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## TePe Orthodontic Kit

We, TePe Munhygienprodukter AB, hereby certify that all our products are intended for human oral care. The products are designed and developed in Sweden under strict hygienic conditions and in accordance with ISO 9001:2019, ISO 14001:2015 and ISO 22716:2007. Relevant products are produced under GMP certification.

We, TePe Munhygienprodukter AB, further declare that none of our products contain any detrimental, unhealthy, or harmful materials or substances, and that there are no restrictions on the sale of this product in Sweden or on other export markets.

### Classification

Consumer Hygiene Product within the EU (Toothbrushes, interdental brushes and picks)  
Medical device class 1 according to MDR within EU (Orthodontic wax)

### Description

TePe Orthodontic kit includes:  
1x TePe Supreme™ Compact  
1x TePe Compact Tuft™  
1x TePe TePe Interdental brush Angle™  
2x TePe Interdental brush original  
2x TePe EasyPick™ XS/S  
2x TePe EasyPick™ M/L  
1x Orthodontic wax  
1x Patient information leaflet

| Content Toothbrushes              | Function              | CAS/EINECS/ELINCS Number                   | INCI Name |
|-----------------------------------|-----------------------|--|-----------|
| ISCC certified Polypropylene (PP) | Handle                | 9003-07-0                                  | N/A       |
| Thermoplastic (TPE)               | Inlay Supreme         | 308079-71-2                                | N/A       |
| Polybutylene (PBT)                | Bristles Supreme      | 24968-12-5                                 | N/A       |
| Polyamide (PA)                    | Bristles Compact Tuft | 63428-84-2                                 | N/A       |
| Corrosion free alloy              | Anchor wire Supreme   | 7440-50-8, 7440-02-0, 7440-66-03/231-159-6 | N/A       |

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| Content Interdental brushes original and Angle   | Function  | CAS/EINECS/ELINCS Number             | INCI Name |
|--|-----------|--------------------------------------|-----------|
| Plastic coated stainless steel                   | Wire      | CAS: 65997-19-5<br>EINECS: 266-048-1 | N/A       |
| Polyamide  | Filaments | 63428-84-2                           | N/A       |
| ISCC certified PP                                | Handle    | 9003-07-0                            | N/A       |
| ISCC certified Polypropylene + UV dry offset ink | Cap       | 9003-07-0                            | N/A       |

| Content EasyPick                 | Function                     | CAS/EINECS/ELINCS Number | INCI Name         |
|----------------------------------|------------------------------|--------------------------|-------------------|
| Polybutylene terephthalate (PBT) | Core                         | 24968-12-5               | N/A               |
| Silicone                         | Film forming/<br>Outer layer | 63394-02-5/613-211-3     | Polysilicon<br>11 |

| Content Orthodontic wax | Function | CAS/EINECS/ELINCS Number           | INCI Name |
|-------------------------|----------|------------------------------------|-----------|
| Microcrystalline wax    | Wax      | 64742-51-4, 92062-09-4, 64742-60-5 | N/A       |

| Packagings     |                |
|----------------|----------------|
| Carton pack    | FSC cardboard  |
| Bag (flowpack) | Propylene (PP) |

| Regulatory Compliance Product, Primary Package and Production Process  |
|--|
| - REACH regulation with amendments. No materials from the SVCH list.   |
| - EU Regulation (EC) No. 1935/2004 – Requirements on materials and articles intended to come in contact with food                  |
| - EU Regulation (EC) No. 2023/2006 – Good manufacturing practice for materials and articles intended to come in contact with food. |
| - EU directive 94/62/EC on packaging and packaging waste   |
| - US Model Toxins in Packaging legislation   |
| - Proposition 65 Toxic Enforcement Act of 1986   |
| - Directive 2005/84/EG – Phthalates in toys and baby articles  |
| - RoHS 2 2011/65/EU and RoHS-3 2015/863– directives with amendments  |
| - FDA requirements in 21 CFR 177.1520 (a) (1) (i) and (c) 1.1a.  |
| - FDA 21 CFR 820   |

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|--|
| - Regulation (EU) MDR 2017/745 (only applicable for Orthodontic wax) |
| - ISO 9001:2015 Quality management system                            |
| - ISO 14001:2015 Environmental management systems                    |
| - ISCC, International Sustainability Carbon Certification            |

#### Other applicable information

The product does not contain nor been used with any latex, PFAS or natural rubber.

The product does not contain any of the materials listed below:

- Zinc pyrithione (CAS 13463-41-7, EC 236-671-3) -Repr. 1B
- Butylphenyl methylpropional (CAS 80-54-6, EC 201-289-8) (lillial) – Repr. 1B
- Sodium hydroxymethylglycinate (CAS 70161-44-2, EC 274-357-8) Carc. 1B, Muta
- 2 Methoxyethyl acrylate (CAS 3121-61-7, EC 221-499-3) – Repr. 1B, Muta. 2
- Metyl-N-metyhlanthranilate (M-N-A), CAS-Nr. 85-91-6

This document is reviewed continuously and updated as needed.

Malmö 2024-02-20

Annika Carlus  
Quality Manager, TePe Munhygienprodukter AB

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