

Animal Origin Free Statement for CT521 and MX521

BioLamina's products CT521-0501 and MX521-0501 are assessed to be animal-origin free to the secondary level according to the guidelines of the "International Society for Cellular Therapy (ISCT) Animal-Free Origin Survey Results – Summary" (see Attachment).

This statement applies to all lots manufactured since 2018.



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ISCT Animal-Free Origin Survey Results - Summary

1. Animal

An animal is defined as any higher eukaryotic organism excluding plants. Note that this definition includes mammals (including humans), birds, insects and fish.

The term does not include lower eukaryotic organisms including plants, fungi, protozoa and algae. It does not include prokaryotic organisms.

This definition excludes established cell lines that have undergone MCB/WCB testing in accordance with ICH cell substrate testing standards that are used to produce a finished product component or sub-components.

2. Animal – origin

A finished product is considered to be of animal-origin if it is derived from or contains components sourced from animal cells, tissues or body fluids. Note that this definition only refers to the ingredients of the finished product.

3. Animal – origin free

A finished product is considered to be animal-origin free to the primary level if all ingredients of the product are not of animal-origin (this includes packaging material used). Note that animal-products may be used in the manufacturing process but are not intended to be present in the final product.

Example: A recombinant protein is produced in a CHO cell line that has undergone MCB/WCB testing but is grown in medium containing FBS.

A finished product is considered to be animal-origin free to the secondary level if no animal-origin components are used directly in its manufacture or isolation (this includes packaging material used).

Example: A recombinant protein is produced in a CHO cell line that has undergone MCB/WCB testing but is grown in an animal-origin free cell culture medium. The medium contains recombinant transferrin that was grown in a human cell line that had not undergone MCB/WCB testing.

A finished product is considered to be animal-origin free to the tertiary level if no animal-origin sub-components are used in its manufacture or isolation (this includes packaging material used).

Example: A recombinant protein is produced in a CHO cell line that has undergone MCB/WCB testing but is grown in an animal-origin free cell culture medium. The medium contains recombinant transferrin that was grown in a cell line that also underwent MCB/WCB testing and was grown in an animal-origin free cell culture medium. The transferrin was, however purified using a recombinant enzyme that was manufactured in a cell line that was grown in cell culture medium containing FBS.

Equipment that is used in the preparation of the finished product may have come in contact with animal-derived components. The following levels are proposed to classify equipment used in the process.

Equipment & Packaging

- Level 1:** The equipment may be used for both animal-origin and animal-free finished products. The equipment is not cleaned using validated methods for removal of product residue.
- Level 2:** The equipment may be used for both animal-origin and animal-free finished products but the equipment is cleaned following a procedure validated to remove product residue
- Level 3:** The equipment is dedicated to, and exclusively used for animal-free products.

Using these definitions, a finished product can be classified as animal-origin free to various different levels.

4. Xeno-free

A finished product is xeno-free if it satisfies all the conditions laid out for animal origin free with the exception that it may contain ingredients, components or sub-components of human origin.

Diagram to explain ingredients, components and sub-components

