KEEP INGREDIENTS CO. LTD

No. 2019, Unit 1, Building 10, Yuexiucheng Phase 1, Guodu Xuefu Street, Chang'an District, Xi'an, Shaanxi, 710119, China

TECHNICAL DATA SHEET

D-alpha Tocopheryl Acetate (1360 IU)

1. PRODUCT DESCRIPTION

D-alpha tocopheryl acetate (RRR-α-tocopheryl acetate) is the acetate ester of natural vitamin E. It is a clear, viscous oily liquid, colourless or slightly greenish-yellow, with a mild taste and odour, standardized to a potency of 1360 IU/g. The acetate ester form is more stable than the non-acetate forms of tocopherol and is used as a nutrient in edible oil, dairy products, flesh products, nutritional and pharmaceutical preparations such as soft-shell capsules, and also used widely in cosmetics. Recommended use: as food additives and antioxidants.

2. PRODUCT INFORMATION

Item	Information
Product name	D-alpha Tocopheryl Acetate (RRR-α-tocopheryl acetate)
Product code	C1360
Specification	1360 IU/g
Empirical formula	C31H52O3
Molecular weight	472.75
CAS No.	58-95-7
Appearance	Clear, viscous oily liquid, colourless or slightly greenish-yellow
Odour & taste	Mild
Form (per SDS)	Oily liquid; light yellow; odourless; melting point 25 °C; boiling point 184 °C; density (20 °C) 0.92–0.96 g/cm³
Solubility	Practically insoluble in water; freely soluble in acetone, anhydrous ethanol and fatty oils; soluble in ethanol
Country of origin	China
Supplier	KEEP INGREDIENTS CO. LTD, Xi'an, Shaanxi, China

3. PRODUCT SPECIFICATION

Item	Standard requirement	Method
Identification — 1. Infrared absorption	Comparing with the spectrum obtained with α-tocopheryl acetate CRS	EP 2.2.24
Identification — 2. Optical rotation	+ 0.25° ~ + 0.35°	EP 2.2.7
Assay	96.0% ~ 101.0%; ≥ 1306 IU/g	EP 2.2.28
Related substances	≤ 4.0%	EP 2.2.28
* Benzo(a)Pyrene	≤ 2 ppb	GC-MS
Solvent residual — Hexane	≤ 290 ppm	EP 5.4
* Heavy metals — Lead	≤ 1 mg/kg	AAS

Item	Standard requirement	Method
* Heavy metals — Arsenic	≤ 1 mg/kg	AFS
* Heavy metals — Cadmium	≤ 1 mg/kg	AAS
* Heavy metals — Mercury	≤ 0.1 mg/kg	AFS
* Microbiology — Aerobic plate count	≤ 1,000 CFU/g	EP 2.6.12
* Microbiology — Yeast and moulds	≤ 100 CFU/g	EP 2.6.12
* Microbiology — E. coli	Negative / g	EP 2.6.13
* Microbiology — Salmonella	Negative / 25 g	EP 2.6.13
* Microbiology — Staphylococcus aureus	Negative / 25 g	EP 2.6.13

** Tested periodically to ensure the requirements are met.*

4. CERTIFICATE OF ANALYSIS - Batch sample

Field	Detail
Product name	D-alpha Tocopheryl Acetate
Product code	C1360
Specification	1360 IU
Batch No.	KYDTA2026050501
Manufacture date	May 27, 2026
Report date	May 30, 2026
Expiry date	May 26, 2028
Test standard	USP-NF 2026

Item	Standard requirement	Method	Result
Identification — 1. Color reaction	Positive	USP	Positive
Identification — 2. Specific rotation [α]D²⁵	≥ +24°	USP <781>	+24.8°
Identification — 3. Retention time	Same as standard preparation	USP	Conform
Acidity	≤ 1.0 mL	USP	0.04 mL
Assay	96.0% ~ 102.0%; ≥ 1306 IU/g	USP	97.3%; 1323 IU/g
Appearance	Clear, colorless to yellow, viscous oily	Visual	Conform
* Benzo(a)Pyrene	≤ 2 ppb	GC-MS	< 2 ppb
Solvent residue — Hexane	≤ 290 ppm	USP <467>	1 ppm
* Heavy metals — Lead	≤ 1 mg/kg	AAS	< 1 mg/kg
* Heavy metals — Arsenic	≤ 1 mg/kg	AFS	< 1 mg/kg
* Heavy metals — Cadmium	≤ 1 mg/kg	AAS	< 1 mg/kg
* Heavy metals — Mercury	≤ 0.1 mg/kg	AFS	< 0.1 mg/kg
* Microbiology — Aerobic plate count	≤ 1,000 CFU/g	USP <61>	< 10 CFU/g
* Microbiology — Yeast and molds	≤ 100 CFU/g	USP <61>	< 10 CFU/g
* Microbiology — Escherichia coli	Negative / g	USP <62>	Negative

Item	Standard requirement	Method	Result
* Microbiology — Salmonella	Negative / 25 g	USP <62>	Negative
* Microbiology — Staphylococcus aureus	Negative / 25 g	USP <62>	Negative

*Conclusion: conforms to USP-NF 2026. * Tested periodically to ensure the requirements are met.*

5. COMPOSITION

Ingredient	Percentage
D-alpha tocopheryl acetate (RRR-α-tocopheryl acetate)	100%

6. NUTRITIONAL INFORMATION (per 100g)

Item	Value
Energy	140 KJ / 100 g
Protein	Not detected
Fat	3.78 g / 100 g
Carbohydrate	0
Sodium	Not detected

7. PRODUCTION PROCESS

Step	Operation
1	Raw materials: acetic anhydride, d-α-tocopherol, catalyst
2	Esterification
3	Filtration
4	Removal of solvent
5	Molecular distillation (CCP)
6	Mixing
7	Filtration
8	Packing

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8. STABILITY DATA

The following stability data are transcribed from the stability report for natural vitamin E (D-alpha tocopheryl acetate 1360 IU), batch C20200304. Quality standard: colourless to yellow, clear, viscous oily liquid; acidity ≤ 0.5 mL; assay 96%–102%; specific rotation ≥ +24.0°.

Long-term stability (25 ± 2 °C, RH 60 ± 10%)

Sampling date	Batch No.	Acidity (mL)	Assay (%)	Specific rotation	Conclusion
Apr 03, 2020	C20200304 (0)	0.03	97.1	24.6	Compliant
Jul 09, 2020	C20200304 (3)	0.03	97.3	24.5	Compliant
Oct 09, 2020	C20200304 (6)	0.03	97.2	24.6	Compliant
Jan 12, 2021	C20200304 (9)	0.03	97.3	24.5	Compliant
Apr 03, 2021	C20200304 (12)	0.03	97.3	24.6	Compliant
Oct 03, 2021	C20200304 (18)	0.06	97.2	24.5	Compliant
Mar 30, 2022	C20200304 (24)	0.06	97.4	24.4	Compliant
Apr 03, 2023	C20200304 (36)	0.04	97.2	24.4	Compliant

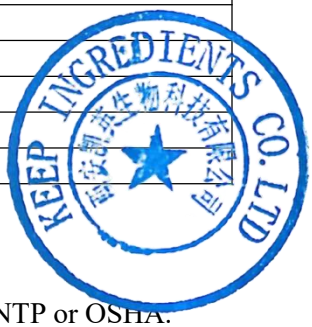
Accelerated stability (40 ± 2 °C, RH 75 ± 5%)

Date	Batch No.	Acidity (mL)	Assay (%)	Specific rotation	Conclusion
Apr 03, 2020	C20200304 (0)	0.03	97.1	24.6	Compliant
May 05, 2020	C20200304 (1)	0.03	97.1	24.5	Compliant
Jun 09, 2020	C20200304 (2)	0.03	97.2	24.6	Compliant
Jul 09, 2020	C20200304 (3)	0.03	97.4	24.6	Compliant
Oct 03, 2020	C20200304 (6)	0.03	97.1	24.6	Compliant

9. STATEMENTS AND COMPLIANCE

Allergen statement (according to (EU) No 1169/2011 and FDA FALCPA)

Allergen	Presence
Wheat	No
Other cereals containing gluten	No
Crustaceans	No
Eggs	No
Fish	No
Peanuts	No
Soybeans	No
Milk (including lactose)	No
Nuts	No
Celery	No
Mustard	No
Sesame seeds	No
Sulphur dioxide and sulphites (> 10 ppm)	No
Lupin	No
Molluscs	No



Safety (per SDS):

- **Hazards:** no particular hazards known; not listed by ACGIH, IARC, NIOSH, NTP or OSHA.
- **Stability:** chemically stable under normal temperatures and pressures; incompatible with air, oxidizing agents and alkali; avoid light, dust generation, exposure to air, alkali, excess heat and strong oxidants.
- **Transport:** not classified as hazardous under transport regulations; not regulated by IMDG.
- **Usage:** as food additives and antioxidants.

10. STORAGE AND TRANSPORTATION

- Shelf life: at least 24 months after date of manufacture in sealed, original containers under normal storage conditions.
- Storage: store in tightly closed original containers, in a cool, dry and ventilated area, away from heat sources and protected from light and oxygen. After opening, use up immediately or seal with nitrogen for further storage. Stable to acid; unstable to alkali and oxidizing agents.
- Packing: 20 / 25 / 50 / 200 kg steel drum.
- Transport: not classified as hazardous under transport regulations; not regulated by IMDG.