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

Palmitoylethanolamide (PEA) — Micronized Grade

1. PRODUCT DESCRIPTION

Palmitoylethanolamide (PEA) is a naturally occurring fatty acid ethanolamide with the molecular formula C18H37NO2 and CAS No. 544-31-0. The product is supplied as a micronized grade, a white micro powder standardized to an assay of 98.0% – 102.0% (on dry basis, HPLC) and a purity of not less than 99.0%. It is intended for use in dietary supplement applications.

2. PRODUCT INFORMATION

Item	Information
Product name	Palmitoylethanolamide "Micronized Grade"
Synonyms / INCI	Palmitoylethanolamide (PEA)
CAS number	544-31-0
Molecular formula	C18H37NO2
Molecular weight	299.49 g/mol
Assay	98.0% – 102.0% (on dry basis)
Purity	NLT 99.0%
Appearance	White micro powder
Particle size	D(0.80 – 1.00): 10 µm (Micronized); D(0.80 – 1.00): 5 µm (Ultra micronized)
Country of origin	P.R. China
Supplier	KEEP INGREDIENTS CO. LTD, Xi'an, Shaanxi, China
Shelf life	2 years (24 months) if sealed and stored properly

3. PRODUCT SPECIFICATION

Item	Specification	Test method
Assay (on dry basis)	98.0% – 102.0%	HPLC
Purity	NLT 99.0%	HPLC
Identification	Positive	IR & 1H NMR
Appearance	White micro powder	Visual
Loss on drying	NMT 1.0%	ChP 2020
Residue on ignition	NMT 0.10%	ChP 2020
Particle size	D(0.80 – 1.00): 10 µm	ChP 2020
Residual solvent – methanol	NMT 3,000 ppm	GC
Residual solvent – ethanol	NMT 5,000 ppm	GC

Item	Specification	Test method

Item	Specification	Test method
Arsenic (As)	NMT 1 ppm	ICP-MS
Cadmium (Cd)	NMT 2.5 ppm	ICP-MS
Lead (Pb)	NMT 0.5 ppm	ICP-MS
Mercury (Hg)	NMT 0.1 ppm	ICP-MS

Item	Specification	Test method
Total plate count	NMT 1,000 CFU/g	USP-NF 2024
Yeast & mould	NMT 100 CFU/g	USP-NF 2024
Coliforms	NMT 0.92 MPN/g	GB 4789.3
E. coli	Negative	USP-NF 2024
Salmonella	Negative	USP-NF 2024
Staphylococcus aureus	Negative	USP-NF 2024
Pseudomonas aeruginosa	Negative	USP-NF 2024

The Ultra Micronized Grade has the same assay, purity, physical, chemical and microbiological controls, differing in particle size D(0.80 – 1.00): 5 µm instead of 10 µm.

4. CERTIFICATE OF ANALYSIS

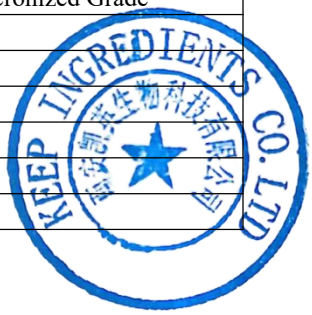
Field	Detail
Product name	Palmitoylethanolamide “Micronized Grade”
Batch No.	KYMPE2026080501
CAS number	544-31-0
Manufacture date	2026.08.05
Expiry date	2028.08.04
Country of origin	P.R. China
Reference	In house

Item	Specification	Result	Test method
Assay (on dry basis)	98.0% – 102.0%	99.65%	HPLC
Purity	NLT 99.0%	99.38%	HPLC
Identification	Positive	Conforms	IR & 1H NMR
Appearance	White micro powder	Conforms	Visual
Loss on drying	NMT 1.0%	0.15%	ChP 2020
Residue on ignition	NMT 0.10%	0.003%	ChP 2020
Particle size	D(0.80 – 1.00): 10 µm	D(0.97): 9.178 – 10.10 µm	ChP 2020
Residual solvent – methanol	NMT 3,000 ppm	51 ppm	GC
Residual solvent – ethanol	NMT 5,000 ppm	ND (< LOQ 30 ppm)	GC
Arsenic (As)	NMT 1 ppm	ND (< 0.03 ppm)	ICP-MS
Cadmium (Cd)	NMT 2.5 ppm	ND (< 0.005 ppm)	ICP-MS
Lead (Pb)	NMT 0.5 ppm	ND (< 0.05 ppm)	ICP-MS
Mercury (Hg)	NMT 0.1 ppm	ND (< 0.003 ppm)	ICP-MS
Total plate count	NMT 1,000 CFU/g	< 10 CFU/g	USP-NF 2024
Yeast & mould	NMT 100 CFU/g	< 10 CFU/g	USP-NF 2024
Coliforms	NMT 0.92 MPN/g	< 0.3 MPN/g	GB 4789.3
E. coli	Negative	Negative	USP-NF 2024
Salmonella	Negative	Negative	USP-NF 2024
Staphylococcus aureus	Negative	Negative	USP-NF 2024

Item	Specification	Result	Test method
Pseudomonas aeruginosa	Negative	Negative	USP-NF 2024

Certificate of Analysis — PEA Ultra Micronized Grade

Field	Detail
Product name	Palmitoylethanolamide "Ultra Micronized Grade"
Batch No.	KYUMP2026061001
CAS number	544-31-0
Manufacture date	Jun. 10th, 2026
Expiry date	Jun. 09th, 2028
Country of origin	P.R. China
Reference	In house



COA — test results (Ultra Micronized Grade)

Item	Specification	Result	Test method
Assay (on dry basis)	98.0% – 102.0%	98.98%	HPLC
Purity	NLT 99.0%	Conforms	HPLC
Identification	Positive	Conforms	IR & 1H NMR
Appearance	White micronized powder	Conforms	Visual
Loss on drying	NMT 1.0%	0.09%	ChP 2020
Residue on ignition	NMT 0.10%	Conforms	ChP 2020
Particle size	D(0.80 – 1.00): 5 µm	D(0.97): 4.917 µm	ChP 2020
Residual solvent – methanol	NMT 3,000 ppm	24 ppm	GC
Residual solvent – ethanol	NMT 5,000 ppm	ND	GC
Arsenic (As)	NMT 1 ppm	Conforms	ICP-MS
Cadmium (Cd)	NMT 2.5 ppm	Conforms	ICP-MS
Lead (Pb)	NMT 0.5 ppm	Conforms	ICP-MS
Mercury (Hg)	NMT 0.1 ppm	Conforms	ICP-MS
Total plate count	NMT 1,000 CFU/g	Conforms	USP-NF 2024
Yeast & mould	NMT 100 CFU/g	Conforms	USP-NF 2024
Coliforms	NMT 0.92 MPN/g	Conforms	GB 4789.3
E. coli	Negative	Conforms	USP-NF 2024
Salmonella	Negative	Conforms	USP-NF 2024
Staphylococcus aureus	Negative	Conforms	USP-NF 2024
Pseudomonas aeruginosa	Negative	Conforms	USP-NF 2024

Note: a matching COA for Batch MPEA260602 (Ultra Micronized Grade) was issued by EffePharm (Shanghai) Co., Ltd with identical results (source: supplied COA).

5. PARTICLE SIZE AND THIRD-PARTY TEST REPORTS

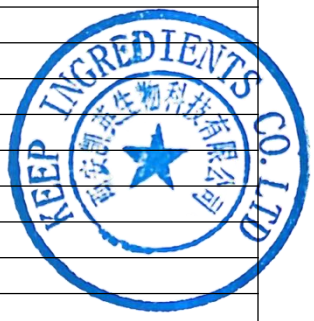
Parameter	Value
D10	1.201 µm
D50	3.690 µm
D90	7.877 µm
D97	9.943 µm
D100	14.91 µm
Span	1.809
Specific surface area	882.6 m²/kg

Item	Result	Unit	Standard	Test method
Arsenic (As)	ND	mg/kg	≤ 1	GB 5009.268-2025 (LOQ 0.03 mg/kg)
Mercury (Hg)	ND	mg/kg	≤ 1.5	GB 5009.268-2025 (LOQ 0.003 mg/kg)
Lead (Pb)	ND	mg/kg	≤ 0.5	GB 5009.268-2025 (LOQ 0.05 mg/kg)
Cadmium (Cd)	ND	mg/kg	≤ 2.5	GB 5009.268-2025 (LOQ 0.005 mg/kg)

Item	Requirement	Result	Test method
Total aerobic microbial count (TPC)	—	< 10 CFU/g	USP-NF 2024 Ch. 61
Total yeasts and molds (YM)	—	< 10 CFU/g	USP-NF 2024 Ch. 61
Staphylococcus aureus	Absence	Absence	USP-NF 2024 Ch. 62
Pseudomonas aeruginosa	Absence	Absence	USP-NF 2024 Ch. 62
Salmonella	Absence	Absence	USP-NF 2024 Ch. 62
Escherichia coli	Absence	Absence	USP-NF 2024 Ch. 62
Coliform count	—	< 0.3 MPN/g	GB 4789.3-2025

6. NUTRITIONAL INFORMATION (per 100g)

Nutrient	Amount
Calories	0
Total fat (g)	0
Saturated fat (g)	0
Polyunsaturated fat (g)	0
Monounsaturated fat (g)	0
Trans fat (g)	0
Cholesterol (mg)	0
Sodium (mg)	≤ 10
Potassium (mg)	0
Total carbohydrate (g)	0
Dietary fiber (g)	0
Soluble fiber (g)	0
Insoluble fiber (g)	0
Sugar (g)	0
Added sugar (g)	0
Protein (g)	0
Vitamin A (mcg RAE)	0
Vitamin C	0
Calcium (g)	0
Iron (mg)	0
Vitamin D (mcg)	0
Vitamin E (mg)	0
Vitamin K (mcg)	0
Thiamin (mg)	0
Riboflavin (mg)	0
Niacin (mg NE)	0
Vitamin B6 (mg)	0
Folic acid (mcg DFE)	0



Nutrient	Amount
Vitamin B12 (mcg)	0
Biotin (mcg)	0
Pantothenic acid (mg)	0
Phosphorus (g)	0
Iodine (mcg)	0
Magnesium (mg)	0
Zinc (mg)	0
Selenium (mcg)	0
Copper (mg)	0
Manganese (mg)	0
Chromium (mcg)	0
Molybdenum (mcg)	0
Chloride (mg)	≤ 20
Caffeine	0
Lactose	0

7. STABILITY

Condition	Duration	Appearance	Purity	Assay	Loss on drying
25 °C ± 2 °C, 60% ± 10% RH	0 – 36 months	White powder	≥ 99.00%	98.0% – 102.0%	≤ 1.0%
40 °C ± 2 °C, 75% RH ± 5%	0 – 12 months	White powder	≥ 99.00%	98.0% – 102.0%	≤ 1.0%

All tested batches remained within the stated specification limits under both long-term (25 °C) and accelerated (40 °C) storage conditions, indicating good stability within the study period.

8. PRODUCTION PROCESS - *Micronized PEA*

Step	Operation
1	Palmitic acid + solid superbase catalyst + 2-aminoethanol + methanol
2	Reflux
3	Thermal filtration (remove catalyst)
4	Cooled to 20 °C
5	Crystallization
6	Filtration
7	Drying and air pulverization
8	QA & QC
9	Final product

9. STATEMENTS AND COMPLIANCE

- **Non-GMO**: the product does not contain raw materials derived from genetically modified organisms; appropriate procedures are in place to prevent GMO cross-contamination.
- **Allergen**: the product does not contain the listed allergens except nuts and nut products (tree nut); for the remaining allergens there is no risk of contamination or cross-contamination.
- **Country of origin**: the product originates from China.
- **Residual solvents**: ethanol is used as a solvent during production; the residual solvent of the product and its ingredients meet the requirements of the ICH guideline for residual solvents Q3C(R5) and the chemical test <467> of USP/NF (residual solvent limits); no other solvents are used.

- **Hazard**: GHS classification includes skin corrosion/irritation Category 2, serious eye damage/eye irritation Category 1 and hazard to the aquatic environment (long-term) Category 2. Acute toxicity LD50 > 2000 mg/kg in rats. The product is stable under normal conditions and is incompatible with strong oxidizing agents.

10. STORAGE AND TRANSPORTATION

- Shelf life: 2 years (24 months) if sealed and stored properly.
- Storage: store in a well-closed container away from moisture, at room temperature and away from direct sunlight; sealed, away from light, moisture-proof storage.
- Packing: packed in paper-drums with two plastic bags inside.
- Transport: ADR/RID, IMDG and IATA — not dangerous goods.