

(Unofficial)

Notification of the Ministry of Public Health

(No. 369) B.E. 2558 (2015)

Re: Feeding Bottles and Milk Containers for Infants and Young Children

It deems appropriate to revise the Notification of the Ministry of Public Health,
Re: Feeding Bottle.

By the virtue of provisions of Section 5 and 6 (6) and (9) of the Food Act B.E. 2522 (1979), the Minister of Public Health hereby issues the notification as follows:

Clause 1 Notification of the Ministry of Public Health No.117 (B.E 2532) (1989) Re: Feeding Bottle dated 15th January B.E.2532 (1989) shall be repealed.

Clause 2 In this notification

“Feeding Bottle” means a container for containing milk or other liquids for consumption of infants or young children which composed of feeding bottle, protective cover, feeding teat, locking ring and optionally sealing disc.

“Milk container for infants and young children” means a container that intended use to contain milk or other liquids for consumption of infants or young children that including reused types such as drinking practice cup and disposable types such as plastic bag for breast milk storage or disposable plastic bag complimented with feeding bottle but excluding feeding bottle.

“Infant and young children” means person at the age of not more than 3 years old.

Clause 3 Bottles shall have the following qualities or standards:

- (1) Clean;
- (2) No migration of toxic substances in amount that may have effects to health;
- (3) Be made of clear materials, colorless except for natural color of such materials and if made of unclear materials, it shall not be opaque causing unable to view liquid in the bottle;
- (4) Heat resisting to such as boil or steam and durable to reuse;

(5) Made of material which is glass or plastic as specified in List No.1 and having qualities or standards as Table 1 of List No.2 annex to this notification;

(6) Having volume scale indication if printing shall not be too much causing unable to view all inner parts of a bottle, quality of color for printing and for volume scale indication shall be food contact grade and shall be permanently attached;

(7) No bending curve or other forms that make difficulty to clean.

Clause 4 Protective cover, feeding teat, locking ring shall have the following qualities or standards:

(1) Clean;

(2) No migration of toxic substances in amount that may have effects to health;

(3) No colors contaminated with food;

(4) Heat resisting to such as boil or steam and durable to reuse;

(5) Be made of material which is plastic as specified in List No.1 and having qualities or standards as Table 1 of List No.2 annex to this notification.

Clause 5 Rubber teat shall have the following qualities or standards:

(1) Clean;

(2) No migration of toxic substances in amount that may have effects to health;

(3) No color except for natural color of such rubber;

(4) Heat resisting to such as boil or steam and durable to reuse;

(5) Having tensile resistance;

(6) Be made of material which is rubber as specified in List No. 1 and having qualities or standards as Table 1 of List No.2 annex to this notification;

Clause 6 Milk Containers for Infants and Young Children shall have the following qualities or standards:

(1) Milk Containers for Infants and Young Children as reused type shall

(a) Be clean;

(b) Not be contained toxic substances migrated in amount that may effect to health;

- (c) Not have colors contaminated with food;
 - (d) Be durable to reuse;
 - (e) Be made of material which is glass or plastic as specified in List No.1 and having qualities or standards as Table 1 of List No.2 annex to this notification;
 - (f) Be permanently attached of printing color and be food contact grade.
- (2) Milk containers for infants and young children as disposable type shall
- (a) Be clean;
 - (b) Not be contained toxic substances migrated in amount that may effect to health;
 - (c) Have no color except for natural color of such rubber;
 - (d) Be made of material which is plastic as specified in List No.1 and having qualities or standards as Table 1 of List No.2 annex to this notification;
 - (e) Be permanently attached of volume scale indication (if any) and printing color of such scale indication shall be food contact grade.

Clause 7 Feeding Bottles and Milk Containers for Infants and young Children that made of materials other than materials specified under Clause 3(5), Clause 4(5), Clause 6(1)(e) and Clause 6(2)(d) as the case maybe shall have an approval from the Food and Drug Administration by submission of the following evidences and documents relevant to material used for production:

- (1) Types of material or plastic;
- (2) Name and address of manufacturer of materials or plastics;
- (3) Name and address of injection molding manufacturers of Feeding Bottles and Milk Containers for Infants and young Children;
- (4) List of chemicals used in preparation of materials or plastics such as monomers, primers, additives or polymer production aid substances;
- (5) Documents presenting of manufacturing process including preparation step of materials or plastics such as process and condition of polymerization preparation and injection molding process of Feeding Bottles and Milk Containers for Infants and young Children;

(6) Documents presenting specification or properties of materials or plastics including chemical for preparation of materials or polymer;

(7) Summary documents of properties or data concerning application method or condition use of Feeding Bottles or Milk Containers for Infant and Young Children made of materials or plastics applied for approval such as food categories used to contain, working maximum temperature, duration of application;

(8) Evidence documents concerning data of approval, law, regulations or requirements of qualities or standards relevant to materials or plastics used to manufacture or relevant to Feeding Bottles or Milk Containers for Infants and Young Children of manufacturing country or reference countries, together with summary of data on control system, law regulations or requirements of qualities or standards as submitted above.

(9) Analysis result of qualities or standards as law, regulations or requirements of qualities or standards of manufacturing country or reference country as referred under (8)

(10) Other documents as necessary (if any).

Clause 8 Feeding Bottles or Milk Containers for Infant and Young Children not complied with this notification that have been approved or sold prior to this notification come into force shall be prolonged to sell but not exceeding 1 year from the day of this notification come into force.

Clause 9 This Notification shall come into force after 180 days as from the day of its publication in the Government Gazette onwards.

Notified on 8th January B.E. 2558 (2015)

(Signed) Rachata Rachatanavin

Mr. Rachata Rachatanavin

Minister of Public Health

(Published in Government Gazette, Volume 132, Special Part 28 Ngor., dated 3rd February 2015)

Note: This English version of the notification is translated to meet the need of the non-Thai speaking people. In case of any discrepancy between the Thai original and the English translation, the former will take priority.

List No.1

Annex to Notification of the Ministry of Public Health (No. 369) B.E. 2558(2015)

Re: Feeding Bottle and Milk Containers for Infants and Young Children

Table 1 Types of Permitted Materials including coating materials

Products	Varieties of Permitted Materials including coating materials
1. Bottle	1. Polypropylene 2. Polyethersulphone 3. Borosilicate glass
2. Protective cover, Locking ring, Sealing disc	1. Polypropylene 2. Polyethersulphone
3. Feeding teat	1. Natural rubber 2. Synthetic rubber
4. Reused Feeding Bottle and Milk Containers for Infants and Young Children	1. Polypropylene 2. Polyethersulphone 3. Borosilicate glass
5. Disposable Feeding Bottle and Milk Containers for Infants and Young Children	1. Polypropylene 2. Polyethylene

List No.2

Annex to Notification of the Ministry of Public Health (No. 369) B.E. 2558(2015)

Re: Feeding Bottle and Milk Containers for Infants and Young Children

Table 1 Qualities or Standards of Migration of Plastic types: Polypropylene, Polyethersulphone and Polyethylene

Analyzed Item	Maximum level (mg per kg) [*]		
	Polypropylene	Polyethersulphone	Polyethylene
1. Heavy metal			
Lead (Pb)	1	1	1
Barium (Ba)	1	1	1
Cobalt (Co)	0.05	0.05	0.05
Copper (Cu)	5	5	5
Iron (Fe)	48	48	48
Lithium (Li)	0.6	0.6	0.6
Manganese (Mn)	0.6	0.6	0.6
Zinc (Zn)	25	25	25
2. Residual substance after evaporation of 50% ethanol as extraction solvent (food representative: milk and water)	60	60	60
3. Residual substance after evaporation of 3% acetic acid as extraction solvent (food representative: fruit juice)	60	60	60
4. 2,2-bis(4-hydroxyphenyl) propane or bisphenol A	Not detected ^{**}	Not detected ^{**}	Not detected ^{**}
5. 4,4'-dichlorodiphenyl sulphone or DCPS	-	0.05	-
6. 4,4'-dihydroxydiphenyl sulphone or DHPS or bisphenol S	-	0.05	-

Remark * means mg/kg food or food simulant

** means not detected at the limit of detection, LOD = 0.25 µg/l

- means not applicable to that item

Table 2 Qualities or Standards of Migration of Substances from Natural and Synthetic rubber

Analyzed Items	Allowance Maximum level	
	Natural rubber	Synthetic rubber
1. Formaldehyde	Not detected [*]	Not detected [*]
2. Zinc	1 mg/dm ³	1 mg/dm ³
3. N-Nitrosamines substances	0.01 mg/kg ^{**}	0.01 mg/kg ^{**}
4. N-Nitrosatable substances	0.1 mg/kg ^{**}	0.1 mg/kg ^{**}
5. Volatile compounds content	-	Not more than 0.5 % by weight (made of silicone only)
6. 2- Mercaptobenzothiazole release or MBT release	8 mg/kg ^{**} (made of valcanized rubber only)	-
7. Antioxidant release 7.1 2,6-bis(1,1-dimethylethyl)-4-methyl-phenol (BHT)	30 µg/100 ml or 60 µg/dm ² (made of valcanized rubber only)	-
7.2 2,2'-methylenebis(6-(1,1-dimethylethyl)-4-methyl-phenol)) (Antioxidant 2246)	15 µg/100 ml or 30 µg/dm ² (made of valcanized rubber only)	-

Remark * means not detected at the limit of detection, LOD = 1 mg/dm³

** means mg release/kg material

- means not applicable to that item