

TSE/BSE Questionnaire

Name of the product: 产品名称: Concentrated Glycerin (JP)
Name of the manufacturer 制造者名称: Sakamoto Yakuhin Kogyo Co., Ltd.
Address of the manufacturer 制造者地址: 1-2-6 Awajimachi, Chuo-ku Osaka 541-0047, Japan

1. Are the starting materials of the product partly or fully of animal or human origin? (e.g. tissue, tissue extract or fluid such as milk, serum, blood) 产品的起始原料是否部分或全部来源于动物或人类?(例如, 动物细胞组织, 细胞组织萃取物或如乳汁, 血清及血液等体液 ☐ YES ☒ NO If no, specify the origin of the starting materials. 如果选 NO, 请说明起始原料 的来源. ☒ Vegetable 植物 ☐ Synthetic 合成物 ☐ Fermentation/cell culture origin 发酵/细胞培养来源 ☐ Without any animal or human derived product in the broth 培养中无任何人类 或动物衍生产品 ☐ Inorganic 无机物 ☐ Other (please specify):其化(请说明)
2. Are other materials (also reagents like chromatographic media, buffers etc.) of animal or human origin used in the manufacturing process of the product? 产品制造过程中是否有使用其他源于动物或人类的物料 (如: 层析媒介物 或缓冲液等) ☐ YES ☒ NO If YES, specify: 如是, 请说明
3. Are there procedures in place to avoid cross-contamination with residue of animal or human origin materials that come into contact with the equipment used for manufacture of the product.

产品的生产过程中是否有适当的程序可避免动物或人类来源之残留物与生产设备交叉污染?

(e.g. other products and /or cleaning or disinfecting agents, media fills)?

(例如, 其它生产的产品和/或清洁, 消毒剂?)

☐ YES

☐ NO

☒ Not applicable 不适用

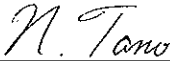
(i.e., no animal / human origin materials come into contact with the equipment)(例如, 无源自动物/人类来源之物质与生产设备接触)

4. Are quality assurance systems such as GMP, ISO9000 or HACCP (Hazard Analysis and Critical Control Point) in place for monitoring the production process, traceability and batch consistency? 质量管理体系如 GMP, ISO9000 或 HACCP 是否适当地控制产品的制造过程, 或追踪性以及批次一致性?

☒ YES Quality assurance system: 如是, 请填写质量管理体系名称

GMP, ISO9001

☐ NO

	Quality Assurance Section Manager, Senboku Factory	2018, Jan. 10
_____ 签名	_____ 职务	_____ 日期(Date)
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