce, whereas metabolite BTS 9608 was present above 10% TRR (0.003–0.013 mg/kg) in all edible crop matrices at all PBIs.

**Study II:** Parent prochloraz in mature plant parts was below 10% TRR (< 0.01 mg/kg, except in mature straw (0.03 mg/kg)). Metabolite BTS 40348 was the major component exceeding 10% TRR in most plant commodities with actual levels in mature edible parts below 0.01 mg/kg. Similarly, metabolite BTS 9608 was present above 10% TRR in cabbage and radish, but in mature edible parts residues were below 0.01 mg/kg.

**Study III:** The TRRs were below 0.01 mg/kg in potato tubers and winter wheat grown as rotational crops for plant back intervals >200 days.

The peer review concluded that the metabolic profile observed in rotational crops was similar to that in primary crops, with metabolites BTS 44595, BTS 44596, BTS 45186 (2,4,6-TCP) and BTS 9608 (2,4,6-trichlorophenoxyacetic acid) being identified as the major components of the residue (EFSA, 2011).

### 1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of prochloraz was investigated in the framework of the EU pesticides peer review which concluded prochloraz to be stable under standard hydrolysis conditions simulating pasteurisation, baking/brewing/boiling and sterilisation (EFSA, 2011).

The effect of processing on the nature of metabolites BTS 44595 and BTS 44596 has not been investigated and the need for such studies will be considered in the framework of the MRL review of prochloraz according to Article 12 of Regulation (EC) No 396/2005.
1.1.4. Methods of analysis in plants

The analytical methods for the determination of prochloraz residues according to the current enforcement residue definition (sum of prochloraz and its metabolites containing the 2,4,6-TCP moiety, expressed as prochloraz) have been submitted for the peer review, but not assessed (Ireland, 2010). Additional method validation data and an independent laboratory validation (ILV) have been submitted in the framework of the current assessment (Belgium, 2017). It is concluded that sufficiently validated analytical methods are available for the determination of prochloraz and its metabolites BTS 44595 and BTS 44595 as 2,4,6-TCP moiety in high water content matrices at the limit of quantification (LOQ) of 0.02 mg/kg and in high starch content matrices at the LOQ of 0.05 mg/kg.

The availability of the analytical enforcement methods for the determination of prochloraz and its metabolites according to the enforcement residue definition proposed by peer review (sum of prochloraz, BTS 44595 and BTS 44596, expressed as prochloraz) was investigated in the framework of the EU pesticides peer review (EFSA, 2011) and in the studies submitted for the current assessment (Belgium, 2017). It is concluded that a method using high-performance liquid chromatography with mass spectrometry (HPLC–MS/MS) is sufficiently validated for the individual determination of prochloraz, BTS 44595, BTS44596 in plant matrices with high water and high starch content at the validated LOQ of 0.01 mg/kg for each compound.

1.1.5. Stability of residues in plants

The stability of prochloraz and its metabolites was investigated in the framework of the EU pesticides peer review and in new studies submitted under the current assessment (EFSA, 2011; Belgium, 2017). In high water/high starch content matrices relevant for the current assessment, prochloraz and its metabolites BTS 44595 and BTS 44596 are stable for 6 months when stored at –18°C. The samples in the storage stability study were analysed using the proposed analytical enforcement method which is the same method used to analyse residue field trial samples.

In addition, the peer review concluded that incurred residues of prochloraz, determined as 2,4,6-TCP moiety, are stable for 12 months in sugar beet root and for 24 months in maize leaves when stored at –20°C.

Residue trial samples of sugar beets before analysis were stored at –18°C for 151 days, which is shorter than the period of 6 months for which the storage stability has been demonstrated for the parent and its metabolites in sugar beet root and leaves. EFSA concludes that additional studies are not required to address the storage stability of prochloraz and its metabolites in beet roots and tops.

1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies, the results of hydrolysis studies, the toxicological significance of metabolites and the capabilities of enforcement analytical methods, the following residue definitions were proposed by the peer review (EFSA, 2011):

- Residue definition for risk assessment: sum of prochloraz and its metabolites containing the 2,4,6-TCP moiety, expressed as prochloraz
- Residue definition for enforcement: sum of prochloraz, BTS 44595 and BTS 44596, expressed as prochloraz

It is noted that the enforcement residue definition in Regulation (EC) No 396/2005 is established as ‘sum of prochloraz and its metabolites containing the 2,4,6-TCP moiety, expressed as prochloraz’. Since this residue definition derived by the peer review has not been implemented in Regulation (EC) No 396/2005 yet, EFSA derived the MRL proposals for the existing and the proposed residue definition.

EFSA notes that the assessment of the existing prochloraz MRLs according to Article 12 of Regulation (EC) No 396/2005 will take into consideration the residue definitions proposed by the peer review.
1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the intended northern Europe (NEU) uses on sugar and fodder beets, the applicant submitted in total 17 residue trials on sugar beet, which were performed in Germany, Belgium, France and The Netherlands over growing seasons of 2001, 2012 and 2014.

All 17 residue trial samples were analysed for residues according to the current enforcement residue definition, whereas 13 of these trials provided information also on residues according to the enforcement residue definition proposed by the peer review. Residue trial samples of roots, whole plant, leaves and leaves with tops were analysed for residues. Some deviations from the intended Good Agricultural Practice (GAP) use patterns related to the application rate were noted but as these were within the acceptable range of 25%, EFSA accepted the submitted residue trials. The analytical methods used to analyse residue trial samples have been sufficiently validated (Belgium, 2017).

The submitted residue data are sufficient to derive an MRL proposal of 0.2 mg/kg for the current enforcement residue definition, which is lower than the MRL proposed by the EMS (0.3 mg/kg); the difference was caused because in the MRL calculation (OECD calculator) performed by the EMS the residue trial at the LOQ was not flagged with an asterisk.

Additionally, an MRL proposal of 0.15 mg/kg was derived in sugar beet root accommodating the residue definition proposed by the peer review; in addition, MRL proposals for sugar and fodder beet tops were derived in case MRLs will be set for feed items in the future.

1.2.2. Magnitude of residues in rotational crops

Field studies investigating the residues of prochloraz in rotational crops are not available. Based on the confined studies where bare soil or primary plant was treated with prochloraz at rates 0.94–1.1 kg/ha, the peer review concluded that no residues above the combined LOQ of 0.03 mg/kg are expected in rotational crops (except straw) when residues are analysed for individual metabolites according to the proposed enforcement residue definition. However, potential values close to the LOQ of 0.05 mg/kg in some crops for the plant-back interval of 30 days, when analysed for total residues as 2,4,6-TCP (according to the existing enforcement residue definition), are not excluded (EFSA, 2011).

As the intended total seasonal application rate of prochloraz on sugar/fodder beets is lower than the application rate in the confined rotational crop studies, EFSA concludes that significant residues of prochloraz and its metabolites will not be present in rotational crops provided that the active substance is used according to the intended use pattern.

1.2.3. Magnitude of residues in processed commodities

New studies investigating the effect of processing on the magnitude of prochloraz residues in processed sugar beet roots have not been submitted under the current assessment. In order to allow a more refined dietary risk assessment, such studies would be required, in particular for a product like sugar beet which is consumed almost exclusively in form of sugar. Thus, processing studies shall be performed for sugar; in these processing studies the residue definitions for prochloraz which may be revised in the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005 need to be taken into account.

1.2.4. Proposed MRLs

The submitted residue data are sufficient to derive a MRL proposal for sugar beet root according to the current enforcement residue definition. Additionally, an MRL proposal for sugar beet root was derived anticipating the enforcement residue definition proposed by the peer review.

2. Residues in livestock

Sugar/fodder beet roots and tops can be used as a livestock feed, and therefore, the potential carry-over of prochloraz residues in the commodities of animal origin has to be assessed.

Currently, according to Regulation (EC) No 396/2005, the existing MRLs for prochloraz are set above the LOQ in the following crops that can be used for livestock feed: citrus fruit (10 mg/kg), peas (0.3 mg/kg), linseed, sunflower seed, rapeseed (0.5 mg/kg), barley, oat, rice (1 mg/kg), wheat and rye (0.5 mg/kg) and sugar beet roots (0.1 mg/kg). In order to estimate how the residues in sugar and fodder beet root/tops from the new uses would affect the actual dietary burden, EFSA first calculated
the dietary burden for the existing MRLs and then added the residue data from the new uses on beets. For citrus fruit and sunflower seed the risk assessment values were available from the JMPR evaluation (FAO, 2004), whereas for the remaining commodities the existing MRLs were used as input values. It is noted that for many by-products the input values were not available. The calculation was performed according to the OECD methodology (OECD, 2013).

The calculated dietary burdens exceed the trigger value of 0.1 mg/kg dry matter (DM) for all livestock species and are mainly driven by residues in citrus from the existing uses and sugar beet tops from the new intended use. Results indicate that the new intended use of prochloraz on sugar beet would require further investigation of the nature and magnitude of prochloraz residues in livestock.

However, since the calculated dietary burden is affected by a high level of uncertainty, EFSA proposes that the magnitude of prochloraz residues in animal matrices is assessed under the Article 12 MRL review, taking into consideration prochloraz residues in the sugar/fodder beet from the intended use and from all authorised European uses and taking into account the different enforcement residue definition proposed by the peer review.

2.1. Nature of residues and methods of analysis in livestock

The nature of prochloraz residues in livestock has been investigated in the framework of the EU pesticides peer review in the metabolism studies with lactating cows, goats and laying hens (EFSA, 2011). All studies were performed with parent prochloraz, although the metabolism studies have shown the parent to be extensively metabolised and not present in plants. These studies were considered acceptable by the peer review since the main metabolites identified in plants are also the major metabolites in ruminant matrices.

Prochloraz was extensively metabolised and only detected in goat liver and fat, but at less than 6% TRR. Radioactive residues were mainly composed of the metabolites BTS 44596, BTS 44595 and BTS 9608, present in almost all matrices and in significant proportions, (above 15% TRR). Metabolite 2,4,6-TCP was also identified as a major metabolite in cow liver (19% TRR). In addition, metabolite BTS 54906 was observed as the most abundant component in milk (58% TRR), but in the cow study only. As its presence was not confirmed in the goat metabolism, or in the cow feeding study even at the highest dose rate, it was finally concluded that BTS 54906 should not be considered as a significant metabolite in milk (EFSA, 2011).

In laying hens, the highest TRR were identified in liver (0.34–0.88 mg eq/kg), and eggs (up to 1.68 mg eq/kg in yolk), with lower levels present in fat (0.03–0.08 mg eq/kg) and muscle (0.02–0.07 mg eq/kg). The main compound in eggs was metabolite BTS 44596 (0.83 mg/kg; 55% TRR in egg yolk) with metabolites BTS 44596, BTS 44770 and BTS 3037 being present at lower levels. In fat, liver and muscle, the main metabolites detected were BTS 44596 (0.14 mg/kg (15% TRR) in liver; 0.007 mg/kg (15% TRR) in muscle and 0.017 mg/kg (17% TRR) in fat) and BTS 9608 (0.14 mg/kg (16% TRR) in liver; 0.03 mg/kg (39% TRR) in muscle and 0.012 (14% TRR) in fat).

Considering that BTS 44595 and BTS 44596 are relevant markers for the residues in all animal matrices, the peer review decided to define the residue for enforcement as 'sum of prochloraz, BTS 44595 and BTS 44596, expressed as prochloraz'. For risk assessment, the residue definition was proposed as 'sum of prochloraz and its metabolites containing the 2,4,6-TCP moiety, expressed as prochloraz'. For ruminants, a conversion factor for risk assessment of 2 was derived from the cow and goat metabolism studies (EFSA, 2011).

The residue definition for enforcement in animal matrices according to Regulation (EC) No 396/2005 is set as 'sum of prochloraz and its metabolites containing the 2,4,6-TCP moiety, expressed as prochloraz'. EFSA notes that the assessment of the existing prochloraz MRLs according to Article 12 of Regulation (EC) No 396/2005 will take into consideration also the residue definitions proposed by the peer review.

Sufficiently validated analytical enforcement methods are available to determine prochloraz and its metabolites BTS 44595 and BTS 44596 either individually or as 2,4,6-TCP moiety in all animal matrices, milk and eggs.

The stability of 2,4,6-TCP moiety under frozen storage has been demonstrated for 12 months in muscle, eggs and milk. According to new storage stability studies submitted in the framework of the current application, prochloraz, BTS 44595 and BTS 44596 are individually stable under frozen storage for 3 months in muscle, fat, liver, eggs and in milk (except metabolite BTS 44595, for which storage stability data are missing). Since prochloraz and its metabolites are individually stable in liver and fat, it can be concluded that also 2,4,6-TCP moiety will be stable for 3 months in these matrices.
2.2. Magnitude of residues in livestock-

The magnitude of prochloraz residues in animal matrices was investigated in feeding studies with cow in the framework of the EU pesticides peer review (EFSA, 2011). Dairy cows were dosed prochloraz for 28 days at a level of 200, 600 and 2,000 mg prochloraz per day (0.308, 0.92 and 3.08 mg/kg body weight (bw) per day) (Ireland, 2007). Cow tissues were analysed for the total 2,4,6-trichlorophenol containing residues; milk samples were analysed for residues of prochloraz, and its individual metabolites BTS 44596, BTS 54906 and BTS 54908.

The highest residues were found in cow liver (from maximum of 3.3 mg/kg in the lowest dose group up to 24 mg/kg in the highest dose group), followed by kidney (0.59 – 3.4 mg/kg), with lower residues observed in fat (0.24 – 1.6 mg/kg) and muscle tissues (< 0.05 – 0.49 mg/kg). The results of milk analysis demonstrated no presence of metabolites BTS 54906 and BTS 54908, whereas metabolite BTS 44596 was present in milk only at the highest administered dose and ranged from < 0.05 to 0.13 mg/kg.

For laying hens, there is no feeding study available. For the current enforcement residue definition in Regulation (EC) No 396/2005, the metabolism data considering TRR could be tentatively used as a surrogate of feeding studies to assess the total residues in poultry tissues and eggs.

Under the current assessment, EFSA did not assess the impact of prochloraz residues in sugar beet on the magnitude of residues in animal commodities since the calculated dietary burden is not completely reliable. Therefore, EFSA proposes that the magnitude of prochloraz residues in animal matrices is assessed under the comprehensive Article 12 MRL review, taking into consideration prochloraz residues in the sugar/fodder beet from the intended use and from all authorised European uses.

3. Consumer risk assessment

EFSA performed a dietary risk assessment using revision 2 of the EFSA PRIMo (EFSA, 2007). This exposure assessment model contains food consumption data for different subgroups of the EU population and allows the acute and chronic exposure assessment to be performed in accordance with the internationally agreed methodology for pesticide residues (FAO, 2016).

The toxicological reference values for prochloraz used in the risk assessment (i.e. acceptable daily intake (ADI) and acute reference dose (ARfD) values) were derived in the framework of the EU pesticides peer review (EFSA, 2011). The risk assessment was performed for the risk assessment residue definition derived by EFSA (2011), i.e. sum of prochloraz and its metabolites containing the 2,4,6-TCP moiety, expressed as prochloraz.

3.1. Short-term (acute) dietary risk assessment

The short-term exposure calculations were based on the highest residue (HR) value in sugar beet roots derived from the supervised field trials submitted under the current assessment (Appendix D.2). For residues in sugar beet root, the short-term exposure did not exceed the ARfD set for prochloraz (see Appendix B).

3.2. Long-term (chronic) dietary risk assessment

The long-term exposure assessment was performed, taking into account the STMR value derived for sugar beet root from the residue trials assessed in this application. Additionally, the STMR values available from the JMPR evaluation (FAO, 2004) for citrus fruits and sunflower seed were included in the exposure calculation. For the remaining commodities the existing EU MRLs according to Commission Regulation (EU) No 520/2011 were used as input values. The complete list of input values is presented in Appendix D.2.

The estimated long-term dietary intake was in the range of 10 – 106% of the ADI (WHO Cluster diet B), indicating a potential risk to consumer health from the long-term intake of prochloraz residues. The contribution of residues in the sugar beet root to the overall long-term exposure accounted for a maximum of 14% of the ADI (UK toddler diet) (see Appendix B). It is noted that in a risk assessment scenario which does not include the intended use on sugar beets, the long-term consumer intake...
calculation exceeds the ADI. Thus, it is necessary that a comprehensive risk assessment is performed, taking into account all existing uses and the intended use on sugar beet and the supporting residue data, before a decision on the amendment of the existing MRL for sugar beet roots is taken. Considering that the MRL review for prochloraz is currently ongoing, the results of the comprehensive risk assessment will be available in due time.

4. Conclusion and Recommendations

The data submitted in support of this MRL application were found to be sufficient to derive an MRL proposal for sugar beet root.

Based on the risk assessment results, EFSA concluded that a risk from a long-term intake of prochloraz residues cannot be excluded also when the new use on sugar beets is not included in the calculation. Thus, it is necessary that a comprehensive risk assessment is performed, taking into account all existing uses of prochloraz and the intended use on sugar beet and the supporting residue data, before a decision on the amendment of the existing MRL for sugar beet root is taken. Considering that the MRL review for prochloraz is currently ongoing, the results of the comprehensive risk assessment will be available in due time.

The MRL recommendations are summarised in Appendix B.4.

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Abbreviations

a.s. active substance
ADI acceptable daily intake
AR applied radioactivity
ARfD acute reference dose
BBCH growth stages of mono- and dicotyledonous plants
bw body weight
DALA days after last application
DAR draft assessment report
DAT days after treatment
DM dry matter
DT₉₀ period required for 90% dissipation (define method of estimation)
EC emulsi
fi
EC
EDS electron capture detector
EMS evaluating Member State
eq residue expressed as a.s. equivalent
FAO Food and Agriculture Organization of the United Nations
GAP Good Agricultural Practice
GC gas chromatography
GC-ECD gas chromatography with electron capture detector
GC-FID gas chromatography with flame ionisation detector
GC-MS gas chromatography with mass spectrometry
GC-MS/MS gas chromatography with tandem mass spectrometry
HPLC-MS high-performance liquid chromatography with mass spectrometry
HPLC-MS/MS high-performance liquid chromatography with tandem mass spectrometry
HR highest residue
IEDI international estimated daily intake
IESTI international estimated short-term intake
ILV independent laboratory validation
ISO International Organisation for Standardisation
IUPAC International Union of Pure and Applied Chemistry
JMPR Joint FAO/WHO Meeting on Pesticide Residues
LOQ limit of quantification
MRL maximum residue level
NEU northern Europe
OECD Organisation for Economic Co-operation and Development
PBI plant-back interval
PF processing factor
PHI preharvest interval
PRIMo (EFSA) Pesticide Residues Intake Model
RA risk assessment
RD residue definition
RMS rapporteur Member State
SANCO Directorate-General for Health and Consumers
SEU southern Europe
STMR supervised trials median residue
TAR total applied radioactivity
TCP trichlorophenoxyacetic acid
TRR total radioactive residue
UV ultraviolet (detector)
WHO World Health Organization
## Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

| Crop and/or situation | NEU, SEU, MS or country | F G or I<sup>(a)</sup> | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|-------------------------|------------------------|-----------------------------------|-------------|--------------------------|-------------------------|-----------|---------|
|                       |                         |                        |                                   | Type<sup>(b)</sup> | Conc. a.s. | Method kind | Range of growth stages & season<sup>(c)</sup> | Number min-max | Interval between application (min) | Water L/ha min-max | Rate Unit |                              |
| Sugar beet and fodder beet | NEU | F | Fungal leaf infection | EC | 400 g/L | Foliar spray | BBCH 16–39 and BBCH 49 | 2 | 14 | 67–200 | 200–600 | 400 g a.s./ha | 28 | Critical GAP |
| Fodder beet | NEU (BE) | F | *Erysiphe betae*, *Uromyces betae* | EC | 400 g/L | Foliar spray | BBCH 16–49 (at first symptoms July–Sept) | 2 | 14 | 133–200 | 200–300 | 400 g a.s./ha | 28 | BE: now 1 L/ha against Uromyces and Erysiphe is on label without specific BBCH-timing |
| Sugar beet, fodder beet | NEU (CZ) | F | *Cercospora beticola* | EC | 400 g/L | Foliar spray | BBCH 16–49 (sugar beet) BBCH 16–39 and 49 (fodder beet) | 2 | 28 | 67–200 | 200–600 | 400 g a.s./ha | 28 |
| Sugar beet | NEU (SK) | F | *Erysiphe betae*, *Cercospora beticola* | EC | 400 g/L | Foliar spray | BBCH 16–39 and 49 | 2 | 14 | 100–133 | 300–400 | 400 g a.s./ha | 28 |

NEU: northern European Union; SEU: southern European Union; MS: Member State; EC: emulsifiable concentrate; MRL: maximum residue level; a.s.: active substance; GAP: Good Agricultural Practice.

(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).

(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide formulation types and international coding system.

(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.

(d): PHI: minimum preharvest interval.
## Appendix B – List of end points

### B.1. Residues in plants

#### B.1.1. Nature of residues and methods of analysis in plants

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

| Primary crops (available studies) | Crop groups | Crop(s) | Application(s) | Sampling (DAT/DALA) | Comment/Source |
|-----------------------------------|-------------|---------|----------------|---------------------|----------------|
| Fruit crops                       | Apple       | Local treatment: 1 × 102 g/L | 0, 16, 24, 33, 48, 63 DAT | 14C-prochloraz radiolabelled in phenyl ring (Ireland, 2007) |
| Cereals/grass                     | Wheat       | Forage: 0 DALA Hay: 24 DALA Straw, chaff, grain: 53 DALA Forage: 66 DAT Hay: 90 DAT Straw, chaff, grain: 118 DAT | 14C-prochloraz radiolabelled in phenyl ring (Ireland, 2010; EFSA, 2011) |
|                                  |             | Seed treatment: 1 × 36 g/ha (20 g/100 kg seeds) | | |
|                                  |             | Foliar spray: 1 × 800-900 g/ha (BBCH 16) Microsyringe: 1 × 0.4 mg/plant (BBCH 16) | Roots, shoots, leaves, grain: BBCH 16 (except grain), 59 and 92 | 14C-prochloraz radiolabelled in phenyl and imidazole rings (Ireland, 2010; EFSA, 2011) |
|                                  |             | 1 × 450 g/ha (BBCH 39) | 20 DAT and at maturity | 14C-prochloraz radiolabelled in phenyl ring (Ireland, 2007) |
|                                  | Barley      | Foliar: 2 × 540 g/ha (BBCH 51/55 and 55/59) | 41 DALA | 14C-prochloraz radiolabelled in phenyl ring (Ireland, 2010; EFSA, 2011) |
|                                  |             | 1) 2 × 600 g/ha (BBCH ca. 30 and 40) 2) 2 × 3,000 g/ha (BBCH ca. 30 and 40) | 1 DAT, 1 DALA, 37, 86 DALA (maturity) | 14C-prochloraz radiolabelled in phenyl ring (Ireland, 2010; EFSA, 2011) |
|                                  |             | Spray solution droplets on leaves: a) 1 × 663 g/ha b) 1 × 6,130 g/ha | 0, 18/19 DAT, 83-90 DAT (maturity) | 14C-prochloraz radiolabelled in phenyl ring (Ireland, 2007) |
|                                  | Miscellaneous | Surface of compost bed (post emergence): 1 × 3 g/m² | 8, 16, 23, 30, 37 DAT | 14C-prochloraz radiolabelled in phenyl ring (Ireland, 2007) |
| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) | Comment/Source |
|-------------------------------------|-------------|---------|----------------|-----------|----------------|
| Root/tuber crops                    | Radish      | a) Soil: $1 \times 1.11$ kg a.s./ha  
b) Soil: $1 \times 1.08$ kg a.s./ha | a) 30, 120, 365 days  
b) 29 | $^{14}$C-prochloraz radiolabelled in phenyl ring (Ireland, 2007; EFSA, 2011) |
| Potato                              | Soil: $1 \times 1.08$ kg a.s./ha | 29 | $^{14}$C-prochloraz radiolabelled in phenyl ring (Ireland, 2010; EFSA, 2011) |
| Leafy crops                         | Cabbage     | Soil: $1 \times 1.08$ kg a.s./ha | 29 | $^{14}$C-prochloraz radiolabelled in phenyl ring (Ireland, 2010; EFSA, 2011) |
| Lettuce                             | Soil: $1 \times 1.11$ kg a.s./ha | 30, 120, 365 days | $^{14}$C-prochloraz radiolabelled in phenyl ring (Ireland, 2007; EFSA, 2011) |
| Cereal (small grain)                | Wheat       | Soil: $1 \times 1.11$ kg a.s./ha | 30, 120, 365 days | $^{14}$C-prochloraz radiolabelled in phenyl ring (Ireland, 2007; EFSA, 2011) |
| Spring barley                       | Soil: $1 \times 1.08$ kg a.s./ha | 29 | $^{14}$C-prochloraz radiolabelled in phenyl ring (Ireland, 2010; EFSA, 2011) |

| Processed commodities (hydrolysis study) | Conditions | Stable? | Comment/Source |
|-----------------------------------------|------------|---------|----------------|
| Pasteurisation (20 min, 90°C, pH 4)     | Yes        |         | Study performed with prochloraz labelled in phenyl ring (Ireland, 2007; EFSA, 2011) |
| Baking, brewing and boiling (60 min, 100°C, pH 5) | Yes |          |                 |
| Sterilisation (20 min, 120°C, pH 6)     | Yes        |         |                 |
| Other processing conditions             | –          |         |                 |

Can a general residue definition be proposed for primary crops?

Rotational crop and primary crop metabolism similar?

Residue pattern in processed commodities similar to residue pattern in raw commodities?

Plant residue definition for monitoring (RD-Mo)

Plant residue definition for risk assessment (RD-RA)

| | Yes |
|---|----|
| Current residue definition according to Regulation (EC) No 396/2005: sum of prochloraz and its metabolites containing the 2,4,6-Trichlorophenol moiety, expressed as prochloraz |
| Proposed residue definition (EFSA, 2011): sum of prochloraz, BTS 44595 and BTS 44596, expressed as prochloraz |
| Sum of prochloraz and its metabolites containing the 2,4,6-TCP moiety expressed as prochloraz |

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

Current enforcement residue definition (prochloraz and its metabolites containing the 2,4,6-trichlorophenol moiety, expressed as prochloraz):
- Matrices with high acid (lemon), high water (cucumber) and high oil content (oilseed rape): GC–MS, LOQ of 0.02 mg/kg in high water content, and 0.05 mg/kg high acid and high oil content. ILV available (Ireland, 2010, 2017). Dry (high starch content) matrices (wheat grain): GC–ECD, LOQ of 0.05 mg/kg (Ireland, 2010; Belgium, 2017).

Proposed enforcement residue definition (sum of prochloraz, BTS 44595 and BTS 44596, expressed as prochloraz):
- Matrices with high water content (lettuce), high oil content (oilseed rape, coffee beans), high acid content (lemon, oranges) and dry (high starch and protein content) matrices (grain, straw, dry bean): HPLC–MS/MS, LOQ 0.01 mg/kg individually for prochloraz, BTS 44595 and BBTS44596 and 2,4,6-trichlorophenol. ILV available for all above mentioned matrices (Ireland, 2010; EFSA, 2011; Belgium 2017)

### B.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category | Commodity | T (°C) | Stability period Value | Units | Compounds covered | Comment/Source |
|-----------------------------------|----------|-----------|--------|------------------------|-------|-------------------|----------------|
| High water content                | Lettuce  | –18       | 8      | Months                 |       | Prochloraz        | Homogenised samples fortified with each compound separately and analysed individually (EFSA, 2011) |
|                                   |          | –18       | 8      | Months                 |       | Metabolite BTS 44595 | |
|                                   |          | –18       | 6      | Months                 |       | Metabolite BTS 44596 | Samples fortified with a mixture of prochloraz, BTS 44595 and BTS 44596 and analysed for individual compounds. Study duration 6 months (Belgium, 2017) |
| Maize (leaves)                    |          | –20       | 24     | Months                 |       | Prochloraz        | Incurred residues (EFSA, 2011) |
|                                   |          |           |        |                        |       | (determined as total residues of 2,4,6-TCP) | |
| High oil content                  | Rape seed| –18       | 6      | Months                 |       | Metabolite BTS 44596 | Samples fortified with a mixture of prochloraz, BTS 44595 and BTS 44596 and analysed for individual compounds. Study duration 6 months (Belgium, 2017) |
|                                   |          | –18       | 8      | Months                 |       | Prochloraz        | Homogenised samples fortified with each compound separately and analysed individually (EFSA, 2011) |
|                                   |          | –18       | 8      | Months                 |       | Metabolite BTS 44595 | |
|                                   |          | –18       | 36     | Months                 |       | Sum of prochloraz, BTS 44595 and BTS 44596 containing the 2,4,6-TCP moiety | Ground samples were fortified with each compound separately and each compound separately determined as 2,4,6-TCP moiety (Ireland, 2007; EFSA, 2011) |
| Plant products (available studies) | Category | Commodity | T (°C) | Stability period | Value | Unit | Compounds covered | Comment/Source |
|---------------------------------|----------|-----------|--------|-----------------|-------|------|--------------------|----------------|
| High starch content             | Sugar beet | –18       | 6 Months |                 |       |      | Prochloraz, BTS 44595 and BTS 44596 | Samples fortified with a mixture of prochloraz, BTS 44595 and BTS 44596 and analysed for individual compounds. Study duration 6 months (Belgium, 2017) |
|                                 |          | –20       | 12 Months |                 |       |      | Prochloraz (determined as total residues of 2,4,6-TCP) | Incurred residues (EFSA, 2011) |
| Grain                           |          | –18       | 6 Months | Metabolite BTS 44596 |       |      | Samples fortified with a mixture of prochloraz, BTS 44595 and BTS 44596 and analysed for individual compounds. Study duration 6 months (Belgium, 2017) |
|                                 |          | –18       | 8 Months | Prochloraz      |       |      | Homogenised samples fortified with each compound separately and analysed individually (EFSA, 2011) |
|                                 |          | –18       | 8 Months | Metabolite BTS 44595 |       |      | |
|                                 |          | –20       | 24 Months | Prochloraz (determined as total residues of 2,4,6-TCP) |       |      | Incurred residues (EFSA, 2011) |
|                                 |          | –18       | 18 Months | Sum of prochloraz, BTS 44595 and BTS 44596 containing the 2,4,6-TCP moiety |       |      | Samples fortified with a mixture of individual compounds (EFSA, 2011). |
| High acid content               | Orange   | –18       | 8 Months | Prochloraz      |       |      | Homogenised samples fortified with each compound separately and analysed individually (EFSA, 2011) |
|                                 |          | –18       | 8 Months | Metabolite BTS 44595 |       |      | |
### B.1.2. Magnitude of residues in plants

#### B.1.2.1. Summary of residues data from the supervised residue trials

| Commodity                      | Region/Indoor(a) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source | Calculated MRL (mg/kg) | HR(b) (mg/kg) | STMR(c) (mg/kg) | CF(d) |
|--------------------------------|------------------|-----------------------------------------------------------------|-----------------|------------------------|---------------|----------------|------|
| **Enforcement (Regulation (EC) No 396/2005) and risk assessment residue definition:** sum of prochloraz and its metabolites containing the 2,4,6-trichlorophenol moiety, expressed as prochloraz |                   |                                                                 |                 |                        |               |                |      |
| Sugar beet and fodder beet     | NEU              | Sugar beet root: < 0.02; 0.03; 0.04; 4 x 0.05; 3 x 0.06; 2 x 0.08; 3 x 0.11; 0.12; 0.14 |                 |                        | 0.20          | 0.14            | 0.06 |
|                                |                  | Sugar beet tops: 0.40; 0.59; 0.90; 2 x 1.20; 1.40; 1.60; 2.0; 2.10; 2.20; 2.40; 2.70; 2.90 |                 |                        |               |                 | n.a. |
|                                |                  | Residue trials on sugar beet compliant with GAP (Belgium, 2017). Extrapolated to fodder beet. |                 |                        | Tops: 5.0      | Tops: 2.90       | Tops: 1.60 |
|                                |                  | MRL\text{OECD} = 0.21/0.20                                      |                 |                        |               |                 |      |
| **Enforcement (Mo) residue definition (peer review):** sum of prochloraz, BTS 44595 and BTS 44596, expressed as prochloraz |                   |                                                                 |                 |                        | 0.15          | 0.07 RA: 0.14   | 0.03 |
|                                |                  | Sugar beet root: < 0.01; 0.03; 0.04; 3 x 0.01; 3 x 0.03; 2 x 0.04; 3 x 0.06; 0.07 |                 |                        | 0.15          | 0.07 RA: 0.14   | 0.06 |
|                                |                  | Sugar beet tops: 0.20; 0.22; 0.29; 0.39; 0.42; 0.43; 0.44; 0.53; 0.56; 0.64; 0.71; 1.0; 1.60 |                 |                        | Tops: 2.0      | Tops: 1.60       | Tops: 2.8 |
|                                |                  | RA: Sugar beet root: < 0.02; 0.03; 0.04; 4 x 0.05; 3 x 0.06; 2 x 0.08; 3 x 0.11; 0.12; 0.14 |                 |                        | Tops: 2.0      | Tops: 1.60       | Tops: 2.8 |
|                                |                  | Sugar beet tops: 0.40; 0.59; 0.90; 2 x 1.20; 1.40; 1.60; 2.0; 2.10; 2.20; 2.40; 2.70; 2.90 |                 |                        |               |                 |      |
|                                |                  | Residue trials on sugar beet compliant with GAP (Belgium, 2017) Extrapolated to fodder beet. |                 |                        | MRL\text{OECD} = 0.12/0.15 |               |                 |      |
|                                |                  | MRL\text{OECD} = 0.12/0.15                                      |                 |                        |               |                 |      |

n.a.: Not applicable; MRL: maximum residue level; GAP: Good Agricultural Practice; OECD: Organisation for Economic Co-operation and Development.

(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.

(b): Highest residue. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.

(c): Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.

(d): Median conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.
B.1.2.2. Residues in rotational crops

Residues in rotational and succeeding crops expected based on confined rotational crop study?

|            | No |
|------------|----|
| – For plant back intervals of 120 and 365 days and application at 1.1 kg/ha on bare soil, TRRs < 0.02 mg/kg in lettuce and radish roots except in cereal forage (0.05 mg/kg) and straw (0.43 mg/kg) |
| – For plant-back interval of 30 days and application at 1.1 kg/ha on bare soil, TRRs in the range of 0.02–0.16 mg/kg in cabbage, lettuce, radish root and leaves. Individual values for prochloraz, BTS 44595 and BTS 44596 < 0.01 mg/kg, except for BTS 44595 in radish roots (0.018 mg/kg) |
| – For plant back intervals > 200 days and application at 1.0 to 0.94 kg/ha on a cereal grown as a primary crop, TRRs < 0.01 mg/kg in potato tubers and winter wheat sown as rotational crop |
| No residues expected above the LOQ (< 0.03 mg/kg) in rotational crops when samples analysed according to the residue definition for enforcement, except in cereal straw. Potential values close to the LOQ of 0.05 mg/kg in some crops for the plant back interval of 30 days, when analysed for total residues as 2,4,6-TCP |
| Not triggered |

Residues in rotational and succeeding crops expected based on field rotational crop study?

Field study not available. See confined study above.

B.1.2.3. Processing factors

No processing studies were submitted in the framework of the present MRL application. Such studies shall be performed once the final residue definitions for prochloraz are agreed.

B.2. Residues in livestock

| Relevant groups (sub groups) | Dietary burden expressed in mg/kg bw per day | Most critical subgroup(a) | Most critical commodity(b) | Trigger exceeded (Y/N) |
|-----------------------------|---------------------------------------------|---------------------------|---------------------------|-----------------------|
|                             | Median | Maximum | Median | Maximum | Maximum DB with existing EU MRLs (mg/kg DM) |                     |                        |
| Cattle (all)                | 0.407  | 0.491   | 10.59  | 12.76   | 7.93 | Dairy cattle | Citrus, dried pulp | Y |
| Cattle (dairy only)         | 0.407  | 0.491   | 10.59  | 12.76   | 7.93 | Dairy cattle | Citrus, dried pulp | Y |
| Sheep (all)                 | 0.158  | 0.206   | 3.72   | 4.85    | 2.56 | Lamb | Sugar beet tops | Y |
| Sheep (ewe only)            | 0.115  | 0.152   | 3.44   | 4.57    | 2.05 | Ram/Ewe | Sugar beet tops | Y |
| Swine (all)                 | 0.185  | 0.215   | 8.00   | 9.30    | 6.51 | Swine (breeding) | Citrus, dried pulp | Y |
| Poultry (all)               | 0.137  | 0.156   | 2.00   | 2.28    | 1.70 | Poultry layer | Sugar beet tops | Y |
### B.2.1. Nature of residues and methods of analysis in livestock

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

| Livestock (available studies) | Animal    | Dose (mg/kg bw per day) | Duration (days) | Comment/Source                                                                 |
|-------------------------------|-----------|-------------------------|-----------------|-------------------------------------------------------------------------------|
|                               | Laying hen| a) 0.68 (1.5 mg/hen per day; 7 hens) | 14              | $^{14}$C-prochloraz radiolabelled in phenyl ring (Ireland, 2007). Assuming bw of 1.9 kg and feed intake of 120 g |
|                               |           | b) 0.34 (0.75 mg/hen day; 2 hens)     |                 |                                                                               |
|                               | Lactating ruminants | 1.5                                   | 3                | Cow. $^{14}$C-prochloraz radiolabelled in phenyl ring (Ireland, 2007)        |
|                               |           | 0.286                                  | 10               | Goat, assuming bw of 70 kg and food intake of 2 kg $^{14}$C-prochloraz radiolabelled in phenyl ring (Ireland, 2010) |

bw: body weight; DM: dry matter; DB: dietary burden; MRL: maximum residue level.

(a): When one group of livestock includes several subgroups (e.g. poultry “all” including broiler, layer and turkey), the result of the most critical subgroup is identified from the maximum dietary burdens expressed as “mg/kg bw per day”.

(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as “mg/kg bw per day”.

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| Relevant groups (sub groups) | Dietary burden expressed in mg/kg bw per day | Maximum DB with existing EU MRLs (mg/kg DM) | Most critical subgroup(a) | Most critical commodity(b) | Trigger exceeded (Y/N) |
|-----------------------------|---------------------------------------------|---------------------------------------------|---------------------------|----------------------------|-------------------------|
| Poultry (layer only)        | Median 0.137 | Maximum 0.156 | Median 2.00 | Maximum 2.28 | 1.70 | Poultry layer | Sugar beet tops | Y |
| Time needed to reach a plateau concentration in milk and eggs (days) | Milk: as from 4 |
|---|---|
| Eggs: 8 |
| Metabolism in rat and ruminant similar | Yes |
| Can a general residue definition be proposed for animals? | Yes |
| Animal residue definition for monitoring (RD-Mo) | Regulation (EC) No 396/2005: sum of prochloraz and its metabolites containing the 2,4,6-trichlorophenol moiety, expressed as prochloraz. Proposed residues definition (EFSA, 2011): sum of prochloraz, BTS 44595 and BTS 44596, expressed as prochloraz. |
| Animal residue definition for risk assessment (RD-RA) | Sum of prochloraz and its metabolites containing the 2,4,6-TCP moiety, expressed as prochloraz. |
| Fat soluble residues | Yes |
| Prochloraz and its main metabolites BTS 22595 and BTS 44596 are fat soluble; moreover, residue levels significantly higher in fat than in muscle (EFSA, 2011). |
| Methods of analysis for monitoring of residues (analytical technique, matrix, LOQs) | Proposed enforcement residue definition (sum of prochloraz, BTS 44595 and BTS 44596, expressed as prochloraz): Milk, eggs, liver, fat, muscle: HPLC–MS/MS for prochloraz, BTS 44595 and BTS 44596 at 0.01 mg/kg (individually). ILV available for all matrices (EFSA, 2011; Belgium, 2017). |
| Current enforcement residue definition (prochloraz and its metabolites containing the 2,4,6-trichlorophenol moiety, expressed as prochloraz): | Eggs: GC-ECD, 0.01 mg/kg (prochloraz as 2,4,6-TCP). ILV available (Ireland, 2010, 2011). GC-MSD: 0.05 mg/kg (metabolites BTS 44595, BTS 44596 and BTS 44770 determined as 2,4,6-TCP). ILV available (Belgium, 2017). |
| Muscle: GC-ECD, 0.01 mg/kg (prochloraz as 2,4,6-TCP). ILV available (Ireland, 2010, 2011). GC-MSD: 0.01 mg/kg (metabolites BTS 44595, BTS 44596 and BTS 9608 determined as 2,4,6-TCP). ILV available (Belgium, 2017). |
| Fat: GC-MSD, 0.01 mg/kg (prochloraz as 2,4,6-TCP). ILV available (Ireland, 2010). GC–MSD: 0.01 mg/kg (metabolites BTS 44595, BTS 44596 and BTS 9608 determined as 2,4,6-TCP). ILV available (Belgium, 2017). |
| Liver: GC-ECD/GC–MS/MS, 0.05 mg/kg (prochloraz as 2,4,6-TCP). ILV available (Ireland, 2010, 2011). GC-MSD: 0.05 mg/kg (metabolites BTS 44595, BTS 44596 and BTS 9608, BTS 44770 determined as 2,4,6-TCP). ILV available (Ireland, 2010; Belgium, 2017). |
| Kidney: GC-ECD, 0.05 mg/kg (prochloraz as 2,4,6-TCP). ILV available (Ireland, 2010, 2011). No data for metabolites. |
| Milk: GC-ECD, 0.01 mg/kg (prochloraz as 2,4,6-TCP). ILV available (Ireland, 2011). GC-MSD: 0.01 mg/kg (metabolites BTS 44595, BTS 44596 and BTS 9608 determined as 2,4,6-TCP). ILV available (Belgium, 2017). |
### B.2.1.2. Stability of residues in livestock

| Animal products (available studies) | Animal | Commodity | T (°C) | Stability period | Compounds covered | Comment/Source |
|-----------------------------------|--------|-----------|--------|-----------------|-------------------|----------------|
|                                   | Bovine | Muscle/Meat | −18 | 3 Months | Prochloraz, BTS 44595, BTS 44596 | Samples fortified with a mixture of prochloraz, BTS 44595 and BTS 44596 and analysed for individual compounds. Study duration 3 months (Belgium, 2017) |
|                                   |        |           | −18 | 12 Months | Prochloraz (determined as total residues of 2,4,6-TCP) | Samples fortified with prochloraz. Study duration 12 months (Ireland, 2007; EFSA, 2011; Belgium 2017) |
|                                   | Bovine | Fat       | −18 | 3 Months | Prochloraz, BTS 44595, BTS 44596 | Samples fortified with a mixture of prochloraz, BTS 44595 and BTS 44596 and analysed for individual compounds. Study duration 3 months (Belgium, 2017) |
|                                   | Bovine | Liver     | −18 | 3 Months | Prochloraz, BTS 44595, BTS 44596 | |
|                                   | Hen    | Eggs      | −18 | 3 Months | Prochloraz, BTS 44595, BTS 44596 | Samples fortified with prochloraz (Ireland, 2007; EFSA, 2011) |
|                                   | Bovine | Milk      | −18 | 12 Months | Prochloraz (determined as 2,4,6-TCP moiety) | Samples fortified with prochloraz (Ireland, 2007; EFSA, 2011) |
|                                   |        |           | −18 | 5 Months  | Prochloraz | Samples fortified with prochloraz. Study duration 12 months (Ireland, 2007; EFSA, 2011; Belgium 2017) |

Cow feeding study (Ireland, 2007)
B.3. Consumer risk assessment

| ARfD | 0.025 mg/kg bw (EFSA, 2011) |
|------|----------------------------|
| Highest IESTI, according to EFSA PRIMo rev.2 | Sugar beet root: 36% of the ARfD |
| Assumptions made for the calculations | The calculation is based on the highest residue level in sugar beet root from the submitted supervised residue field trials |

| ADI | 0.01 mg/kg bw per day (EFSA, 2011) |
|-----|----------------------------------|
| Highest IEDI, according to EFSA PRIMo rev.2 | 106% ADI (WHO Cluster diet B) |
| Contribution of crops assessed: | Sugar beet: 14% of ADI (UK Toddler diet) |
| Assumptions made for the calculations | The calculation is based on the median residue level derived for sugar beet root from the submitted supervised residue field trials. For citrus fruits and sunflower seed, the risk assessment values as derived by the JMPR were used. For the remaining commodities, EU MRLs according to Regulation (EU) No 520/2011 were used. Lacking specific processing studies, the risk assessment could not be further refined |

B.4. Recommended MRLs

| Code(a) | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|---------|-----------|------------------------|-------------------------|-----------------------|
|         | Sugar beet roots | 0.1 | No proposal | The submitted residue data are sufficient to derive a MRL proposal of 0.2 mg/kg for the NEU use. For the new residue definition derived in the peer review, a MRL of 0.15 mg/kg would be appropriate. A long-term consumer health concern was identified for the existing prochloraz MRLs. Lacking specific processing studies and detailed information on other existing uses, the risk assessment could not be further refined |
| 0900010 | Swine liver | 0.1* | No proposal | The MRL proposals in swine and ruminant kidney and liver will be considered in the framework of the Article 12 MRL review |
| 1011030 | Bovine liver | 2.0 | | |
| 1012030 | Sheep liver | 0.1* | | |
| 1013030 | Goat liver | 0.1* | | |
| 1012040 | Bovine kidney | 0.5 | | |
| 1013040 | Sheep kidney | 0.1* | | |
| 1014040 | Goat kidney | 0.1* | | |
| 1011040 | Swine kidney | 0.1* | | |
| 1012040 | Bovine kidney | 0.5 | | |
| 1013040 | Sheep kidney | 0.1* | | |
| 1014040 | Goat kidney | 0.1* | | |

MRL: maximum residue level; NEU: northern Europe.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
Appendix C – Pesticide Residue Intake Model (PRIMo)

**Sum of prochloraz and its metabolites containing 2,4,6- TCP moiety, expressed as prochloraz**

| Region of the active substance | Code no. | LOQ (mg/kg bw) | Proposed LOQ |
|-------------------------------|----------|----------------|--------------|
|                               |          |                |              |

**Toxicological end points**

| ADI (mg/kg bw per day) | ARfD (mg/kg bw) |
|------------------------|-----------------|
| 0.01                   | 0.025           |

| Source of ADI | Source of ARfD |
|---------------|----------------|
| EFSA          | EFSA           |

| Year of evaluation | Year of evaluation |
|--------------------|--------------------|
| 2011               | 2011               |

| No of diets exceeding ADI | Sum of prochloraz and its metabolites containing 2,4,6- TCP moiety, expressed as prochloraz |
|---------------------------|----------------------------------------------------------------------------------|
| 1                         | 106                                                                               |

**Chronic risk assessment – refined calculations**

| TMDI (range) in % of ADI | Minimum – Maximum |
|--------------------------|-------------------|
|                         |                   |

**Conclusion:**

The estimated Theoretical Maximum Daily Intakes based on MS and WHO diets and pTMRLs were in the range of 10.1 – 106% of the ADI. For 1 diet, the ADI is exceeded. Further refinements of the dietary intake estimates have not been performed. A public health risk can not be excluded at the moment.

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The acute risk assessment is based on the ARfD.

For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation.

In the IESTI 1 calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce, a variability factor of 5 was used.

In the IESTI 2 calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variability factor of 3.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation. (***)

For processed commodities, no exceedance of the ARfD/ADI was identified. For unprocessed commodities, no exceedance of the ARfD/ADI was identified.

| Commodity                  | pTMRL (mg/kg) | No of critical MRLs (IESTI 1) | No of critical MRLs (IESTI 2) |
|----------------------------|---------------|------------------------------|------------------------------|
| Sugar beet (root)          | 0.14          | ---                          | ---                          |
| Sugar beet (root)          | 0.14          | ---                          | ---                          |
| Sugar beet (root)          | 0.14          | ---                          | ---                          |
| Sugar beet (root)          | 0.14          | ---                          | ---                          |
| Sugar beet (root)          | 0.14          | ---                          | ---                          |

Conclusion:

For Sum of prochloraz and its metabolites containing 2,4,6,-TCP moiety, expressed as prochloraz, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.

In the IESTI 1 calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used.

In the IESTI 2 calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variability factor of 3.

No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Processed commodities:

For processed commodities, no exceedance of the ARfD/ADI was identified.
Appendix D – Input values for the exposure calculations

D.1. Livestock dietary burden calculations

| Feed commodity                  | Median dietary burden | Maximum dietary burden |
|---------------------------------|-----------------------|------------------------|
|                                 | Input value (mg/kg)   | Comment                | Input value (mg/kg)   | Comment                |
| Mangel beet fodder              | 1.6 STMR (leaves)     | 2.9 HR (leaves)        |
| Sugar beet tops                 | 1.6 STMR (leaves)     | 2.9 HR (leaves)        |
| Barley, oat grain               | 1.0 MRL               | 1.0 MRL                |
| Dry peas                        | 0.30 MRL              | 0.30 MRL               |
| Wheat, rye grain                | 0.5 MRL               | 0.5 MRL                |
| Dried pulp of sugar beet        | 1.08 STMR (roots) × PF 18<sup>(a)</sup> | 1.08 STMR (roots) × PF 18<sup>(a)</sup> |
| Ensiled pulp of sugar beet      | 0.18 STMR (roots) × PF 3<sup>(a)</sup> | 0.18 STMR (roots) × PF 3<sup>(a)</sup> |
| Sugar beet molasses             | 1.68 STMR (roots) × PF 28<sup>(a)</sup> | 1.68 STMR (roots) × PF 28<sup>(a)</sup> |
| Dried brewer`s grain            | 3.30 MRL (barley grain) × PF 3.3<sup>(a)</sup> | 3.30 MRL (barley grain) × PF 3.3<sup>(a)</sup> |
| Rape seed meal                  | 1.0 MRL × PF 2<sup>(a)</sup> | 1.0 MRL × PF 2<sup>(a)</sup> |
| Dried citrus pulp               | 34 STMR<sup>(b)</sup> (FAO, 2004) × PF10<sup>(a)</sup> | 34 STMR<sup>(b)</sup> (FAO, 2004) × PF10<sup>(a)</sup> |
| Distillers grain                | 1.65 MRL wheat grain × PF 3.3 | 1.65 MRL wheat grain × PF 3.3 |
| Linseed meal                    | 1.0 MRL × PF 2<sup>(a)</sup> | 1.0 MRL × PF 2<sup>(a)</sup> |
| Sunflower meal                  | 0.2 STMR (FAO, 2004) × PF 2<sup>(a)</sup> | 0.2 STMR (FAO, 2004) × PF 2<sup>(a)</sup> |
| Wheat gluten meal               | 0.90 MRL wheat grain × PF 1.8<sup>(a)</sup> | 0.90 MRL wheat grain × PF 1.8<sup>(a)</sup> |
| Wheat milled by-products        | 3.50 MRL wheat grain × PF 7<sup>(a)</sup> | 3.50 MRL wheat grain × PF 7<sup>(a)</sup> |

**Risk assessment residue definition:** Sum of prochloraz and its metabolites containing the 2,4,6-TCP moiety, expressed as prochloraz.

STMR: supervised trials median residue; HR: highest residue; PF: processing factor; MRL: maximum residue level.

(a): In the absence of processing factors supported by data, default processing factors were included in the calculation to consider the potential concentration of residues in these commodities.

(b): The STMR of 3.4 mg/kg recalculated for the whole fruit from residue trials reported in the JMPR Evaluation report 2004 (FAO, 2004).

D.2. Consumer risk assessment

| Commodity                      | Chronic risk assessment | Acute risk assessment |
|--------------------------------|-------------------------|-----------------------|
|                                | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
| Sugar beet root                | 0.06 STMR               |                       | 0.14 HR             |
| Citrus                         | 0.1 STMR pulp (FAO, 2004)|                      |
| Sunflower seed                 | 0.1 STMR (FAO, 2004)    |                       |
| Other commodities of plant and animal origin | MRL Commission Regulation (EU) No 520/2011 | Acute exposure assessment performed only for sugar beet root |

**Risk assessment residue definition:** Sum of prochloraz and its metabolites containing the 2,4,6-TCP moiety, expressed as prochloraz.

STMR: supervised trials median residue; HR: highest residue; MRL: maximum residue level.
## Appendix E – Used compound codes

| Code/trivial name | IUPAC name/SMILES notation/InChiKey<sup>(a)</sup> | Structural formula<sup>(b)</sup> |
|-------------------|-------------------------------------------------|----------------------------------|
| **Prochloraz**    | *N*-propyl-*N*-[2-(2,4,6-trichlorophenoxy)ethyl]imidazole-1-carboxamide  
O=CN(CCoc1cC(CccCl)CCC)n2ccnc2  
TVLSRxXIMLFWEO-UHFFFAOYSA-N | ![Prochloraz](image) |
| BTS 44596, M201-03 | *N*: propyl[2-(2,4,6-trichlorophenoxy)ethyl]carbamoyl]formamide  
Clc1 cc(C)cc(C)c10CCN(CCC)C(=O)NC=O  
RHDVQZWBQXOJW-UHFFFAOYSA-N | ![BTS 44596](image) |
| BTS 44595, M201-04 | *N*-propyl-*N*-[2-(2,4,6-trichlorophenoxy)ethyl]urea  
Clc1 cc(C)cc(C)c10CCN(CCC)C(N)\(\text{N}\)C=O  
MPNJTIZLDHWFJX-UHFFFAOYSA-N | ![BTS 44595](image) |
| BTS 44770, M201-05 | *N*-[2-(2,4,6-trichlorophenoxy)ethyl]urea  
Clc1 cc(C)cc(C)c10CCN(CCC)C(N)=O  
ZIWFBODNCWIEJRV-UHFFFAOYSA-N | ![BTS 44770](image) |
| BTS 40348, M201-07 | *N*-[2-(2,4,6-trichlorophenoxy)ethyl]propan-1-amine  
Clc1 cc(C)cc(C)c10CCNCCC  
CLFQSOXBYICELN-UHFFFAOYSA-N | ![BTS 40348](image) |
| BTS 3037 M201-11 | 2-(2,4,6-trichlorophenoxy)ethanol  
Clc1 cc(C)cc(C)c10CCO  
LZTSCANFAWWRCCW-UHFFFAOYSA-N | ![BTS 3037](image) |
| BTS 9608, M201-13 | (2,4,6-trichlorophenoxy)acetic acid  
Clc1 cc(C)cc(C)c10CC(=O)O  
KZDCLQ8OHGBWOI-UHFFFAOYSA-N | ![BTS 9608](image) |
| **2,4,6-TCP (BTS 45186, M201-15)** | 2,4,6-trichlorophenol  
Clc1 cc(C)cc(C)c10  
LINPIYWGCPVIE-UHFFFAOYSA-N | ![2,4,6-TCP](image) |
| **BTS 54906 M201-21** | 2,4,6-trichloro-3-(2-hydroxyethoxy)phenol  
Clc1c(O)c(C)cc(C)c10CCO  
IXSVWXIPLCRJURG-UHFFFAOYSA-N | ![BTS 54906](image) |

IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system.  
<sup>(a)</sup> ACD/Name 2015 ACD/Labs 2015 Release (File version N20E41, Build 75170, 19 December 2014).  
<sup>(b)</sup> ACD/ChemSketch 2015 ACD/Labs 2015 Release (File version C10H41, Build 75059, 17 December 2014).