

Material Safety Data Sheet (MSDS)

Product Name: Vitamin E Acetate Pharma Grade (BASF)

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Supplier:

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1. Identification of the Substance/Preparation and Company

- **Product identifier:** Vitamin E Acetate (Tocopheryl Acetate) — Pharma Grade (BASF)
- **Relevant identified uses:** Pharmaceutical intermediate, excipient, vitamin formulations, nutritional supplements, topical formulations (cosmetics), research and development.
- **Uses advised against:** Use in applications requiring a chemically reactive ingredient; do not use for routes of administration not approved by regulatory authorities without further evaluation.

2. Hazards identification

- **GHS classification:** Not classified as hazardous under current GHS criteria for health, physical or environmental hazards (based on typical pharma-grade tocopheryl acetate).
- **Label elements:** None required for GHS hazard labeling for the neat material.
- **Other hazards:** May act as a combustible organic material at elevated temperatures; spills make surfaces slippery creating slip hazard.

3. Composition / information on ingredients

- **Substance:** Tocopheryl acetate (α -Tocopheryl acetate)
- **Purity:** Pharma grade (typical ≥ 97 –99% depending on batch).
- **Impurities / stabilizers:** May contain small amounts of related tocopherol esters, residual solvents depending on manufacturing (refer batch certificate).

4. First aid measures

- **Inhalation:** If inhaled (e.g., aerosolized during processing), move to fresh air. If symptoms occur (cough, shortness of breath), seek medical attention.
- **Skin contact:** Remove contaminated clothing. Wash affected area with soap and water. If irritation persists, seek medical attention.
- **Eye contact:** Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do — continue rinsing. If irritation persists, get medical attention.
- **Ingestion:** Do not induce vomiting unless directed by medical personnel. Rinse mouth and seek medical advice if large quantity ingested or symptoms occur.
- **Notes to physician:** Symptomatic/supportive treatment. No specific antidote.

5. Firefighting measures

- **Suitable extinguishing media:** Foam, dry chemical, carbon dioxide (CO₂), water spray. Use extinguishing media appropriate for surrounding fire.
- **Unsuitable extinguishing media:** Do not use high-volume water jet as it may spread burning liquid.
- **Special hazards:** On decomposition may form carbon oxides and other combustible/irritant products.
- **Protective equipment for firefighters:** Full protective clothing and self-contained breathing apparatus (SCBA) when fighting fire in confined areas.

6. Accidental release measures

- **Personal precautions:** Avoid contact; wear appropriate PPE (gloves, eye protection, suitable protective clothing). Eliminate ignition sources. Prevent slips.
- **Environmental precautions:** Prevent entry into drains, sewers, and waterways. If release reaches waterways, notify authorities per local regulations.

- **Methods for containment and clean up:** Contain spill. Absorb with inert material (e.g., sand, vermiculite), collect mechanically into suitable containers for disposal. Decontaminate area with detergent and water. Dispose according to local regulations.

7. Handling and storage

- **Handling:** Handle in well-ventilated area. Avoid generation of dust or aerosol. Avoid contact with skin and eyes. Use good industrial hygiene. Wash hands after handling.
- **Storage:** Store in tightly closed containers in a cool, dry, well-ventilated place away from oxidizing agents and strong acids. Protect from heat and direct sunlight. Recommended storage temperature: ambient to cool (e.g., 2–25 °C) depending on manufacturer's storage guidance. Keep containers upright.
- **Special packaging:** Use containers compatible with organic oils (stainless steel, HDPE) and inert to product.

8. Exposure controls / personal protection

- **Occupational exposure limits:** No widely established OEL for tocopheryl acetate. Use engineering controls and general exposure minimization. If dust/aerosol is generated, use local exhaust ventilation.
- **Respiratory protection:** If airborne concentrations exceed recommended limits or dust/aerosol generated, use respiratory protection (filtering half mask with P2/P3 or supplied air as appropriate).
- **Hand protection:** Chemical-resistant gloves (nitrile) for prolonged contact.
- **Eye protection:** Safety glasses with side shields or goggles.
- **Skin/body protection:** Lab coat or protective clothing to prevent repeated/prolonged skin contact.
- **Hygiene measures:** Avoid eating, drinking, smoking in work area. Wash hands and exposed skin after handling.

9. Physical and chemical properties

- **Appearance:** Viscous oily liquid. Color: pale yellow to yellow.
- **Odor:** Mild, characteristic.
- **pH:** Not applicable (non-aqueous).

- **Melting / freezing point:** Approx. $< 0\text{ }^{\circ}\text{C}$ to low positive depending on grade (viscous oil).
- **Boiling point / range:** Decomposes before boiling; very high boiling point ($> 300\text{ }^{\circ}\text{C}$).
- **Flash point:** Generally $> 200\text{ }^{\circ}\text{C}$ (closed cup) — not readily flammable under normal storage/handling.
- **Flammability (solid, gas):** Not applicable.
- **Auto-ignition temperature:** Not established — organic material can ignite at sufficiently high temperatures.
- **Vapor pressure:** Very low.
- **Relative density (g/cm^3):** $\sim 0.95\text{--}1.0$ (typical for tocopheryl acetate) — check batch CoA for exact.
- **Solubility:** Practically insoluble in water; soluble in oils, organic solvents (ethanol, ethyl acetate).
- **Partition coefficient ($\log P_{ow}$):** High (lipophilic).
- **Viscosity:** Viscous oil.

10. Stability and reactivity

- **Reactivity:** Stable under recommended storage and handling conditions.
- **Chemical stability:** Stable under normal ambient conditions. Avoid prolonged exposure to heat, strong oxidizing agents.
- **Possibility of hazardous reactions:** None under normal conditions. Avoid strong oxidizers.
- **Conditions to avoid:** Excess heat, open flames, strong oxidizing conditions.
- **Incompatible materials:** Strong oxidizing agents, strong acids.
- **Hazardous decomposition products:** Carbon oxides, smoke and other decomposition products if combusted.

11. Toxicological information

- **Acute toxicity:** Oral LD_{50} values for tocopheryl acetate indicate low acute toxicity (high oral LD_{50} in animal studies); not considered acutely toxic in routine handling.
- **Inhalation:** Low inhalation toxicity expected; aerosols may irritate respiratory tract.

- **Skin corrosion/irritation:** Not expected to be a skin corrosive; may cause mild irritation in sensitive individuals.
- **Serious eye damage/irritation:** May cause transient irritation on eye contact.
- **Sensitisation:** Not generally considered a skin sensitizer, but sensitization reactions cannot be ruled out in susceptible individuals.
- **Repeated dose toxicity / Chronic toxicity / Carcinogenicity / Reproductive toxicity:** Tocopheryl acetate is widely used as a vitamin source and in topical pharmaceutical/cosmetic products; available data do not indicate major chronic toxicity at typical use levels. For high-dose systemic exposure, consult toxicological dossiers and regulatory monographs.
- **Other information:** Refer to regulatory monographs (e.g., pharmacopeia and BASF technical data) for detailed toxicology.

12. Ecological information

- **Ecotoxicity:** Low acute toxicity expected for aquatic organisms but high lipophilicity suggests potential to partition to sediments/biota. Avoid release to the environment.
- **Persistence and degradability:** Expected to be biodegradable under environmental conditions, but persistence can be moderate due to low water solubility and high partitioning.
- **Bioaccumulative potential:** Lipophilic nature indicates potential for bioaccumulation; however biodegradation may limit long-term accumulation.
- **Mobility in soil:** Low mobility due to strong partitioning to organic matter.
- **Other adverse effects:** Avoid discharge into waterways.

13. Disposal considerations

- **Waste treatment methods:** Dispose of in accordance with local/regional/national/international regulations. Incineration in approved facility is preferred for large quantities. Small amounts may be disposed of as non-hazardous industrial waste subject to local rules.
- **Packaging disposal:** Empty containers may retain residue — handle as hazardous if contaminated. Rinse/triple-rinse where appropriate and recycle or dispose according to local regulations.

14. Transport information (DETAILED)

Summary: Vitamin E acetate (tocopheryl acetate) — Pharma Grade is not classified as a dangerous good for transport by road (ADR/RID), air (IATA/ICAO) or sea (IMDG) in its normal commercial form. The following details provide explicit guidance for transport documentation, labeling, packing and emergency response considerations. Always verify with carrier and local regulations for specific shipments and consult the product's Certificate of Analysis or vendor technical data for any additives or solvent residues which might alter classification.

14.1 UN Number

- **UN number:** None assigned (Not regulated as dangerous goods under normal conditions).

14.2 Proper shipping name

- **Proper Shipping Name:** Not regulated — ship as “NON-HAZARDOUS, organic viscous oil” or similar non-regulated description. For customs/invoice use product name: *Vitamin E Acetate (Tocopheryl Acetate)*.

14.3 Transport hazard class(es)

- **ADR / RID / IMDG / IATA:** Not classified as a hazardous material / dangerous good. No Class label required.

14.4 Packing group

- **Packing group:** Not applicable (no PG assigned for non-regulated material).

14.5 Environmental hazards

- **Marine pollutant:** NO — not listed as a marine pollutant. However, prevent release to the environment; large quantities may affect aquatic life due to oiliness. Use standard spill precautions.

14.6 Special precautions for user

- Although not regulated, follow these recommended precautions:
 - Securely close containers and stow upright to prevent leakage.
 - Avoid extreme temperatures — protect from heat sources and direct sunlight.
 - Prevent contamination with incompatible materials (strong oxidizers).
 - Provide secondary containment for bulk shipments to prevent accidental release.
 - Use absorbent/containment materials during loading/unloading to control spills.

- For inland waterway and sea shipments, ensure bilge and tank spaces are free of spills.

14.7 Transport in bulk (annex II of MARPOL 73/78 and the IBC Code)

- **Transport in bulk:** Not specifically regulated under MARPOL/IBC for this substance. For bulk liquid shipments, follow good tanker practice, applicable regulations, and ensure tank compatibility (materials compatible with organic oils: stainless steel/lined tanks, etc.). Use inerting if required by carrier for specific circumstances.

14.8 Emergency response guidance

- **Fire during transport:** Use foam, dry chemical or CO₂. Avoid water jet. Keep containers cool with water spray if safe to do so. For large spills or fire, notify emergency responders and provide product name and shipping info.
- **Spill during transport:** Stop leak if safe. Contain and collect with absorbent. Prevent entry into drains/soil/water. For maritime incidents, report to appropriate maritime authorities if material enters water.
- **Documentation to carry with shipment:** Product MSDS, commercial invoice specifying product identity, and any local paperwork required by consignee or carriers. Even though non-regulated, carriers may request SDS and declarations of non-hazardous status.

14.9 Notes & regulatory caveats

- **Solvent or additive exceptions:** If product contains residual flammable solvent or is shipped in a flammable formulation (e.g., in solvent carrier), classification may change — always consult batch paperwork.
- **Air carriage caution:** IATA/ICAO typically treat neat tocopheryl acetate as non-dangerous; however, carriers may have own restrictions. Notify airline/forwarder.
- **Country variations:** Regulatory classification may vary by jurisdiction — always check local transport regulations before shipping internationally.
- **Recommended shipping practices:** Label packaging with product name, batch number and “For Pharmaceutical Use / Non-Hazardous” where helpful for handlers. Use appropriate packing for viscous liquids (inner drums, overpacks, sealed containers). For LQ (limited quantities) rules — typically not applicable but check with carrier.

15. Regulatory information

- **Safety, health and environmental regulations:** Product is commonly listed/recognized as an approved excipient or vitamin ingredient in many pharmacopeias and cosmetic regulations. Not classified as hazardous substance under many national hazard classification schemes in its neat form.

- **Chemical inventories:** Generally listed on major inventories (e.g., TSCA, EINECS) — verify with supplier/batch certificate for confirmation.
- **Labeling:** Follow local regulatory requirements for pharmaceutical excipients and cosmetic ingredients. Provide appropriate labeling for allergens or other regulatory labeling where applicable.

16. Other information

- **Key references / data sources:** Supplier technical data sheet (BASF), pharmacopeial monographs, and standard toxicology references. For full regulatory compliance consult original manufacturer documentation and national regulations.
- **Disclaimer:** The information provided in this MSDS is believed to be accurate as of the revision date. It is furnished without warranty of any kind. User must determine suitability for their application and assume all responsibility. This MSDS does not constitute a guarantee of product properties.
- **MSDS Generate Date:** 20-05-2017
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- **Website:** www.rawpharmabiz.com
- MSDS are based on the manufacturer's provided information.