

## Safety Statements

### 安全性声明

BSE/TSE · residual solvents (ICH Q3C) · melamine-free · allergen declaration.

BSE/TSE · 残留溶剂 (ICH Q3C) · 三聚氰胺-free · 过敏原声明。

**TEMPLATE / 模板.** This document is a formatted template prepared for the Unibest excipient range. Fields marked [ to be confirmed ] must be completed from the manufacturing site's stamped originals, and every declaration or certificate must be issued and signed by the manufacturing site before this pack is sent to a customer.

**模板说明.** 本文件为 Unibest 辅料产品线的标准格式模板。标注【待确认】的字段须由生产场地盖章原件补齐；凡属声明或证书性质的文件，必须由生产场地出具并签章后，方可对外提供。

|                   |                                                                                                                                |
|-------------------|--------------------------------------------------------------------------------------------------------------------------------|
| Product 产品        | Polyethylene Oxide (PEO) · Benzalkonium Chloride (BKC) · Trehalose Dihydrate, injectable grade<br>聚环氧乙烷 · 苯扎氯铵 · 海藻糖二水合物 (注射级) |
| Issued by 出具方     | Unibest Industrial Co., Ltd. · Ningbo, China 中国宁波                                                                              |
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### 1 BSE / TSE statement BSE / TSE 声明

We confirm that the products listed below are manufactured from raw materials of non-animal origin. No material of bovine, ovine, caprine or other ruminant origin, and no material classified as a specified risk material, is used at any stage of manufacture, including fermentation media, filters, processing aids and packaging. The products are therefore considered free of transmissible spongiform encephalopathy risk.

兹确认：下列产品的生产原料均非动物来源。生产全过程（含发酵培养基、过滤介质、加工助剂与包装材料）均未使用牛、羊、山羊或其他反刍动物来源物料，亦未使用特定风险物料。据此判定产品不存在传染性海绵状脑病风险。

| Product 产品          | Origin of raw materials 原料来源 | Testing 检测 |
|---------------------|------------------------------|------------|
| PEO                 | 全合成，石油基原料                    | 不适用        |
| BKC                 | 全合成，石油基原料                    | 不适用        |
| Trehalose Dihydrate | 酶法转化淀粉 → 精制结晶；发酵/酶制剂来源须由工厂确认 | 不适用        |

### 2 Residual solvents statement 残留溶剂声明

Residual solvents are controlled in accordance with ICH Q3C(R) and the corresponding general chapter of the applicable pharmacopoeia. Class 1 solvents are not used in any step of manufacture. Class 2 solvents, where used, are controlled below the concentration limit; Class 3 solvents are controlled by loss on drying.

残留溶剂按 ICH Q3C(R) 及适用药典通则控制。生产过程各步骤均不使用第一类溶剂；如使用第二类溶剂， 控制于浓度限度以下；第三类溶剂以干燥失重控制。

| ICH class 类别 | Solvent 溶剂          | Use in process 工艺使用 | Control limit 控制限度 | Status 状态 |
|--------------|---------------------|---------------------|--------------------|-----------|
| Class 1 第一类  | 苯、四氯化碳、1,2-二氯乙烷等    | Not used 未使用        | —                  | Declared  |
| Class 2 第二类  | [ to be confirmed ] | [ to be confirmed ] | 按 ICH Q3C 限度       | Pending   |
| Class 3 第三类  | 乙醇、丙酮、异丙醇等（按工艺）     | [ to be confirmed ] | ≤ 0.5%（干燥失重）       | Pending   |

A solvent-by-solvent declaration for the specific manufacturing route is issued by the site on request.  
针对具体工艺路线的逐项溶剂声明由工厂依需求出具。

### 3 Melamine-free statement 三聚氰胺-free 声明

We confirm that no melamine, melamine-related compound, protein or nitrogen-rich additive is used as an ingredient, processing aid or adulterant at any stage of manufacture, and that no raw material of dairy, plant-protein or animal-protein origin is used. Where required, each batch is tested for melamine by LC-MS/MS with a limit of [ to be confirmed ] ppm.

兹确认：生产全过程未将三聚氰胺、三聚氰胺类化合物、蛋白或富氮添加剂用作原料、加工助剂或掺假物， 亦不使用乳源、植物蛋白或动物蛋白来源原料。如客户要求，可按批以 LC-MS/MS 检测三聚氰胺，限度 [ 待确认 ] ppm。

### 4 Allergen statement 过敏原声明

The products are chemically defined substances produced in dedicated equipment. They contain no intentionally added allergenic material. The following categories are declared as absent:  
本产品为化学定义明确的物质，使用专用设备生产，未有意添加任何致敏物质。以下类别声明为不含：

| Category 类别 | Present 含有 | Declared substances 涉及物质 |
|-------------|------------|--------------------------|
| 乳及乳制品       | No 不含      | 乳糖、乳蛋白                   |
| 麸质谷物        | No 不含      | 小麦、黑麦、大麦、燕麦              |
| 大豆          | No 不含      | 大豆及其衍生物                  |
| 蛋类          | No 不含      | 蛋清、卵磷脂（蛋源）               |
| 坚果与花生       | No 不含      | 各类坚果、花生                  |
| 亚硫酸盐        | No 不含      | 亚硫酸盐类                    |
| 动物源成分       | No 不含      | 明胶、乳糖、动物油脂               |
| 乳胶          | No 不含      | 天然橡胶（含包装接触材料）            |

### 5 Declaration and sign-off 声明与签章

We confirm the statements in sections 1 to 4 are accurate as of the date of issue, and apply to all grades and supply forms of the products listed. Any change affecting these statements will be communicated before shipment.

兹确认第 1 至 4 节的声明截至本文件签发之日真实准确，适用于所列产品的所有规格与供应形态。任何影响上述声明的变更，将在发货前通知客户。

|                     |          |               |          |
|---------------------|----------|---------------|----------|
| Prepared by 编制      | Name 姓名: | Signature 签名: | Date 日期: |
| Checked by 审核       | Name 姓名: | Signature 签名: | Date 日期: |
| Approved by 批准 (QA) | Name 姓名: | Signature 签名: | Date 日期: |

Signed by the manufacturing site 由生产场地签章 · Company chop required on the released version 正式版须加盖企业公章