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| **Form** | | |
| **Full declaration** | | |
| **Identification number:** | ZL000\_00\_032 |
| **Version:** | 3.2 |
| **Valid from:** | 11.07.2023 |

# Basic information

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| --- | --- |
| Name of medicinal product: | …… |
| Authorisation no.: *If known* | …… |
| Application ID:  *If known* | …… |
| Date: | …… |

# Further information

Please state the **structured and complete quantitative composition of the medicinal product:**

* The following priorities apply to the substance names: DCI/INN, Ph. Eur., Ph. Helv., other national pharmacopoeias, internationally recognised names (e.g. USAN, BAN, CTFA, etc.), scientific (systematic) names. Trade names should be stated only as additional information.
* For salts of chemical synthetic active substances (free acids or bases) and hydrate forms, the active principle should also be declared.
* For biological substances, the starting material should be stated.
* For herbal substances and preparations, the botanical name of the primary plant and the plant part used should be stated.
* Herbal extracts should be declared according to the Ph. Eur. monograph "Plantarum medicinalium extracta".
* Active substances in Asian medicinal products should be declared with the pharmaceutical name and the name commonly used in the relevant specialist field (e.g. Pin-Yin name for Chinese medicinal products).
* Active substances in transplant products / for gene therapy and for treatments with genetically modified organisms should be declared with the following additional details:

Source and type of virus, cell and tissue, (e.g. chondrocytes, intestinal cells, etc.).

* The active substance quantities should be stated as nominal values, while manufacturing and stability overages or overfills should be listed only as additional information.
* The function of all excipients must be stated.
* For composite flavours and fragrances (aromatic substances) in human medicinal products, the qualitative composition should be stated in addition to the trade name (for excipients of particular interest, quantities should also be stated if possible, as per Annex 3a TPLRO).
* If there are grounds for secrecy, the composition of these mixtures may also be provided directly by the manufacturer. This must be mentioned in the cover letter.
* For other excipient mixtures, specify the quantitative composition.
* For excipients of particular interest according to Annex 3a TPLRO, the total quantity per dose/unit should also be stated if applicable (e.g. the total sodium content per tablet).
* Active substances manufactured according to a homeopathic manufacturing process should be listed in accordance with Ann. 1a no. 1, para. 1 let. e, nos. 1 and 2, and Ann. 1a no. 1, paras. 2 and 3 TPLRO. The clarifications in the guidance document *Authorisation of homeopathics, anthroposophics and other complementary medicines HMV4* should be noted.
* For medicinal products containing active substances manufactured according to a homeopathic manufacturing process, the vehicles or excipients used during manufacture/potentisation (e.g. ethanol, water, lactose monohydrate, glycerol) and accounting for at least 1% of the finished product should be listed separately under the heading "Contents from manufacture/potentisation". In the case of potentisation with an isotonising agent, the sodium-containing substances contained therein must also be listed, regardless of the quantity. Excipients for the pharmaceutical form must be listed separately.
* In the case of anthroposophic medicinal products, active substances that are derived from plant-based starting materials but not manufactured according to a homeopathic process, or for which the homeopathic section of a pharmacopoeia contains no manufacturing instructions, must be declared in accordance with the requirements for herbal substances and preparations.
* For transplant products / for gene therapy and for treatments with genetically modified organisms, the excipients should be declared as follows:

All substances that may remain in the ready-to-use product must be listed (e.g. cytokines, growth factors, antibiotics), incl. reagents and cell culture media (all components to be stated precisely). As far as possible, all substances must be classified according to their function.

* For alcohol-containing medicinal products for oral administration, the alcohol content in the finished product should be stated in percent by volume.
* For preparations with multi-chamber bags, the information should be stated for each bag compartment and compartment size. In addition, the constituents and quantities of the resulting mixed bag can also be stated.
* If known, and in addition to the substance name, a standard substance code can also be stated (e.g. Unique Ingredient Identifier [UNII], EudraVigilance Substance Code [EV Code] or the Chemical Abstracts Service Registry Number [CAS no.]).

All dosage strengths of the medicinal product should be stated in one form.

## Composition

## Calculation of the amount of excipients of particular interest in human medicinal products

Change history

| **Version** | **Change** | **sig** |
| --- | --- | --- |
| 3.3 | New layout, no content adjustments to the previous version. | dei |
| 3.2 | Correction in EN translation for bullet point 10 on page 2 (section 2): from «combined colourants and aromatic substances” to «for composite flavours and fragrances (aromatic substances)». | stb |
| 3.1 | Clarification explaining that the information in section 2.2 is required only for human medicinal products (and not for veterinary medicinal products as well). | stb |
| 3.0 | Inclusion of a sub-section for the calculation of the amount of excipients of particular interest | nma |
| 2.0 | Clarification of declaration requirements for homeopathics and anthroposophics | spm |
| 1.2 | Clarification in section 2 ("Further information"): If, for combinations of colourants and aromatic substances of special interest, it is not possible in individual cases to state quantities as per Annex 3a TPLRO, then a qualitative statement is accepted. | dts |
| 1.1 | Section 2 (Further information):  Linguistic clarifications   * Additional information: For excipients of particular interest according to Annex 3a TPLRO, the total quantity per dose/unit should also be stated if applicable (e.g. the total sodium content per tablet)   Declaration requirements modified for homeopathics and anthroposophics | wph / spm |
| 1.0 | Implementation of HMV4 | dts |