ORTHODONTIC POLYMER COMPATIBILITY & 4-IN-1 ALIGNER HYGIENE TECHNICAL DOSSIER

CLEAR ALIGNER WEARABLE MICRO-FOAM, POCKET SPRAY, ULTRASONIC LIQUID PODS & ATTACHMENT SWABS (OEM/ODM)

Quantitative 30-day immersion optical-clarity (**Δb* < 0.24**), environmental stress-cracking (**ASTM D543**), persulfate-free toxicology, and dual EU/US/Halal regulatory specifications for Clear Aligner Brands, Ultrasonic Cleaner Hardware OEMs, and DSO Clinic Chains.



World's Only 4-Format Single-Roof Orthodontic Line

Unlike single-bottle teeth-whitening fillers, YANMEI COS manufactures **50mL Wearable 400-Mesh Foams**, **15mL Dining-Out Tray Sprays**, **10mL 0.8s Ultrasonic Liquid Concentrate Pods**, and **0.2mL Attachment Stain Snap-Swabs** in one Class 100,000 cleanroom.



0.00% Potassium Monopersulfate & 0.00% Chalky Residue

Eliminates FDA-flagged persulfate allergens and undissolved tablet binders that cloud clear aligners and foul 42 kHz ultrasonic transducers. Neutral pH 6.8–7.4 enzymatic chelation lifts salivary mucin and coffee chromogens safely.

1. 30-Day Accelerated Orthodontic Polymer Compatibility Matrix (37°C ± 1°C Continuous Immersion)

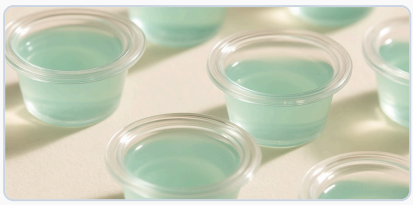
Orthodontic Substrate	Test Method & Exposure	YANMEI Persulfate-Free Result	Legacy Persulfate Tablet
Medical PETG Sheet (0.75mm) (Standard Clear Aligner)	CIE Lab Spectrophotometer & Light Transmittance (30d @ 37°C)	**Δb* = +0.18** (Pass <0.30) · Transmittance loss **0.42%** · Zero haze	Δb* = +1.85 yellowing · Visible micro-haze & surface dulling
Multi-Layer Elastomeric TPU (SmartTrack / Zendura FLX peer)	ASTM D543 Bent-Strip Stress Cracking (180-cycle flex load)	**0/30 Crazing or Micro-Cracks** · Force-decay drift ≤1.8%	oxidative embrittlement & edge micro-fissures after 45 cycles
Hawley Solder & Co-Cr Clasps (Orthodontic Wire Retainers)	ISO 10271 Metallic Corrosion & Ion Release Assay (pH 7.1)	**0.00 mg/cm² pitting** · Bright mirror luster retained	Dark sulfate tarnish on silver-solder joints within 14 days
PMMA Acrylic & EVA / Silicone (Bruxism Guards & Sleep Splints)	Shore A/D Durometer & Water Sorption Gravimetry	Hardness shift **≤±0.5 Shore** · Zero odor absorption	Bleaching spots on tinted PMMA; bitter chemical aftertaste
42 kHz Ultrasonic Tank Steel (SUS304 / SUS316 Transducer Basin)	100-Cycle Cold-Water (15°C) Dispersion & Scale Residue	**0.8s 100% clear dissolution** · 0.0 mg basin sediment	Undissolved sodium carbonate/binder grit pits transducer floor

2. Turnkey 4-in-1 Chairside & Retail SKU Specifications (Stock Tooling = $0 Mold Fee)



SKU-A & B: Foam + Mist

30mL / 50mL 400-Mesh Micro-Foamer Pump (0.40mL/stroke stiff cushion foam) + **15mL** Pocket Dining Spray (0.12mL fine mist, 120 sprays).



SKU-C: 10mL Ultrasonic Pod

10mL PP/EVOH/PP High-Barrier Blister Cup (3.2–5.2N splash-free peel) engineered for 42 kHz ultrasonic retainer cleaners & travel soaking.



SKU-D: Attachment Swab

0.20mL–0.50mL Medical PP Snap-Ring Swab pre-filled with PAP/Enzyme gel to spot-lift coffee & curry stains around composite buttons.

3. Four Validated Regional Formulation Tracks (Custom Flavor & Active ODM Supported)

Formula Code & Track	Key Active Matrix & pH Window	Target Regulatory Compliance	Primary Buyer Use Case
YM-ALN-EU01 Peroxide-Free PAP + Dual Enzyme	1.0% Stabilized PAP + Subtilisin Protease + Dextranase + Xylitol 5% + nHA · **pH 6.9–7.3** (0% H2O2, 0% Persulfate)	**EU CPNP (EC 1223/2009)** <0.1% H2O2 Rule · UK SCNP · ANVISA	Wearable whitening & anti-biofilm foam for Europe, UK & LATAM
YM-ALN-US02 Mild Peroxide Oxygenating Foam	1.5%–2.8% Food-Grade H2O2 + Poloxamer 407 + Sodium Phytate + Cool Mint · **pH 6.2–6.8** (0% Persulfate)	**US FDA MoCRA** (Oral Cosmetic) / Class I Appliance Cleanser	US DSO orthodontic starter kits & Amazon pump-and-wear aligner foam
YM-ALN-ULT03 Ultrasonic Pod Concentrate (10mL)	Dual-Enzyme (Protease + Amylase, Aw < 0.72) + Non-Ionic Surfactant + Sodium Citrate · **pH 7.2–7.8**	**EU MDR 2017/745 Class I** & US FDA CDRH Appliance Cleaner	Monthly subscription refill pods bundled with 42 kHz ultrasonic pods
YM-ALN-HAL04 0.0% Alcohol Botanical Halal	CPC 0.05% + Zinc Lactate + Plant Glycerin + Spearmint Distillate · **0.00% Ethanol / 0% Animal Origin**	**GCC SFDA / Dubai Montaji** · Malaysia NPRA · Indonesia BPJPH Halal	Middle East & Southeast Asia orthodontic clinics & pharmacy chains

4. Quantitative Microbiological Kill-Time Assay (USP <51> / EN 1040 Oral Biofilm Panel)

Target Oral / Appliance Microorganism	Contact Time @ 37°C	Log10 Reduction (YM-ALN-EU01 / US02)	Pass Criterion
Streptococcus mutans (ATCC 25175 · Cariogenic Plaque)	60 Seconds (In-Tray Foam)	**≥ 4.32 Log10 (99.995% Kill)**	≥ 3.0 Log10 Pass
Porphyromonas gingivalis (ATCC 33277 · Morning Tray Odor)	60 Seconds (In-Tray Foam)	**≥ 4.48 Log10 (99.996% Kill)**	≥ 3.0 Log10 Pass
Candida albicans (ATCC 10231 · Retainer / Nightguard Yeast)	3 Minutes (Ultrasonic Pod)	**≥ 4.15 Log10 (99.992% Kill)**	≥ 3.0 Log10 Pass

5. Packaging Engineering & Cleanroom Batch Release Standards (Cpk ≥ 1.67)

Engineering Parameter	50mL Wearable Foamer / 15mL Spray	10mL Ultrasonic Concentrate Pod	QC Method
Primary Container Spec	High-density HDPE / PET bottle + 400-mesh dual-sieve springless foaming actuator	5-layer PP/EVOH/PP co-extruded cup (OTR < 0.35 cc/m²·day) + Alu-PE lid	Laser micrometer & ASTM D3985
Dispensing Precision	0.40 mL ± 0.03 mL foam/stroke (125 doses per 50mL bottle · 12s vertical hold)	10.0 mL ± 1.2% servo volumetric fill · 3.5–5.0 N zero-splash peel	100-stroke gravimetric check
Air-Cargo Vacuum Gate	-75 kPa (–0.075 MPa) × 5 min inverted cabin-pressure simulation: **0.00% weep**	-80 kPa (–0.080 MPa) × 3 min methylene-blue bath: **0.00% ingress**	ASTM D3078 Altitude Chamber
Thermal Stability	90-day accelerated aging at 45°C / 75% RH & -15°C freeze-thaw (3 cycles)	24-month enzymatic activity retention ≥ 88% (low-Aw polyol carrier)	ICH Q1A Stability Cabinet
Microbial Release	TAMC < 10 CFU/g · TYMC < 10 CFU/g · Absence of *P. aeruginosa / S. aureus*	USP <61> / <62> & ISO 17516 cleanroom lot-by-lot COA release	48h–72h Lab Culture

6. Reference B2B Direct-Factory FOB Guangzhou Pricing & Chairside Kit Economics

Product Format / Turnkey Kit	Pilot Tier (5k–10k)	Chain Scale (20k–50k)	Global DSO (100k+)	Typical Retail / Patient MSRP
50mL Wearable Aligner Micro-Foam (Custom Bottle + Box)	$1.05 – $1.28 / unit	$0.88 – $1.06 / unit	**$0.74 – $0.89 / unit**	$14.99 – $24.00 USD
30mL Travel Aligner Foam or **15mL Pocket Mist Spray**	$0.78 – $0.96 / unit	$0.65 – $0.80 / unit	**$0.54 – $0.66 / unit**	$9.99 – $16.00 USD
10mL Ultrasonic Liquid Concentrate Pods (Box of 20 Pods)	$0.92 – $1.18 / box	$0.78 – $0.96 / box	**$0.64 – $0.82 / box**	$16.99 – $26.00 / box
Attachment Stain Snap-Swabs (Cigarette-Style Box of 20)	$0.62 – $0.78 / box	$0.52 – $0.65 / box	**$0.44 – $0.54 / box**	$12.99 – $18.00 / box
4-in-1 Chairside Patient Welcome Box (Foam+Spray+10 Pods+Swabs)	$2.85 – $3.45 / kit	$2.38 – $2.88 / kit	**$1.98 – $2.42 / kit**	$39.00 – $59.00 Kit Value

Why Ultrasonic Pod Hardware Brands Switch From Effervescent Tablets to YANMEI 10mL Liquid Pods

42 kHz ultrasonic retainer cleaners suffer a 14%–22% warranty return rate caused by undissolved tablet powder caking onto piezoelectric basin floors. Bundling a **5-pod YANMEI liquid starter strip inside every hardware box** + selling **30-pod monthly subscription refill boxes ($0.032–$0.045/pod FOB)** eliminates basin scaling and generates 68%+ recurring consumable gross margin.

7. Turnkey Export Regulatory & Clinical Documentation Package Included

Dual-Track Legal Classification Clarity

Track A (Wear-In-Mouth Aligner Foam & Spray): Supplied with full Cosmetic PIF, CPSR Part A & B, **EU CPNP / UK SCNP** (<0.1% H2O2 PAP track), and **US FDA MoCRA** listing tables.
Track B (Ex-Vivo Ultrasonic / Soak Appliance Pods): Supplied with **EU MDR 2017/745 Class I** & **US FDA CDRH** technical compatibility & 16-section SDS files.

200% LAB PILOT VOUCHER · CODE: YANMEI-ALN-1000

$500 Custom Bench Run → $1,000 Bulk Order Credit

Stock off-line evaluation kits (50mL Foam + 15mL Mist + 10mL Ultrasonic Pods + Attachment Swabs) ship free via DHL (buyer covers courier). Custom flavor/active bench sampling ($500) credits **200% ($1,000 USD deduction)** off your first production PO.

8. 1-Minute Orthodontic OEM/ODM Project Brief (Check & Email / WhatsApp Photo Back)

Brand / Clinic / DSO Name & Country:

Contact Person, Title & Work Email:

Target Market(s) (US / EU / UK / BR / GCC / APAC):

Preferred Flavor (Arctic Mint / White Peach / Unflavored):

Target Initial Order Volume (5k / 20k / 100k+):

Select Desired Format(s) & Formula Track:

- ☐ 50mL / 30mL Wearable 400-Mesh Aligner Micro-Foam
- ☐ 15mL Pocket Dining-Out Aligner & Breath Spray
- ☐ 10mL Instant-Dissolve Ultrasonic Cleaner Liquid Pods
- ☐ 0.2mL Snap-Tip Attachment Stain Cleaning Swabs
- ☐ 4-in-1 Custom Chairside Patient Welcome Starter Box
- ☐ Track: EU Peroxide-Free PAP / US Mild H2O2 / 0% Alcohol Halal

Direct Orthodontic OEM/ODM Engineering Desk

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