

烟台赛普生物技术有限公司  
CelluPro, Ltd.

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## 关于细胞培养基中黄曲霉毒素的声明

### Statement on Aflatoxin in Cell Culture Media

No: QS-23-016

敬启者:

**To whom it may concern:**

黄曲霉毒素是由两种曲霉菌产生的真菌毒素，具有遗传毒性和致癌性。

Aflatoxins are mycotoxins produced by two species of *Aspergillus* and are known to be genotoxic and carcinogenic.

特此声明，赛普生物的细胞培养基生产过程中未使用黄曲霉毒素（经欧盟委员会法规（EU）No 165/2010 修订的欧盟委员会法规（EC）No 1881/2006 中规定的黄曲霉毒素 B1、B2、G1、G2 和 M1 以及美国食品药品监督管理局（FDA）监管指南中规定的黄曲霉毒素、脱氧雪腐镰刀菌烯醇和伏马菌素），且产品生产中未见黄曲霉毒素引入风险。

It is hereby stated that aflatoxin (including aflatoxins B1, B2, G1, G2, and M1 listed in EC Commission Regulation No 1881/2006 as amended by EU Commission Regulation No 165/2010, as well as aflatoxin, deoxynivalenol and fumonisin involved in FDA regulatory guidance) is not used during the manufacture of CelluPro cell culture media, and there is no risk of introducing aflatoxins during manufacture of the product.

最终培养基中可能存在的黄曲霉毒素污染未进行检测。

Testing for possible contamination of aflatoxins in our final media is not performed.

烟台赛普生物技术有限公司  
CelluPro, Ltd.  
质量保证部

Quality Assurance Department  
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