

|  |
| --- |
| **Form** |
| **Confirmation regarding substances from GMO** |
| **Identification number:** | ZL000\_00\_028 |
| **Version:** | 2.2 |
| **Valid from:** | 30.06.2023 |

# Basic information

|  |  |
| --- | --- |
| Name of the medicinal product: | …… |
| Authorisation no.:*If known* | …… |

# Further information

## Information regarding the components of the medicinal product obtained from genetically modified organisms (GMO)

|  |  |  |
| --- | --- | --- |
| **Substance** (active substance / excipient)e.g. polysorbate, sorbitolActive substance Y | **Type / name of the GMO**e.g. cornChinese hamster ovary cells | **Are the conditions for exemption from the mandatory labelling fulfilled in accordance with GMFO?** |
| *Art. 8 para. 8(see point* ***1*** *below)* | Art. 8 para. 7 letters a and b (see point **2** below) |
| °°°°° | °°°°° | [ ]  yes [ ]  no | [ ]  yes [ ]  no |
| °°°°° | °°°°° | [ ]  yes [ ]  no | [ ]  yes [ ]  no |
| °°°°° | °°°°° | [ ]  yes [ ]  no | [ ]  yes [ ]  no |
| °°°°° | °°°°° | [ ]  yes [ ]  no | [ ]  yes [ ]  no |
| °°°°° | °°°°° | [ ]  yes [ ]  no | [ ]  yes [ ]  no |

* + If the "no" box has been checked twice for a substance manufactured from GMOs in the table, then the substance must be declared. Drafts of the product information texts and the packaging materials with the required GMO labelling should be submitted.
	+ In all other cases (if the "yes" box has been checked once or twice) this substance does not have to be labelled.

## Conditions for the omission of labelling

According to Art. 27 para. 3 of the Therapeutic Products Ordinance ([TPO; SR 812.212.21](http://www.admin.ch/ch/d/sr/c812_212_21.html)) in conjunction with Art. 7 of the Ordinance of the Federal Department of Home Affairs concerning genetically modified foods ([GMFO; SR 817.022.51](http://www.admin.ch/ch/d/sr/c817_022_51.html)), substances obtained from GMO must be labelled accordingly.

The GMO labelling may be omitted if:

1. the active substance or excipient was obtained from genetically modified microorganisms, has been separated from the organisms, has been purified, can be chemically defined and has been manufactured in a contained system (in accordance with Art. 8 para. 8 GMFO)

or

1. the fraction of the active substance or excipient manufactured from a GMO is equal to, or less than, 0.9% of the total mass (per component) and it can be proved that appropriate measures have been taken to prevent the presence of such a material in the active substance/excipient (in accordance with Art. 8 para. 7, letters a and b GMFO).

Further information about the requirements for mandatory GMO labelling can be found in the guidance document *Product information for human medicinal products HMV4* and the guidance document *Packaging for human medicinal products HMV4*.

Change history

| **Version** | **Change** | **sig** |
| --- | --- | --- |
| 2.2 | New layout, no content adjustments to the previous version. | dei |
| 2.1 | Formal adjustments to the header and footerNo content adjustments to the previous version. | dei |
| 2.0 | Adjustment to the GMFO revised on 01.07.2020 | stb |
| 1.0 | Implementation of TPO4 | er |