

烟台赛普生物技术有限公司
CelluPro, Ltd.

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关于细胞培养基中三聚氰胺的声明

Statement on Melamine in Cell Culture Media

No: QS-240509-02

敬启者：

To whom it may concern:

美国食物及药物管理局 (FDA) 于 2009 年 8 月 6 日发布《三聚氰胺污染风险药物成分》的指导文件，文件提醒成品制药商、药剂生产商、再包装商和供应商注意药物成分中三聚氰胺污染的潜在风险。

A guidance document entitled Pharmaceutical Components at Risk for Melamine Contamination was issued by the US Food and Drug Administration (FDA) on August 6, 2009. This guidance alerted pharmaceutical manufacturers of finished products, pharmacy compounders, re-packers, and suppliers to the potential risk of melamine contamination in pharmaceutical components.

赛普生物基于上述指导文件，对三聚氰胺污染风险进行系统评估，结果在所有培养基产品的生产过程中均未见引入三聚氰胺的风险。所有培养基产品不含三聚氰胺，且使用的原材料未见三聚氰胺污染风险。

CelluPro has performed a systematic assessment of melamine contamination risk based on the guidance document, and there is no risk of introducing melamine during the manufacture of all cell culture media products. Melamine is not present in CelluPro cell culture media and no components in the media pose a risk for melamine contamination.

特此声明，赛普生物在细胞培养基的生产过程中未使用三聚氰胺，所有细胞培养基产品均无三聚氰胺污染风险。

It is stated that melamine is not used in the manufacturing processes of CelluPro cell culture media, and there is no potential risk of melamine contamination in cell culture media.



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质量保证部

Quality Assurance Department

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