

Summary of product characteristics (SPC) quality checklist

Language

- The English version of the SPC should only contain text in English.
- Consistent text and vocabulary (e.g. technical terms) is used throughout the SPC.
- Do not use words with first capital letters in the middle of a sentence, avoid repetition of words and sentences without verbs.
- Each instruction must be complete and understandable for non-experts, avoid jargon.
- No repetition of text, e.g. for one use it is not necessary to repeat use instructions in several fields and no need to repeat the use specific information in the general section.
- Abbreviations should be explained when they first appear in the text: e.g. high density polyethylene (HDPE).
- Conclusive messages are given with the words 'need to', 'shall' or 'must' where appropriate.
- The words 'and' and 'or' are used instead of a slash (/).
- Correct units are used:
 - Volume and weight are expressed as e.g., ml or g, kg.
 - Surface and volume are indicated with superscript (m², m³)¹.
 - Time is expressed as minutes, seconds, hours, not as "min", "sec" and "h".
- A comma is used for decimals, not a point (e.g., use 0,5 and not 0.5).
- Non-relevant sections should not be left empty but a "-" should be indicated.
- If there are no use specific instruction for use include in that section "see general directions use".

Content

- The description of the uses, application rates etc. is clear and coherent with the information in the PAR and BPC opinion.
- It should be ensured that in the SPC the content of each section is coherent with the content of the other sections.
- The following information has been included for each use:
 - Application rate and volume or weight of the product (e.g., volume applied per unit of surface (ml/m²))
 - Frequency of use
 - Dilution of the product expressed in percentage (%) of the active substance in the final diluted product and identification of the solvent to be used when applicable. Otherwise "indication ready-to-use (RTU) product"
 - Instructions for use
 - Risk mitigation measures.

¹ Superscript can be used only in the free field texts of the SPC editor. E.g., it is not possible to include under field application method – method.

- Units are included for all provided numbers, where percentage is indicated (e.g., do not use just %, explain –%(v/v), %(w/w), %(v/w)).²
- Risk mitigation measures are included in such a way that it is clear for which use and which user category they should be implemented.
- Information on the frequency of use is clearly given in the SPC, terms such as “use as required”, “use as many times as needed”, “daily use” are not acceptable³.
- Specify the type of equipment, including any European Standard to be complied with, to be worn by the professional users and when (during mixing and loading, handling of the product, application, removal of residues, disposal of product and or packaging) if required.

Example of sentence: *Wear protective chemical resistant gloves classified under the European Standard EN 374 or equivalent during product handling phase. Glove material to be specified by the authorisation holder within product information.*

- When an EN standard or EU law is referred to, a full reference (i.e. full title of the EN norm or EU law) is included when the EN standard or EU law is mentioned. EN standards and EU laws should be also listed Section 6 of the SPC “Other information”.
- Precautionary statements should be completed as indicated in the CLP regulation and specific to the case.
- There are no misleading terms present in trade names in accordance with Article 69.2 of the BPR, e.g., ‘bio’, ‘eco’ ‘green’, ‘nature’, ‘natural’, ‘safe’, ‘organic’⁴) as prefix or suffix likely to be considered as misleading in the trade names of any biocidal product. See CA-June23-Doc.4.9.Final.rev1-Misleading terms in trade names⁵.

Administrative items

- In case of Union authorisation applications, the market area is set to ‘European Union’ for all products and trade names.
- There are no annotations in the SPC file.
- It is recommended that trade names are listed in alphabetic order.
- Trade names should be reported in separate entries.

Alignment with other documents

- Check also the document [‘Recommendations on preparing SPC for single biocidal products and biocidal product families’](#)
- The sentences as listed in the agreed document [‘Frequently used sentences in the SPC and translations’](#) are used.

² This is not relevant for Section 2 Composition. The content of active substance and substance of concern is always given as % of w/w.

³ “Unless safe use is shown by a reverse reference scenario” – see document: CG-54_e-c Use of the term as required for the application frequency in CIRCABC: [S-CIRCABC - General agreements \(europa.eu\)](#)

⁴ This list is not to be intended as exhaustive.

⁵ CIRCABC: [Circabc \(europa.eu\)](#)