User Manual for Polysorbate 20 (EP, Tween 20)

1. Introduction

Polysorbate 20, also known as Tween 20, is a nonionic surfactant and emulsifier widely used in food, cosmetics, pharmaceuticals, and scientific applications. It is a polyoxyethylene sorbitan monolaurate, identified by the CAS Number 9005-64-5 and the European food additive number E432. This manual provides detailed information on its properties, applications, handling, safety, and regulatory considerations.

2. Product Overview

2.1 Chemical Identity

- **Name**: Polysorbate 20 (Tween 20)
- **CAS Number**: 9005-64-5
- **Molecular Formula**: C58H114O26 (approximate, as it is a mixture of related compounds)
- **Synonyms**: Polyoxyethylene (20) sorbitan monolaurate, PEG(20) sorbitan monolaurate, Tween 20, Alkest TW 20, Kolliphor PS 20, Kotilen-20
- **European Food Additive Number**: E432

2.2 Physical and Chemical Properties

- **Appearance**: Clear, yellow to yellow-green viscous liquid
- **Solubility**: Soluble in water, ethanol, methanol, and ethyl acetate. Insoluble in liquid paraffin and fixed oils.
- **Molecular Weight**: Approximately 1,225 daltons (assuming 20 ethylene oxide units, 1 sorbitol, and 1 lauric acid)
- **HLB (Hydrophile-Lipophile Balance)**: 16.7 (highly hydrophilic, suitable for oil-in-water emulsions)
- **Critical Micelle Concentration (CMC)**: 59 µM
- **Odor**: Mild

2.3 Composition

Polysorbate 20 is a mixture of partial laurate esters of sorbitol and its mono- and dianhydrides, condensed with approximately 20 moles of ethylene oxide. The ethoxylation process results in a product with 20 repeat units of polyethylene glycol distributed across four chains, leading to a range of chemical species in the commercial product.

3. Applications

Polysorbate 20 is a versatile compound used across multiple industries due to its emulsifying, stabilizing, wetting, and dispersing properties. Below are its primary applications:

3.1 Food Industry

- **Function**: Emulsifier, stabilizer, wetting agent
- **Common Uses**:
    - Indirect food additive (FDA classification in the U.S.) for stabilizing emulsions in baked goods, ice cream, margarine, and other processed foods.
    - Direct food additive in Europe (E432) for similar applications.
- **Regulatory Notes**: Approved by the FDA, EFSA, and JECFA as a safe ingredient. The Acceptable Daily Intake (ADI) is 25 mg/kg body weight/day.

3.2 Cosmetics and Personal Care

- **Function**: Emulsifier, surfactant, viscosity modifier, dispersing agent, solubilizer, stabilizer
- **Common Uses**:

    - Shampoos, lotions, face washes, and other personal care products to blend oil and water phases.
    - Enhances texture and stability in creams and emulsions.
- **Example**: Used in moisturizers to ensure a smooth, homogeneous mixture of ingredients.

3.3 Pharmaceuticals

- **Function**: Excipient, stabilizer, solubilizer
- **Common Uses**:
    - Stabilizes emulsions and suspensions in drug formulations, vaccines, nasal sprays, and eye drops.
    - Enhances drug solubility and bioavailability in oral and topical medications.
- **Regulatory Notes**: Approved by the FDA as a direct and indirect food additive and widely used in pharmaceutical formulations.

3.4 Scientific and Laboratory Applications

- **Function**: Nonionic detergent, solubilizer, blocking agent
- **Common Uses**:
    - Solubilization of membrane-bound proteins during protein isolation.
    - Blocking agent in membrane-based immunoassays (e.g., Western blotting, ELISAs) at concentrations of 0.05–0.5%.
    - Lysing mammalian cells at concentrations of 0.005–0.5%.
    - Preventing non-specific antibody binding and minimizing background staining in immunohistochemistry.

3.5 Industrial Applications

- **Function**: Cleaner, defoamer, wetting agent
- **Common Uses**:
    - Cleaning agent in industrial processes.
    - Wetting agent in rubber balers in the elastomer industry.
    - Shape-directing agent in nanotechnology (e.g., synthesis of magnetite nanoassemblies).

4. Usage Guidelines

4.1 Dosage Recommendations

- **Food**: Typically used at concentrations of 0.1–5% depending on the application. Follow regulatory guidelines for maximum allowable levels.
- **Cosmetics**: Concentrations vary based on formulation needs, often 0.5–5%.
- **Pharmaceuticals**: Dosage depends on the specific drug formulation; consult pharmacopeial standards (e.g., BP, EP, USP).
- **Laboratory**:
    - For protein solubilization: 0.005–0.5%.
    - For immunoassays: 0.05% as a blocking agent.

4.2 Emulsification Process

- **Step 1**: Combine Polysorbate 20 with the oil phase of the emulsion.
- **Step 2**: Gradually add the water phase while stirring or mixing vigorously to ensure proper dispersion.
- **Step 3**: Adjust the concentration as needed to achieve stability and prevent phase separation.

4.3 Storage and Handling

- **Storage Conditions**: Store at 25°C (77°F) maximum and 80% relative humidity maximum, away from sunlight and odorous products.

- **Packaging**: Typically supplied in steel drums, plastic barrels, or intermediate bulk containers (IBCs). For laboratory use, it is often available in smaller bottles (e.g., 100 mL travel-size bottles).
- **Stability**: Polysorbate 20 is stable under recommended storage conditions but is susceptible to autoxidation at moderate temperatures and hydrolysis at higher temperatures. Avoid prolonged exposure to heat and light.

5. Safety and Regulatory Information

5.1 Safety Profile

- **Toxicity**: Polysorbate 20 is considered nontoxic and safe for use in food, cosmetics, and pharmaceuticals at approved levels.
- **Genotoxicity and Carcinogenicity**: No concerns regarding genotoxicity, carcinogenicity, or developmental toxicity (EFSA re-evaluation, 2018).
- **Metabolism**: The polyoxyethylene-sorbitan part is excreted unchanged primarily via urine and partly in feces, indicating biliary excretion. Limited metabolism occurs in the body.

5.2 Regulatory Approvals

- **FDA**: Approved as a direct and indirect food additive (21 CFR 172.840, 21 CFR 178.3400).
- **EFSA**: Authorized as a food additive (E432) under EU Regulation No 231/2012.
- **JECFA**: Established an ADI of 25 mg/kg body weight/day.
- **Pharmacopeial Standards**: Complies with BP, EP, and USP standards for pharmaceutical use.

5.3 Precautions

- **Allergies**: Rare cases of hypersensitivity have been reported. Discontinue use if irritation occurs.
- **Degradation**: Avoid conditions that promote autoxidation (e.g., exposure to air, light, or heat), as degradation products (e.g., peroxides) may affect stability in formulations.

6. Frequently Asked Questions (FAQs)

6.1 What is the difference between Polysorbate 20 and Polysorbate 80?

- Polysorbate 20 has a shorter fatty acid chain (lauric acid) and a higher HLB value (16.7) compared to Polysorbate 80 (oleic acid, HLB 15.0). Polysorbate 20 is more hydrophilic and better suited for aqueous solutions, while Polysorbate 80 is more lipophilic and surface-active.

6.2 Is Polysorbate 20 natural?

- No, Polysorbate 20 is a synthetic compound produced by the ethoxylation of sorbitan monolaurate. It is derived from sorbitol (a natural sugar alcohol) but undergoes chemical modification.

6.3 Can Polysorbate 20 be used in organic products?

- Polysorbate 20 is not typically allowed in certified organic products due to its synthetic nature. Check specific organic certification standards for confirmation.