

GENETICALLY MODIFIED ORGANISMS INFORMATION FORM

Under EU and German legislation controlling the use of genetically modified organisms ("Gentechnikgesetz" and "Gentechnik-Sicherheitsverordnung"; Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work) it is necessary for Glycotope Biotechnology to prepare a risk assessment prior to any testing of genetically modified cells or viral vectors. **If you have already prepared a risk assessment under the above legislation, please provide us with a copy of your risk assessment and disregard the following questions. Please use additional paper if required.**

**1. Description of cell line prior to transfection
(species, tissue origin, whether obtained from culture collection)**

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2. Description of vector used to transfect cell line:

2.1. Description of parent vector:

2.2. Has the vector been modified from the parent vector in a way that would change the risk assessment?

Yes No

If Yes, please provide further information:

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2.3. Does the vector contain transposable elements, provirus sequences or genes related to transfer and mobilisation functions?

Yes No

If Yes, please provide further information:

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2.4. Does the vector contain genes coding for potentially harmful or pathological characteristics (e. g., virulence determinant, toxins etc.)?

Yes No

If Yes, please provide further information:

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2.5. Host range of vector:

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3. Description of inserted gene

3.1. Nature of structural gene in insert:

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3.2. Origin of insert (species):

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3.3. Does the insert contain any regulatory or marker genes that should be considered in a risk assessment?

Yes No

If Yes, please provide further information:

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3.4. Does the insert contain transposable elements and/or provirus sequences?

Yes No

If Yes, please provide further information:

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3.5. Does the insert contain potentially harmful sequences?

Yes No

If Yes, please provide further information:

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4. For recombinant viral vectors (gene therapy products) or recombinant viral vaccines please provide the following information. Please indicate if this section is applicable.

Yes No

If Yes, please answer questions 4.1. – 4.4.

4.1. Description of parent viral vector:

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4.2. Has the parent viral vector been modified in a way that would change the risk assessment?

Yes No

If Yes, please provide further information:

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4.3. Does the viral vector contain genes coding for potentially harmful or pathological characteristics?

Yes No

If Yes, please provide further information:

.....

4.4. Host range of viral vector:

.....

Signature

Date

Print Name

Print Company