Modification of the existing maximum residue level for captan in cranberries

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the Belgian Federal Public Service (FPS) for Health, Food chain safety and Environment, submitted an application as the competent national authority in Belgium to modify the existing maximum residue level (MRL) for the active substance captan in cranberries. The data submitted in support of the request were found to be sufficient to derive MRL proposal for cranberries. Adequate analytical methods for enforcement are available to control the residues of captan in plant matrices at the validated limit of quantification (LOQ) of 0.01 mg/kg for each analyte in the crops assessed. Based on the exposure calculation, EFSA concluded that the short-term and long-term intake of residues resulting from the use of captan according to the reported agricultural practice will not result in a consumer exposure exceeding the existing toxicological reference values.

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, the Belgian Federal Public Service (FPS) for Health, Food chain safety and Environment submitted an application as the competent national authority in Belgium and evaluating member state (EMS) to modify the existing maximum residue level (MRL) for the active substance captan in cranberries. 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 1 June 2018. To accommodate for the intended use of captan, the EMS proposed to raise the existing MRL in cranberries from the limit of quantification (LOQ) of 0.03 to 30 mg/kg.

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 the peer review under Directive 91/414/EEC, the data evaluated under previous MRL assessments, including the review of the existing MRLs for captan according to Article 12 of Regulation (EC) No 396/2005 and the additional data provided by the EMS in the framework of this application, the following conclusions are derived.

The metabolism of captan following foliar application has been investigated in crops belonging to the group of fruit crops. Studies investigating the effect of processing on the nature of captan (hydrolysis studies) demonstrated that the active substance captan is not stable and almost totally degraded to THPI under hydrolytic conditions representative of pasteurisation, boiling/brewing/baking and sterilisation. While THPI was hydrolytically stable under conditions representing pasteurisation, backing, boiling/brewing, it was shown to be slightly unstable under sterilisation conditions, forming low levels of degradation products.

As the proposed use of captan is on permanent crops, investigations of residues in rotational crops are not required. Based on the metabolic pattern identified in the metabolism studies, the results of hydrolysis studies, the toxicological significance of metabolites and/or degradation products, and the capabilities of enforcement analytical methods, the residue definitions for plant products for enforcement and risk assessment were proposed by the MRL review as ‘sum of captan and THPI, expressed as captan’. This residue definition is applicable to the group of fruits and fruiting vegetables. The same residue definition is applicable to primary crops, rotational crops and processed products. EFSA concluded that for the crop assessed in this application, metabolism of captan in primary crops, and the possible degradation in processed products have been sufficiently addressed and that the previously derived residue definitions are applicable.

Sufficiently validated analytical methods based on GC-MS are available to quantify residues in the crops assessed in this application according to the enforcement residue definition. The methods enable quantification of residues at or above 0.01 mg/kg for each analyte in the crops assessed (LOQ).

The available residue trials are sufficient to derive an MRL proposal of 30 mg/kg for cranberries. Specific processing studies for the crops under assessment are not available. Processing studies are not required as they are not expected to affect the outcome of the risk assessment. If there was the intention to derive processing factors for cranberries, in particular for enforcement purposes, additional processing studies would be required.

Residues of captan in commodities of animal origin were not assessed since the crop under consideration in this MRL application is normally not fed to livestock.

The toxicological profile of captan was assessed in the framework of the EU pesticides peer review under Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 0.1 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 0.3 mg/kg bw. It is noted that in the framework of the renewal of the approval under Regulation (EC) No 1107/2009, the rapporteur Member State (RMS) proposed to revise the toxicological reference values for captan and for the metabolite THPI.

For the metabolite THPI (included in the residue definition), experts agreed during the peer review under Directive 91/414/EEC that the toxicological studies demonstrated the lower toxicity of this metabolite compared with captan. However, the toxicity of the metabolite THPI may need to be reconsidered during the renewal of approval under Regulation (EC) No 1107/2009 because recent studies indicate the acute oral toxicity of THPI may be higher than that of the parent captan. The risk assessment performed in the current reasoned opinion is based on the existing toxicological reference values derived previously, assuming that THPI is of similar toxicity as parent captan. The risk
assessment may need to be revised, once a decision on the modification of the ADI/ARfD for the parent compound and the metabolite is taken.

The consumer risk assessment was performed with revision 3 of the EFSA Pesticide Residues Intake Model (PRIMo). Although uncertainty remains regarding the acute toxicity of the metabolite THPI and the toxicological reference values used in the risk assessment, the indicative exposure calculation did not indicate a risk to consumer health. For cranberries, the estimated maximum exposure in percentage of the ARfD accounted for 11%. The highest estimated long-term dietary intake accounted for 54% of the ADI (NL toddler). The highest contribution of residues expected in cranberries accounted for 0.16% of the ADI (GEMS Food G10 diet).

EFSA concluded that, based on the risk assessment, the proposed use of captan on cranberry will not result in a consumer exposure exceeding the existing toxicological reference values.

The peer review of the draft Renewal Assessment Report (dRAR) for the renewal of the active substance in accordance with Regulation (EC) No 1107/2009 is currently ongoing and therefore the conclusions reported in this reasoned opinion might need to be reconsidered in the light of the outcome of the peer review.

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

Full details of all end points and the consumer risk assessment can be found in Appendices B–D.

| Code(a) | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|---------|------------|------------------------|-------------------------|-----------------------|
| 0154020 | Cranberries | 0.03* | 30 | The submitted data are sufficient to derive an MRL proposal for the indoor use. EFSA concluded that the proposed use of captan on cranberries does not result in a consumer exposure exceeding the existing toxicological reference values and therefore did not indicate a risk to consumer health. The conclusions reported in this reasoned opinion may need to be reconsidered in the light of the outcome of the peer review. |

MRL: maximum residue level.
*: 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 applicant requested the modification of the existing maximum residue level (MRL) for captan in cranberries. The detailed description of the intended use of captan which is the basis for the MRL application is reported in Appendix A.

Captan is the ISO common name for N-(trichloromethylthio)cyclohex-4-ene-1,2-dicarboximide (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix E.

Captan was evaluated in the framework of Directive 91/414/EEC1 with Italy designated as the rapporteur Member State (RMS); the representative uses assessed were foliar treatments on pome fruits, peaches/nectarines and tomatoes. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by the European Food Safety Authority (EFSA, 2009). Captan has been approved2 for use as a fungicide on 1 October 2007. The process for renewal of the approval of the active substance captan under Regulation (EC) No 1107/2009 is currently ongoing, with Austria designated as RMS and Italy designated as co-rapporteur Member State (co-RMS). The European Union (EU) MRLs for captan are established in Annex II of Regulation (EC) No 396/20053. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed (EFSA, 2014). For a number of crops, EFSA identified some information on analytical methods as unavailable and therefore proposed tentative MRLs. The proposed MRLs (including the tentative MRLs) have been implemented in the MRL legislation by Commission Regulation (EU) 2016/4524.

In accordance with Article 6 of Regulation (EC) No 396/2005 the Belgian Federal Public Service (FPS) for Health, Food chain safety and Environment submitted an application as the competent national authority in Belgium and as the evaluating member state (EMS) to modify the existing maximum residue level (MRL) for the active substance captan in cranberries. 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 EFSA on 1 June 2018. To accommodate for the intended use of captan, the EMS proposed to raise the existing MRL from the limit of quantification (LOQ) of 0.03 to 30 mg/kg.

EFSA based its assessment on the evaluation report submitted by the EMS (Belgium, 2018), the DAR (and its addendum) prepared under Council Directive 91/414/EEC (Italy, 2003, 2009), the Commission review report on captan (European Commission, 2008), the EFSA conclusion on the peer review of the pesticide risk assessment of the active substance captan (EFSA, 2009), the EFSA reasoned opinion the review of the existing MRLs for captan according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2014), and the draft Renewal Assessment Report (dRAR) prepared in the framework of the renewal of the active substance under Regulation (EC) No 1107/2009 (Austria, 2017), as well as the conclusions from previous EFSA reasoned opinions on captan (EFSA, 2011b, 2018b).

For this application, the data requirements established in Regulation (EU) No 544/20115 and the guidance documents applicable at the date of submission of the 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 546/20116.

As the EU pesticides peer review of the active substance captan in accordance with Regulation (EC) No 1107/2009 is not yet finalised, the conclusions reported in this reasoned opinion might need to be reconsidered in the light of the outcome of the peer review.

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1 Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32.
2 Commission Directive 2007/5/EC of 7 February 2007 amending Council Directive 91/414/EEC to include captan, folpet, formetanate and methiocarb as active substances. OJ L 35, 8.2.2007, p. 11–17.
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, 16.3.2005, p. 1–16.
4 Commission Regulation (EU) 2016/452 of 29 March 2016 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for captan, propiconazole and spiroxamine in or on certain products. OJ L 79, 30.3.2016, p. 10–27.
5 Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances. OJ L 155, 11.6.2011, p. 1–66.
6 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.
A selected list of end points of the studies assessed by EFSA in the framework of 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, 2018) 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.

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 metabolism of captan in primary crops has been investigated in the framework of the EU pesticides peer review under Directive 91/414/EEC and in the framework of the MRL review (Italy 2003, 2009; EFSA, 2009, 2014). The MRL review concluded that the group of fruits and fruiting vegetable is adequately covered by the available metabolism studies.

1.1.2. Nature of residues in rotational crops

As the proposed use of captan is on perennial crops, investigations of residues in rotational crops are not required.

1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of captan was investigated in the framework of previous MRL applications (Austria, 2010; France, 2010; EFSA, 2011a). These studies showed that the captan is not stable and almost totally degraded to THPI under hydrolytic conditions representative of pasteurisation (20 mins at 90°C, pH 4), boiling/brewing/baking (60 mins at 100°C pH 5) and sterilisation (20 mins at 120°C, pH 6) (EFSA, 2011a). While THPI was hydrolytically stable under conditions representing pasteurisation, backing, boiling/brewing, it was shown to be slightly unstable under sterilisation conditions, forming low levels of degradation products at individual amounts up to 11.4% applied radioactivity (AR). Consequently, as for primary crops, EFSA proposed to set the residue definition for enforcement and risk assessment in processed commodities as the ‘sum of captan and THPI, expressed as captan’ (EFSA, 2014).

1.1.4. Methods of analysis in plants

Analytical methods for the determination of captan and the metabolite THPI were assessed during the EU pesticides peer review under Directive 91/414/EEC and during the MRL review (EFSA, 2009, 2014). The methods were sufficiently validated for residues of captan in food of plant origin with an LOQ of 0.05 mg/kg in acidic and in high water content commodities. The metabolite THPI can be enforced in food of plant origin with an LOQ of 0.01 mg/kg in high water content commodities. However, the MRL review identified that an independent laboratory validation (ILV) and a confirmatory method for the determination of THPI in high water commodities and a fully validated method with its ILV and with a confirmatory method for the determination of THPI in acidic commodities were missing (EFSA, 2014). The data gaps for information on analytical methods in high water content and in acidic commodities have been implemented in the MRL legislation as confirmatory data requirements by Commission Regulation (EU) No 2016/452. Cranberries are a high acid matrix for analytical methods.

In the present MRL application, no information was submitted regarding the data requirement for analytical methods in acidic commodities (Belgium, 2018). However, new methods of analysis for the determination of captan residues and residues of THPI have been submitted in the dossier for the renewal of the approval under Regulation (EC) No 1107/2009 for which the peer review is currently ongoing (Austria, 2017). The methods allow quantifying residues at or above the LOQ of 0.01 mg/kg for each analyte in crops belonging to the groups of high water content, high oil content, high acid content and dry matrices, with confirmatory method and ILV available (Austria, 2017).
1.1.5. Stability of residues in plants

The storage stability of captan and the metabolite THPI in plants stored under frozen conditions was investigated in the framework of the EU pesticides peer review under Directive 91/414/EEC (EFSA, 2014). The frozen storage stability of total residues of captan and THPI (expressed as captan equivalents) was demonstrated for 20 months in high water content commodities (tomatoes) and for 14 months in high acid content commodities (strawberries), when stored at −20°C (Italy, 2003). Cranberries are a high acid content commodity, and therefore storage stability is expected for a period of 14 months at −20°C.

1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in the metabolism studies, the results of hydrolysis studies, the toxicological significance of metabolites and/or degradation products, and the capabilities of enforcement analytical methods, the following residue definition was proposed by the MRL review for plant products (EFSA, 2014):

- Residue definition for risk assessment and enforcement for plant products: sum of captan and THPI, expressed as captan

This residue definition is applicable to the group of fruits and fruiting vegetables. The same residue definition is applicable to primary crops, rotational crops and processed products. The residue definition for enforcement set in Regulation (EC) No 396/2005 is identical with the above mentioned residue definition.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the intended indoor Good Agricultural Practice (GAP), the applicant submitted eight indoor residue trials on red currants which have been performed during the 2009 growing season in the Netherlands. The applicant proposed to extrapolate from currants to cranberries, which is acceptable according to the EU guidance documents (European Commission, 2017). The residue trials submitted with the current application have been evaluated during a previous EFSA assessment (EFSA, 2011b). One trial was disregarded by EFSA and the EMS because the control sample from the same trial site contained significant residues of captan and THPI.

The GAP for the intended use on cranberry foresees a maximum of eight applications per annum: two are to be performed after harvest (BBCH 93–97) and were considered not relevant regarding residues; and maximum of six applications are allowed between beginning of flowering and end of harvest (BBCH 60–87). In the submitted residues trials, the growth stage at last treatment was BBCH 81 (five trials) or BBCH 87 (two trials) and is sufficiently GAP compliant. Overall, seven indoor residue trials on red currants are considered valid for deriving the MRL proposal and risk assessment values for the intended use on cranberry. The residues measured as THPI were re-calculated to captan using molecular weight adjustment.

1.2.2. Magnitude of residues in rotational crops

As the proposed use of captan is on perennial crops, investigations of residues in rotational crops are not required.

1.2.3. Magnitude of residues in processed commodities

Processing studies were not submitted in the present MRL application and specific processing studies for the crops under assessment are not available. Processing studies were reported in the framework of the peer review under Directive 91/414/EEC (Italy, 2009), and in the framework of previous MRL applications allowing robust processing factors to be derived for apples (juice, sauce and wet pomace), peaches (canned), apricots (sauce) and tomatoes (paste, ketchup and juice) (EFSA, 2014). Indicative processing factors were derived for tomatoes (peeled and canned) and cherries (canned, jam and juice) but these are not supported by sufficient number of studies and a detailed evaluation of these studies was not available to EFSA (2014). The MRL review concluded that further processing studies are not required as they are not expected to affect the outcome of the risk
assessment (EFSA, 2014). These conclusions are also applicable to commodities under consideration in the present MRL application. If there would be the intention to derive processing factors for cranberries, in particular for enforcement purposes, additional processing studies would be required.

### 1.2.4. Proposed MRLs

The available data are considered sufficient to derive an MRL proposal as well as risk assessment values for cranberries (see Appendix B.1.2.1). In Section 3, EFSA assessed whether residues on these crops resulting from the intended uses are likely to pose a consumer health risk.

#### 2. Residues in livestock

An assessment of residues in livestock is not required because the commodities under consideration are not used for feed purposes.

#### 3. Consumer risk assessment

EFSA performed a dietary risk assessment using revision 3 of the EFSA PRIMo (EFSA, 2018a). 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 existing toxicological reference values for captan used in the risk assessment (i.e. acceptable daily intake (ADI) of 0.1 mg/kg body weight (bw) per day and acute reference dose (ARfD) of 0.3 mg/kg bw) were derived in the EU pesticides peer review in the framework of the EU pesticides peer review under Directive 91/414/EEC (EFSA, 2009). It is noted that in the framework of the renewal of the approval under Regulation (EC) No 1107/2009 (AIR III), the RMS proposed new toxicological reference values for captan (Austria, 2017) for which the peer review is currently ongoing.7

For the metabolites THPI, 3-OH THPI and 5-OH THPI, it was agreed during the peer review in the framework of the approval under Directive 91/414/EEC that the toxicological studies demonstrated the lower toxicity of these metabolites compared with captan (EFSA, 2009). Mechanistic data indicated also that THPI, 3-OH-THPI and 5-OH-THPI do not have the potential to induce critical effects (carcinogenic, reproductive toxicity effects). Nevertheless, as it was not possible to set specific reference values for these metabolites, the peer review concluded that the reference values for captan would also apply for these three metabolites (EFSA, 2009). The toxicity of the metabolite THPI may need to be reconsidered during the renewal of approval under Regulation (EC) No 1107/2009 (AIR III) as proposed by the RMS Austria, because recent studies indicate the acute oral toxicity of THPI may be higher than that of the parent captan, and significantly higher than reported in the original DAR of 2003 (Austria, 2017).

The risk assessment performed in the current reasoned opinion is based on the existing toxicological reference values derived by the pesticides peer review in 2009 (EFSA, 2009), assuming that THPI is of similar toxicity as parent captan. It is however noted that the peer review of the risk assessment of captan for renewal of the approval under Regulation (EC) No 1107/2009 (AIR III) is currently on going; and the risk assessment may need to be revised if the toxicological reference values for the compounds included in the residue definition for risk assessment are revised.

For further details on the exposure calculations, a screenshot of the Report sheet of the PRIMo is presented in Appendix C.

#### 3.1. Short-term (acute) dietary risk assessment

The acute exposure assessment was performed only with regard to the commodities under consideration assuming the consumption of a large portion of the food items as reported in the national food surveys (EFSA, 2018a). The calculations were based on the highest residue (HR) derived from supervised field trials (see Appendix D.2).

The risk assessment performed under the assumption that THPI is of similar toxicity as captan did not indicate a risk to consumer health. For cranberries, the estimated maximum exposure in percentage of the ARfD accounted for 11% (see Appendix B.3).

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7 The RMS proposed in the draft Renewal Assessment Report new ADI (0.25 mg/kg bw per day) and a new ARfD (0.9 mg/kg bw) for captan (Austria, 2017).
3.2. Long-term (chronic) dietary risk assessment

In the framework of the MRL review a comprehensive long-term exposure assessment was performed, taking into account the existing uses at EU level of the active substance captan (EFSA, 2014). EFSA updated the calculation using PRIMo revision 3, including the STMR value derived from the residue trials submitted in support of this MRL application and the STMR derived in a contemporaneous assessment for hops (EFSA, 2018b). The input values used in the exposure calculations are summarised in Appendix D.2.

Although uncertainty remains regarding the appropriateness of the toxicological reference values used in the risk assessment, the risk assessment did not indicate a risk to consumer health. The highest estimated long-term dietary intake accounted for 54% of the ADI (NL toddler). The highest contribution of residues expected in cranberries accounted for 0.16% of the ADI (GEMS Food G10 diet). The contribution of residues expected in the commodities assessed in this application to the overall long-term exposure is presented in more detail in Appendix B.3.

EFSA concluded that, the indicative exposure calculation, based on the estimated the long-term intake of residues of captan resulting from the intended use on cranberries and the existing uses, did not indicate a risk to consumer health.

4. Conclusion and Recommendations

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

Uncertainty remains regarding the appropriateness of the existing toxicological reference values for captan and the metabolite THPI used in the risk assessment. The short-term toxicity of the metabolite THPI may need to be reconsidered as proposed by the RMS Austria during the renewal of the approval of the active substance captan under Regulation (EC) No 1107/2009, since recent studies indicate the acute oral toxicity of THPI may be higher than that of the parent captan, and significantly higher than reported in the original DAR of 2003 (Austria, 2017). EFSA concluded that the proposed use of captan on cranberries does not result in a consumer exposure exceeding the existing toxicological reference values and therefore did not indicate a risk to consumer health.

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

The MRL recommendations are summarised in Appendix B.4.

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**Abbreviations**

| Abbreviation | Description |
|--------------|-------------|
| 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 |
| CF           | conversion factor for enforcement to risk assessment residue definition |
| DAR          | draft assessment report |
| DAT          | days after treatment |
| dRAR         | draft Renewal Assessment Report |
| EMS          | evaluating Member State |
| FAO          | Food and Agriculture Organization of the United Nations |
| FPS          | Belgian Federal Public Service |
| GAP          | Good Agricultural Practice |
| GC–MS        | gas chromatography with mass spectrometry |
| GEMS Food    | Global Environment Monitoring System/Food Contamination Monitoring and Assessment Programme |
| HR           | highest residue |
IEDI international estimated daily intake
IESTI international estimated short-term intake
InChIKey International Chemical Identifier Key
ILV independent laboratory validation
ISO International Organisation for Standardisation
IUPAC International Union of Pure and Applied Chemistry
LOQ limit of quantification
MRL maximum residue level
MS Member States
MW molecular weight
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
WG water-dispersible granule
## 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(a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|-------------------------|-------------|-----------------------------------|-------------|-------------|---------------------------------|--------------|---------|
| Cranberries BE I      |                         |             | Botrytis fuckeliana               | WG          | 800 g/kg   | Spraying Begin flowering – harvest BBCH 60-87 | 1–6          | 7 days  | 1.44 kg/ha | Maximum total application 8.64 kg/ha |
| Cranberries BE I      |                         |             | Botrytis fuckeliana               | WG          | 800 g/kg   | Spraying After harvest BBCH 93-97 | 1–2          | 7 days  | 1.44 kg/ha | Maximum total application 2.88 kg/ha |

MRL: maximum residue level; GAP: Good Agricultural Practice; NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance; WG: water-dispersible granule.

(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)** | **Comment/Source** |
|--------------------------------------|----------------|-------------|--------------------|--------------------|--------------------|
| **Fruit crops**                      | Tomatoes       | Foliar, G 4 x 4.48 kg a.s./ha 7-day interval | 0                  | 14C-trichloromethyl EFSA (2014) |
|                                      | Tomatoes       | Foliar, G 4 x 4.48 kg a.s./ha 7-day interval | 0                  | 1,2-14C-cyclohexene EFSA (2014) |
|                                      | Apples         | Foliar, F 1 x 0.12 kg a.s./hl 7-day interval | 0, 20              | 14C-carbonyl EFSA (2014) |
|                                      | Apples         | Foliar, F 2 x 0.12 kg a.s./hl 7-day interval | 20                 | 14C-carbonyl EFSA (2014) |
|                                      | Apples         | Foliar, F 3 x 0.12 kg a.s./hl 7-day interval | 20                 | 14C-carbonyl EFSA (2014) |
| **Leafy crops**                      | Lettuce        | Foliar, G 4 x 4.48 kg a.s./ha 7-day interval | 0                  | 14C-trichloromethyl EFSA (2014) |
|                                      | Lettuce        | Foliar, G 4 x 4.48 kg a.s./ha 7-day interval | 0                  | 1,2-14C-cyclohexene EFSA (2014) |
| **Rotational crops** (available studies) | **Crop groups** | **Crop(s)** | **Application(s)** | **PBI (DAT)** | **Comment/source** |
|                                      | Root/tuber crops | Beet          | Bare soil, G 4.48 kg a.s./ha (for each labelled form) | Sowing: 34 DAT Harvest: 43, 54, 61, 126, 131 DAT | 14C-trichloromethyl and 1,2-14C-cyclohexene EFSA (2014) |
|                                      | Root/tuber crops | Beet          | Bare soil, G 4.48 kg a.s./ha (for each labelled form) | Sowing: 88 DAT Harvest: 105, 116, 158, 186 DAT | 14C-trichloromethyl and 1,2-14C-cyclohexene EFSA (2014) |
|                                      | Leafy crops    | Lettuce       | Bare soil, G 4.48 kg a.s./ha (for each labelled form) | Sowing: 34 DAT Harvest: 43, 54, 61, 75 DAT | 14C-trichloromethyl and 1,2-14C-cyclohexene EFSA (2014) |
|                                      | Leafy crops    | Lettuce       | Bare soil, G 4.48 kg a.s./ha (for each labelled form) | Sowing: 88 DAT Harvest: 105, 116, 138, 158 DAT | 14C-trichloromethyl and 1,2-14C-cyclohexene EFSA (2014) |
|                                      | Cereal (small grain) | Wheat      | Bare soil, G 4.48 kg a.s./ha (for each labelled form) | Sowing: 34 DAT Harvest: 43, 54, 61, 75, 131 DAT | 14C-trichloromethyl and 1,2-14C-cyclohexene EFSA (2014) |
|                                      | Cereal (small grain) | Wheat      | Bare soil, G 4.48 kg a.s./ha (for each labelled form) | Sowing: 88 DAT Harvest: 105, 116, 224 DAT | 14C-trichloromethyl and 1,2-14C-cyclohexene EFSA (2014) |
### Processed Commodities

| Conditions                        | Stable? | Comment/Source |
|----------------------------------|---------|----------------|
| Pasteurisation (20 min, 90°C, pH 4) | No      | EFSA (2014)    |
| Baking, brewing and boiling (60 min, 100°C, pH 5) | No      | EFSA (2014)    |
| Sterilisation (20 min, 120°C, pH 6) | No      | EFSA (2014)    |

Other processing conditions: –

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

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### Can a General Residue Definition Be Proposed for Primary Crops?

| Question                                           | Answer       | Source   |
|----------------------------------------------------|--------------|----------|
| Rotational crop and primary crop metabolism similar? | Not triggered| EFSA (2014) |
| Residue pattern in processed commodities similar to residue pattern in raw commodities? | Yes | EFSA (2014) |

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### Plant Residue Definition for Monitoring (RD-Mo)

Sum of captan and THPI, expressed as captan

### Plant Residue Definition for Risk Assessment (RD-RA)

Sum of captan and THPI, expressed as captan

### Methods of Analysis for Monitoring of Residues (Analytical Technique, Crop Groups, LOQs)

**Methods of analysis submitted in the framework of the approval under Directive 91/414/EEC**
- Matrices with high water content and high acid content matrices: GC–MS, LOQ 0.05 mg/kg for captan
- Matrices with high water content: GC–MS, LOQ 0.01 mg/kg for THPI

**Confirmatory method and ILV missing for determination of THPI in high water content matrices**
- Validated method with its ILV and confirmatory method missing for determination of THPI in high acid content matrices (EFSA, 2014)

**New methods of analysis submitted in the framework of the Annex I renewal under Regulation (EC) No 1107/2009 and assessed in the Draft Renewal Assessment Report (peer-review ongoing)**
- Matrices with high water content, high oil content, high acid content and dry matrices: GC–MS, LOQ 0.01 mg/kg for captan and THPI
- Confirmatory method available. ILV available (Austria, 2017; EFSA, 2018b)

**DAT:** days after treatment; **a.s.:** active substance; **PBI:** plant-back interval; **GC–MS:** gas chromatography with flame photometric detector; **LOQ:** limit of quantification; **ILV:** independent laboratory validation.
### B.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category   | Commodity       | T (°C)  | Stability period | Compounds covered                                                                 | Comment/Source                      |
|-----------------------------------|------------|-----------------|---------|-----------------|----------------------------------------------------------------------------------|-------------------------------------|
|                                   | High water content | Tomatoes         | –20°C   | 20 Month        | Total captan and THPI residues, expressed as captan equivalents                    | Italy (2003), EFSA (2014)          |
|                                   | High oil content  | –                | –       | –               | –                                                                                | –                                   |
|                                   | High protein content | –                | –       | –               | –                                                                                | –                                   |
|                                   | Dry/High starch  | –                | –       | –               | –                                                                                | –                                   |
|                                   | High acid content | Strawberries     | –20°C   | 14 Month        | Total captan and THPI residues, expressed as captan equivalents                    | Italy (2003), EFSA (2014)          |
|                                   | Processed products | Hop cones, dried | –18°C   | 12 Month        | Captan, THPI                                                                      | EFSA (2018b)                       |
|                                   | Others         | –                | –       | –               | –                                                                                | –                                   |

### B.1.2. Magnitude of residues in plants

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

| Commodity | Region/indoor | Residue levels observed in the supervised residue trials (b) (mg/kg) | Comments/source                                                                 | Calculated MRL (mg/kg) | HR(c) (mg/kg) | STMR(d) (mg/kg) | CF(e) |
|-----------|---------------|---------------------------------------------------------------------|---------------------------------------------------------------------------------|------------------------|--------------|----------------|-------|
| Cranberries | Indoor     | Red currants: 4.17, 4.29(f), 6.13, 7.86, 8.15, 10.29(f), 13.06 | Residue trials on red currents compliant with GAP. Extrapolation to cranberries possible | 30                     | 13.06        | 7.86           | n.a.  |

MRL: maximum residue level; GAP: Good Agricultural Practice.
*: Indicates that the MRL is proposed at the limit of quantification.
(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): The sum of captan and THPI, expressed as captan obtained after molecular weight adjustment (300.578/151.162).
(c): Highest residue. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.
(d): Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.
(e): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.
(f): Peak residue value detected after the GAP minimum PHI.
B.1.2.2. Residues in rotational crops

| Residues in rotational and succeeding crops expected based on confined rotational crop study? | Not triggered | EFSA, 2014 |
| Residues in rotational and succeeding crops expected based on field rotational crop study? | Not triggered | EFSA, 2014 |

B.1.2.3. Processing factors

No processing studies were submitted in the framework of the present MRL application.

B.2. Residues in livestock

Not relevant for the commodities under consideration.

B.3. Consumer risk assessment

| ARFD | 0.3 mg/kg bw (EFSA, 2009) |
| Highest IESTI, according to EFSA PRIMo | Cranberries: 11% of ARFD |
| Assumptions made for the calculations | The calculation is based on the highest residue levels expected in raw agricultural commodities. The risk assessment is based on the toxicological reference values derived in 2009 (EFSA, 2009), assuming that THPI is of similar toxicity as parent captan. The risk assessment may need to be revised if the toxicological reference values for the compounds included in the residue definition for risk assessment are revised |

| ADI | 0.1 mg/kg bw per day (EFSA, 2009) |
| Highest IEDI, according to EFSA PRIMo | 54% ADI (NL toddler) |
| Assumptions made for the calculations | Contribution of crops assessed: Cranberries: 0.16% of ADI (GEMS Food G10 diet) |
| | The calculation is based on the median residue levels derived for raw agricultural commodities. The contributions of commodities where no GAP was reported in the framework of the MRL review were not included in the calculation. The risk assessment is based on the toxicological reference values derived in 2009 (EFSA, 2009), assuming that THPI is of similar toxicity as parent captan. The risk assessment may need to be revised if the toxicological reference values for the compounds included in the residue definition for risk assessment are revised |

ARFD: acute reference dose; bw: body weight; IESTI: international estimated short-term intake; PRIMo: (EFSA) Pesticide Residues Intake Model; ADI: acceptable daily intake; IEDI: international estimated daily intake; MRL: maximum residue level.
## B.4. Recommended MRLs

| Code<sup>(a)</sup> | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|-------------------|-----------|------------------------|-------------------------|-----------------------|
| 0154020           | Cranberries | 0.03*                  | 30                      | The submitted data are sufficient to derive an MRL proposal for the indoor use of captan. EFSA concluded that the proposed use of captan on cranberries does not result in a consumer exposure exceeding the existing toxicological reference values and therefore did not indicate a risk to consumer health. The conclusions reported in this reasoned opinion may need to be reconsidered in the light of the outcome of the peer review. |

**Enforcement residue definition:** Sum of captan and THPI, expressed as captan.

**MRL:** maximum residue level.
### Appendix C – Pesticide Residue Intake Model (PRIMo)

**Captain**

| MRLs set at the LOQ (in % of ADI) | Commodities not under assessment (in % of ADI) |
|----------------------------------|--------------------------------------------|
| Currants (red, black and white)  | 54%                                        |
| Currants (red, black and white)  | 10%                                        |
| Milk: Cattle                     | 12%                                        |
| Milk: Cattle                     | 8%                                         |
| Milk: Cattle                     | 6%                                         |
| Milk: Cattle                     | 5%                                         |
| Milk: Cattle                     | 4%                                         |
| Milk: Cattle                     | 3%                                         |
| Milk: Cattle                     | 2%                                         |
| Milk: Cattle                     | 2%                                         |
| Gooseberries (green, red and yellow) | 8%                                           |
| Pears                            | 8%                                         |
| Milk: Cattle                     | 8%                                         |
| Milk: Cattle                     | 7%                                         |
| Milk: Cattle                     | 7%                                         |
| Milk: Cattle                     | 6%                                         |
| Milk: Cattle                     | 6%                                         |
| Milk: Cattle                     | 5%                                         |
| Milk: Cattle                     | 4%                                         |
| Milk: Cattle                     | 4%                                         |
| Milk: Cattle                     | 3%                                         |
| Milk: Cattle                     | 3%                                         |
| Milk: Cattle                     | 3%                                         |
| Milk: Cattle                     | 2%                                         |
| Milk: Cattle                     | 2%                                         |
| Milk: Cattle                     | 2%                                         |
| Milk: Cattle                     | 1%                                         |
| Milk: Cattle                     | 1%                                         |
| Milk: Cattle                     | 1%                                         |

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

| Commodity / group of commodities | Exposure resulting from | Calculated exposure (µg/kg bw per day) | Highest contributor to MS diet (in % of ADI) | 2nd contributor to MS diet (in % of ADI) | 3rd contributor to MS diet (in % of ADI) | Commodity / group of commodities |
|----------------------------------|-------------------------|----------------------------------------|---------------------------------------------|------------------------------------------|----------------------------------------|----------------------------------|
| Currants (red, black and white)  |                         |                                        |                                             |                                         |                                        | Currants (red, black and white)  |
| Currants (red, black and white)  |                         |                                        |                                             |                                         |                                        | Currants (red, black and white)  |
| Milk: Cattle                     |                         |                                        |                                             |                                         |                                        | Milk: Cattle                     |
| Milk: Cattle                     |                         |                                        |                                             |                                         |                                        | Milk: Cattle                     |
| Milk: Cattle                     |                         |                                        |                                             |                                         |                                        | Milk: Cattle                     |
| Milk: Cattle                     |                         |                                        |                                             |                                         |                                        | Milk: Cattle                     |
| Milk: Cattle                     |                         |                                        |                                             |                                         |                                        | Milk: Cattle                     |
| Milk: Cattle                     |                         |                                        |                                             |                                         |                                        | Milk: Cattle                     |
| Milk: Cattle                     |                         |                                        |                                             |                                         |                                        | Milk: Cattle                     |
| Milk: Cattle                     |                         |                                        |                                             |                                         |                                        | Milk: Cattle                     |
| Milk: Cattle                     |                         |                                        |                                             |                                         |                                        | Milk: Cattle                     |
| Milk: Cattle                     |                         |                                        |                                             |                                         |                                        | Milk: Cattle                     |
| Milk: Cattle                     |                         |                                        |                                             |                                         |                                        | Milk: Cattle                     |
| Milk: Cattle                     |                         |                                        |                                             |                                         |                                        | Milk: Cattle                     |
| Milk: Cattle                     |                         |                                        |                                             |                                         |                                        | Milk: Cattle                     |
| Milk: Cattle                     |                         |                                        |                                             |                                         |                                        | Milk: Cattle                     |
| Milk: Cattle                     |                         |                                        |                                             |                                         |                                        | Milk: Cattle                     |
| Milk: Cattle                     |                         |                                        |                                             |                                         |                                        | Milk: Cattle                     |
| Milk: Cattle                     |                         |                                        |                                             |                                         |                                        | Milk: Cattle                     |
| Milk: Cattle                     |                         |                                        |                                             |                                         |                                        | Milk: Cattle                     |
| Milk: Cattle                     |                         |                                        |                                             |                                         |                                        | Milk: Cattle                     |
| Milk: Cattle                     |                         |                                        |                                             |                                         |                                        | Milk: Cattle                     |
| Milk: Cattle                     |                         |                                        |                                             |                                         |                                        | Milk: Cattle                     |
| Milk: Cattle                     |                         |                                        |                                             |                                         |                                        | Milk: Cattle                     |
| Milk: Cattle                     |                         |                                        |                                             |                                         |                                        | Milk: Cattle                     |
| Milk: Cattle                     |                         |                                        |                                             |                                         |                                        | Milk: Cattle                     |
| Milk: Cattle                     |                         |                                        |                                             |                                         |                                        | Milk: Cattle                     |
| Milk: Cattle                     |                         |                                        |                                             |                                         |                                        | Milk: Cattle                     |
| Milk: Cattle                     |                         |                                        |                                             |                                         |                                        | Milk: Cattle                     |
| Milk: Cattle                     |                         |                                        |                                             |                                         |                                        | Milk: Cattle                     |
| Milk: Cattle                     |                         |                                        |                                             |                                         |                                        | Milk: Cattle                     |

**Conclusion:**

The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI. The long-term intake of residues of Captan is unlikely to present a public health concern.
The acute risk assessment is based on the ARfD. The calculation is based on the large portion of the most critical consumer group. (IESTI new calculations:)

The calculation is performed with the MRL and the penning/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations, a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

The calculation is based on the large portion of the most critical consumer group.

### Results for children

| Commodities | MRL / input (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI |
|-------------|---------------------|---------------------|----------------------|
| Cranberries | 30 / 13.06          | 34                   | 26%                  |

### Results for adults

| Commodities | MRL / input (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI |
|-------------|---------------------|---------------------|----------------------|
| Apples      | 0 / 7.86            | 225                  | 35%                  |

### Results for children

| Commodities | MRL / input (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI |
|-------------|---------------------|---------------------|----------------------|
| Currants (red, black and white) | 0 / 7.86 | 100 | 56% |

### Results for adults

| Commodities | MRL / input (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI |
|-------------|---------------------|---------------------|----------------------|
| Tomatoes / sauce/puree | 0 / 0.34 | 1.1 | 0.4% |

### Conclusion:

The total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI new calculation) is zero. For processed commodities, no exceedance of the ARfD/ADI was identified.

The calculation is performed with the MRL and the penning/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations, a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.
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  |
| Commodities under assessment are not fed to livestock |

D.2. Consumer risk assessment

| Commodity                | Chronic risk assessment | Acute risk assessment |
|--------------------------|-------------------------|-----------------------|
|                          | Input value (mg/kg)     | Comment               | Input value (mg/kg)   | Comment  |
| Risk assessment residue definition: Sum of captan and THPI, expressed as captan |
| Cranberries              | 7.86 STMR               | 13.06 HR              |
| Pome fruits              | 3.11 STMR (EFSA, 2014)  |
| Apricots                 | 1.34 STMR (EFSA, 2014)  |
| Cherries                 | 1.00 STMR (EFSA, 2014)  |
| Peaches                  | 1.34 STMR (EFSA, 2014)  |
| Plums                    | 1.20 STMR (EFSA, 2014)  |
| Strawberries             | 0.47 STMR (EFSA, 2014)  |
| Blackberries             | 5.32 STMR (EFSA, 2014)  |
| Raspberries              | 5.32 STMR (EFSA, 2014)  |
| Blueberries              | 7.86 STMR (EFSA, 2014)  |
| Currants (black, red and white) | 7.86 STMR (EFSA, 2014)  |
| Gooseberries             | 7.86 STMR (EFSA, 2014)  |
| Tomatoes                 | 0.34 STMR (EFSA, 2014)  |
| Hops                     | 33.1 STMR (EFSA, 2018b) |

Risk assessment residue definition: Sum of THPI, 3-OH THPI and 5-OH THPI, expressed as captan

| Commodity                | Chronic risk assessment | Acute risk assessment |
|--------------------------|-------------------------|-----------------------|
|                         | Input value (mg/kg)     | Comment               | Input value (mg/kg)   | Comment  |
| Ruminant muscle          | 0.08 STMR (EFSA, 2014)  |
| Ruminant fat             | 0.05 STMR (EFSA, 2014)  |
| Ruminant liver           | 0.08 STMR (EFSA, 2014)  |
| Ruminant kidney          | 0.08 STMR (EFSA, 2014)  |
| Milk: cattle, sheep, goat | 0.03* STMR (EFSA, 2014) |

STMR: supervised trials median residue; HR: highest residue.
* Indicates that the MRL is set at the limit of analytical quantification (LOQ).
## Appendix E – Used compound codes

| Code/trivial name | Chemical name/SMILES notation/InChiKey\(^{(a)}\) | Structural formula\(^{(b)}\) |
|-------------------|-----------------------------------------------|-----------------------------|
| Captan            | \(N\)-(trichloromethylthio)cyclohex-4-ene-1,2-dicarboximide ClC(Cl)(Cl)SN1C(=O)C2CC--CCC2C1=O LDVVMCZRFWMZSG-UHFFFAOYSA-N | ![Structural formula for Captan](image) |
| THPI              | 3a,4,7,7a-tetrahydro-1H-isooindole-1,3(2H)-dione O=C1NC(=O)C2CC--CCC12 CIFFBTOJCKSRJY-UHFFFAOYSA-N | ![Structural formula for THPI](image) |
| 3-OH THPI         | (4RS)-4-hydroxy-3a,4,7,7a-tetrahydro-1H-isooindole-1,3(2H)-dione O=C1NC(=O)C2CC--CCC12 MLJWDNXRMUBJJU-UHFFFAOYSA-N | ![Structural formula for 3-OH THPI](image) |
| 5-OH THPI         | (5RS)-5-hydroxy-3a,4,5,7a-tetrahydro-1H-isooindole-1,3(2H)-dione O=C1C--CCC2(=O)NC(=O)C2C1 GNUDNAYOODXBQP-UHFFFAOYSA-N | ![Structural formula for 5-OH THPI](image) |

SMILES: simplified molecular-input line-entry system; InChiKey: International Chemical Identifier Key.

\(^{(a)}\): ACD/Name 2015 ACD/Labs 2015 Release (File version N20E41, Build 75170, 19 December 2014).

\(^{(b)}\): ACD/ChemSketch 2015 ACD/Labs 2015 Release (File version C10H41, Build 75059, 17 December 2014).