

Guidance for filling out the composition statement (February 2013)

Without proper knowledge of the composition statement of the formulation it is not possible for the Ctgb to perform an assessment. The composition statement is the 'recipe' for your formulation, and is comprised of information about the technical active substances and all co-formulations that have been used during the formulation-process of the product.

The following stepwise guidance has been written to offer support with filling out the composition statement in Ctgb format. For further explanation you can consult the PowerPoint presentation on this website, where the guidance text is further illustrated with screen-shots of the Ctgb composition statement. The information in the composition is treated as confidential by the Ctgb. Sometimes it might be necessary for the benefit of your application that a third party submits confidential information to the Ctgb on your behalf. Please take care that the third party also states the application number of your request (when available), and the name of your formulation in an accompanying text (both in writing and on CD/DVD).

The lay-out of the composition statement

The composition statement is build up from several sections that need to be filled out.

1. Basic information about the composition statement.
2. A (blue) table for information about the active substance.
3. A table for information about the added co-formulants.
4. A (blue) table for information about the manufacturing sites of the active substance.

Following is further guidance per section on how to fill out the required information.

Please note: Over several columns there are multiple options (CAS/Einecs/Elincs; g/L or g/kg). In the first column only a CAS-number is required, the Einecs- or Elincs-number can be omitted. For the second column you need to make a choice between g/L and g/kg, and not place multiple data in one cell.

1. Basic information

- In the cell after 'Formulation name', you need to fill out the full name of the product concerning the application. This name needs to correspond to the name on the header page of the application form.
- The 'Specificatie code' is your own specification or number for the composition, for instance to be used for filing the information.
- Below the table for co-formulants you fill out the date when the Ctgb composition statement has been drafted.

2. Informatie over de werkzame stof

Following you can find an explanation on filling out all necessary information about the active substance. The difference on technical and pure active substance is addressed. There is also additional information on special situations, such as when the active substance is present as an ester or salt, or when the active substance is formed from precursors.

General information about the active substance(s)

This information is filled out in the top blue part of the Ctgb composition statement.

- In the column 'Trade name' you enter the trade or brand name of the active substance. This name is provided by the supplier. The name that is entered here needs to correspond to the name on the MSDS for this substance.
- In the column 'Chemical name' the chemical name of the active substance is entered, preferably according to IUPAC nomenclature. This information can be found on the label of the active substance, or on the corresponding MSDS.

- The cell in the column 'Description' can be used to provide further information on the active substance that does not automatically follow from the chemical or trade name. For instance when the active substance is formed from precursors. (see also section below).
- The CAS-number of the active substance needs to be entered in the corresponding column.

Information concerning the active substance content.

After the cell 'active substance', information about the technical active substance is entered. This is the active substance as provided by the supplier, including any impurities, solvents, stabilisers and other additives. This technical active substance is used as such during the formulation of the product.

- In the column 'w/w (%)' you always fill out the content of the technical active substance, in mass percentage.
- In the column 'g/L or g/kg' you need to enter the content of the technical active substance in one of the mentioned units.
- Only when the content technical active substance can be better expressed in a not-mentioned unit (in the case of enzymes etc.), you can use the middle column: '(other; unit)'.
- In the last column, 'minimal purity', the specification (e.g. minimal purity) of the technical active substance needs to be entered. This number has to reflect the minimal purity, and not a mean or nominal purity of the active substance. This specification can not always be derived from an MSDS or Listing of Endpoints, but can be checked with the supplier.

Please note: Any other components than the active substance need **not** be entered in the composition statement. For example: does the technical active compound contain active substance and a stabiliser, then no information about the stabiliser is required.

Information about the pure active substance content

After the cell 'pure active substance', information about the pure active substance is entered. This is the active substance as provided by the supplier, **excluding** any impurities, solvents, stabilisers and other additives. The pure active substance content is the content mentioned on the label of the requested product, and any monitoring and enforcement will be based on this content. This number is also leading for the risk assessment, and is to be entered in the GAP-table. The required information is roughly the same as for the technical active substance:

- In the column 'w/w (%)' you always fill out the content of the pure active substance, in mass percentage. This content needs to follow from calculations using the specification. For example: if the formulation contains 80.0% w/w technical active substance with a specification of 96%, then the pure active substance content is 76.8% w/w.
- In the column 'g/L or g/kg' you need to enter the content of the technical active substance in one of the mentioned units.
- Only when the content technical active substance can be better expressed in a not-mentioned unit, you can use the middle column: '(other; unit)'.

When the active substance is formulated as an ester or salt

When the used active substance is formulated as a salt or ester, you need to enter the (calculated) free acid content, apart from the technical and pure active substance content. For example: when propamocarb.HCL is used as active substance, content information about both propamocarb.HCl (salt) and propamocarb (free acid equivalent) has to be provided. The free acid equivalent often has a separate CAS-number, please fill this out in the Ctgb composition statement as well.

Please note: there are several special situations, such as for diquat and other compounds that can not be expressed as a free acid equivalent. In these cases the ion or compound name on which approval under 1107/2009/EC is based needs to be mentioned.

When the active substance is formed from precursors

When the active substance is not added as such to the product, but is formed from precursors present in the formulation, two different situations can be distinguished.

1. The product only contains the precursors. The active substance is formed during application of the product. Only the precursors need to be filled out in the Ctgb composition statement as active substances.
2. The active substance has been formed from precursors during production of the product. Since the active substance is present in the product, it needs to be mentioned in the composition statement. In the column 'Description' the precursors can be described. Because the active substance has not been added as a technical formulation, technical active substance content and specification do not have to be entered. However, the (calculated) pure active substance content is required.
Please note: when one of the precursors is an active substance (e.g. formation of peracetic acid from hydrogen peroxide and acetic acid), the (calculated) pure active substance content of all active substances has to be filled out in the Ctgb composition statement.

3. Information about co-formulants

All information about remaining formulants that are added to the product, is entered in the second table. This table contains therefore no further information about the (technical) active substance. The required information is roughly the same as for the active substance, but minimal purity or specification does not have to be taken into account.

- In the column 'Trade name' you enter the trade or brand name of the active substance. This name is provided by the supplier. The name that is entered here needs to correspond to the name on the MSDS for this substance.
- In the column 'Chemical name' the chemical name of the active substance is entered, preferably according to IUPAC nomenclature. This information can be found on the label of the active substance, or on the corresponding MSDS.
- In column 'Function' the function of the co-formulant in the product is described (solvent, safener, thickener etc.).
- The CAS-number of the main constituent of the co-formulant is to be entered in the corresponding column. If you do not have the CAS-number at your disposal, because the supplier considers this to be confidential information, the supplier can send the requested information directly to the Ctgb. All submitted data shall be treated as confidential.
- In the column 'w/w (%)' you always fill out the content of the co-formulant, in mass percentage.
- In the column 'g/L or g/kg' you need to enter the content of the co-formulant in one of the mentioned units.
- Only when the content of co-formulant can be better expressed in a not-mentioned unit, you can use the middle column: '(other; unit)'.
- Finally you need to indicate whether the co-formulant is a 'Substance of concern'. Further information about this topic can be found at the bottom of the composition statement.

Please note: Some co-formulants are comprised of multiple compounds (information to be found on the MSDS). For each co-formulant, only the main constituent is reported in the Ctgb composition statement. The co-formulant content does have to relate to the total of compound (not just the main constituent). No indication of co-formulant purity is required in the composition statement.

Please note 2: It might be necessary to add a safener or synergist to your product. Although this is an important addition, these compounds are co-formulants. The corresponding information (including function) has to be entered in the co-formulant table.

The sum of contents

At the bottom of the table for co-formulants you will find two cells that indicate the sum of the contents. For your and our convenience, we recommend not to change or delete these cells, because they facilitate a quick check of the composition statement.

- Underneath the column 'w/w (%)', the sum of contents in mass percentage is indicated. When all components of the product have been filled out, the total sum is 100%.

- Underneath the column 'g/L or g/kg', there are two options. When all contents have been filled out in g/L, the sum corresponds to the density of the product. When all contents have been expressed in g/kg, the total sum is 1000 g/kg.

4. Manufacturing sites of the active substance

As on the application form, this last part of the Ctgb composition statement should contain full details of the manufacturing sites for each active substance.