Medicare Colgate Ltd
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Food Contact Declaration of Compliance

Regarding Products Identified as;

14095/14195, 14096/14196 & 14097/14197 Breast Milk Storage/feeding bottles

1. **Business Operator:**

Medicare Colgate Ltd, Post Cross Business Park, Cullompton, Devon, England EX15 2BB

2. **Final product manufactured by:**

Medicet Plant Ltd, 7, Dimitar Blagoev str., 2180 Etropole, Bulgaria

On behalf of Medicare Colgate Ltd, Unit 1/2 Post Cross Business Park, Cullompton, Devon, England, EX15 2BB

3. **Identification of Product Materials**

Bottle Material: Lotte SB-540 Polypropylene
Manufactured by Lotte Chemical Corporation. Tech Center, 115 Gajeongbuk-ro, Yuseong-Gu, Daejeon-City, Korea, (34110)
Ink: Ruco 945UV-MA
Manufactured by: A.M. Ramp & Co GmbH, Ruco Druckfarben, Lorsbacher Str.28, D-65817 Eppstein, Germany
Cap Material: Topilene R901
Manufactured by: Hyosung Corporation, 235, Banpo-daero, Seocho-gu, Seoul, Korea 06578
Foil Seal: Lift -n-Peel- LPE
Manufactured by: Selig UK Ltd 635-637 Ajax Avenue, Slough Trading Estate Berkshire SL1 4BH

- Information of the materials, the articles, products from intermediate stages of manufacture or the substances intended for the manufacturing of those materials and articles;

There are no intermediate stages of manufacture or added substances

4. **Declaration Date: 27/05/26**

5. **Confirmation that plastic materials/articles meet the relevant requirements and comply with the following regulations:**

We declare that the above referenced products comply with the following regulations:

- EU Regulation 1935/2004 on materials and articles to come into contact with food. We also have a system in place fulfilling the relevant aspects on traceability.
- EU Regulation 2023/2006 on good manufacturing practice. The products are manufactured using Quality Management System ISO 9001:2015
- EU Regulation 10/2011 and its amendments up to and including EU2025/351 on plastic materials and articles intended to come into contact with food;

- EU Regulation 2024/3190 on the use of bisphenol A (BPA) and other bisphenols and bisphenol derivatives with harmonised classification for specific hazardous properties in certain materials and articles intended to come into contact with food, amending Regulation (EU) No 10/2011 and repealing Regulation (EU) 2018/213

6. Information on Test Results

The above products have been tested for overall migration using Simulant D1 using exposure conditions of 10 days at 40°C. The product/s met the overall migration requirements in these tests.

The above products have been tested for specific migration using Simulant D1 using exposure conditions of 10 days at 40°C. The product/s met the specific migration requirements in these tests.

Compliance of Non-Intentionally added substance (NIAS)

Annex I Table 1 of Regulation (EU) No. 10/2011 enlisted permitted amounts of monomers, other starting substances, macromolecules obtained from microbial fermentation, additives, and polymer production aids at specific migration limit (SML) with stated conditions.

Substance	CAS Number	SML (mg/person/ day)	Test Result (mg/kg)
9-Octadecenamide, (Z)- (Foil Seal)	301-02-0	60	0.363
Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate (Foil Seal)	2082-79-3	6	0.467
Tributyl acetylcitrate (Caps)	77-90-7	60	0.092

NIAS not listed in Regulation (EU) No.10/2011

NIAS could be impurities, reaction, and degradation products. There is currently no legal limit for NIAS not listed in Regulation (EU) No. 10/2011. Self-derived SML is derived based on toxicological studies according to Plastics Europe recommendation. When toxicological studies are unavailable, TTC (Threshold of Toxicological Concern) approach is adopted (Annex I).

Substance	CAS Number	SML (mg/person/ day)	Test Result (mg/kg)
Dodecane, 4,6-dimethyl- (Bottle)	61141-72-8	50	1.754
Heneicosane (Bottle)	629-94-7	300	5.110
Eicosane (Bottle)	112-95-8	300	11.245
Hexadecanoic acid, ethyl ester (Bottle)	628-97-7	200	0.377
Squalene (Caps)	111-02-4	132	0.506

7. The constituents used to make this product are accompanied by declarations of compliance. The product contains the following substances which are subject to restrictions under EU Regulation 10/2011 as amended;

Substance	**Screen Method**	**SML (mg/person/ day)**	**Test Result (mg/kg)**
Aluminium (Foil Seal)	Migration Testing	1	<0.30

Based on information supplied to **Medicare Colgate Ltd**, the above product contains Zero substances which are classed as Dual Use Additives.

A substance is defined as a "Dual Use Additive" if the chemical identity of the plastic additive matches that of an authorized food additive or flavoring, regardless of its purity or whether or not the substance is subject to a restriction in food and/or in the plastic. In the case of salts it is the salt that matters, not the authorized acid, phenol or alcohol.

Number (E or FL)	**Name**
E 1521	Polyethylene glycol
E 321	Butylated hydroxytoluene (BHT)
E 551	Silicon dioxide
E 173	Aluminium
E 470a	Sodium, potassium and calcium salts of fatty acids (example: Calcium Stearate)
FL 2.082	2-Ethylhexan-1-ol
FL 8.015	Octadecanoic acid
FL 5.001	Acetaldehyde

The purity of the Dual Use Additives used in this Product respect the purity criteria set out in Annex I of Regulation (EU) No 10/2011.

The final products, therefore, meet the migration requirements of EU regulation 10/2011, as amended, for use in contact with breast milk and infant formula milk products when used in accordance with the instructions for use.

8. **Conditions of use:**

- The Articles above are intended to be used with Human Breast Milk & Formula Milk
- This product is not intended for use during cooking
- This product is only suitable for use at a temperature of 70-80°C for a maximum of 20 minutes
- This product is not suitable for use at temperatures exceeding 80°C
- This product is suitable for freezing to -25°C for up to 6months
- Caps are for single use only!
- Bottles are for Reusable use.
- Do not overfill the bottle past the maximum graduation
- Not suitable for microwaving
- The ratio of food contact surface area to volume used to establish the compliance of the material or article: The compliance testing was done under conditions set out in Regulation 9EC)No. 10/2011 using surface to volume (s/v) contact ratio of 6dm²/Kg

9. Functional barrier:

This Product contains a functional barrier: YES

Substances behind this functional barrier that are not authorized by Regulation (EU) No 10/2011 will not migrate in quantities above the detection limit of 0.01mg/kg.

These non-authorized substances are not classified as "mutagenic", "carcinogenic" or "toxic to reproduction" in accordance with the criteria set out in sections 3.5, 3.6 and 3.7 of Annex I to CLP Regulation (EC) No 1272/2008 of the European Parliament and the Council.

These non-authorized substances are not in Nano form as defined by the Commission Recommendation on the 18th of October 2011 on the definition of nanomaterial (2011/696/EU).

Signed: 
Printed: Daniel Hall
Date: 27/05/26
Position: Quality Manager