
Changes to legislation: There are outstanding changes not yet made to Commission Regulation (EU) No 283/2013. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

ANNEX

PART A

CHEMICAL ACTIVE SUBSTANCES

SECTION 1

Identity of the active substance

1.10. Identity and content of additives (such as stabilisers) and impurities

The minimum and maximum content in g/kg of each additive shall be provided.

The maximum content in g/kg of each further component other than additives shall also be provided.

If the active substance is manufactured as technical concentrate (TK), the maximum content of each impurity shall be given, along with their content in the theoretical dry weight material.

Isomers that are not part of the ISO common name are considered as impurities.

Where the information provided does not fully identify a component (for example condensates), detailed information on the composition shall be provided for each such component.

Where the required information is provided for a pilot plant production system, that information shall again be provided once industrial scale production methods and procedures have stabilised. Where available, industrial scale data shall be provided before approval under Regulation (EC) No 1107/2009. Where data on industrial scale production are not available, a justification shall be provided.

For plant extracts, a different approach may be taken if adequately justified.

1.10.1. Additives

The trade name of components added to the active substance, prior to manufacture of the plant protection product, to preserve stability and facilitate ease of handling, hereinafter 'additives', shall also be provided. The following information shall, where relevant, be provided for such additives:

- (a) chemical name in accordance with IUPAC and CA nomenclature;
- (b) ISO common name or proposed common name if available;
- (c) CAS number, EC number;
- (d) molecular and structural formula;
- (e) molar mass;
- (f) minimum and maximum content in g/kg; and
- (g) function (for example stabiliser).

1.10.2. Significant impurities

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Impurities present in quantities of 1 g/kg or more shall be considered as significant. For significant impurities the following information, where relevant, shall be provided:

- (a) chemical name in accordance with IUPAC and CA nomenclature;
- (b) ISO common name or proposed common name, if available;
- (c) CAS number, EC number;
- (d) molecular and structural formula;
- (e) molar mass; and
- (f) maximum content in g/kg.

Information on how the structural identity of the impurities was determined shall be given.

1.10.3. *Relevant impurities*

Impurities that are particularly undesirable because of their toxicological, ecotoxicological or environmental properties, shall be considered as relevant. For relevant impurities the following information, where relevant, shall be provided:

- (a) chemical name in accordance with IUPAC and CA nomenclature;
- (b) ISO common name or proposed common name if available;
- (c) CAS number, EC number;
- (d) molecular and structural formula;
- (e) molar mass; and
- (f) maximum content in g/kg.

Information on how the structural identity of the impurities was determined shall be reported.

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Changes and effects yet to be applied to the whole legislation item and associated provisions

- Signature words omitted by [S.I. 2019/556 reg. 21\(4\)](#)
- Annex Pt. A s. 8 word omitted by [S.I. 2019/556 reg. 21\(5\)\(b\)\(xiv\)](#)
- Annex Pt. A s. 1 point 1.4 word substituted in earlier amending provision S.I. 2019/720, Sch. 2 para. 176(2)(a)(i) by [S.I. 2020/1567 Sch. 2 para. 61](#)
- Annex Pt. A s. 1 point 1.4.1 word substituted in earlier amending provision S.I. 2019/720, Sch. 2 para. 176(2)(b) by [S.I. 2020/1567 Sch. 2 para. 61](#)
- Annex Pt. B s. 9 words omitted by [S.I. 2019/556 reg. 21\(5\)\(c\)\(vi\)](#)
- Art. 1(1) Art. 1 renumbered as Art. 1(1) by [S.I. 2019/556 reg. 21\(2\)\(a\)](#)
- Art. 1(2) inserted by [S.I. 2019/556 reg. 21\(2\)\(b\)](#)