



France issues new decree of the Food Contact Rubber Products and Baby Pacifiers

On August 11, 2020, France issued a decree of August 5, 2020 (Arrêté du 5 août 2020 relatif aux matériaux et objets en caoutchouc destinés à entrer en contact avec des denrées alimentaires et aux sucettes pour nourrissons et enfants en bas-âge), The decree will replace and repeal the old decree of November 9, 1994, and will take effect on July 1, 2021. Food-grade rubber products that are on the market before July 1, 2021 and comply with the requirements of the old law can continue to be sold until the inventory is emptied. Main amendments as below:

- Clarify the definition of rubber, which covers vulcanized thermoplastic elastomers, but not silicone elastomers;
- Update the list of authorized substances;
- Updated the restrictions and parameters of authorized substances, including specific migration limits;
- Update the requirements of the declaration of conformity;
- Increase the specific migration of aromatic primary amines, the migration of hexamethylenetetramine and formaldehyde, the migration and content of heavy metals and other requirements;
- Added test conditions for specific migration and full migration.

Comparison of new and old decree:

Test items	New Decree of August 5, 2020	Old Decree of November 9, 1994
Volatile organic compounds	$\leq 0.5\% \pm 0.1\%$	$\leq 0.5\%$
Full migration	10mg/dm ² (In the case of infant food contact products, bottle nipples, and other products such as seals, valves with known actual S/V, 60mg/kg)	10mg/dm ² (If it is a container, lid, stopper, sealing ring and other products , 60mg/kg)
Specific migration of nitrosamines	N-nitrosamine: $\leq 1\mu\text{g}/\text{dm}^2$; N-nitroso substances: $\leq 10\mu\text{g}/\text{dm}^2$ (Nitrosamines in pacifiers are less than 0.01mg/kg; Nitroso substances are less than 0.1mg/kg)	N-nitrosamine: $\leq 1\mu\text{g}/\text{dm}^2$; N-nitroso substances: $\leq 10\mu\text{g}/\text{dm}^2$ (Nitrosamines in pacifiers are less than 0.01mg/kg , Nitroso substances are less than 0.1mg/kg)
Specific migration of primary aromatic amines	ND(DL $\leq 0.01\text{mg}/\text{kg}$)	No requirements
Specific migration of primary and secondary aromatic amines	$\leq 1\text{mg}/\text{kg}$	$\leq 1\text{mg}/\text{kg}$
specific migration of Formaldehyde	$\leq 3\text{mg}/\text{kg}$	$\leq 3\text{mg}/\text{kg}$
The total migration of hexamethylenetetramine and formaldehyde	$\leq 15\text{mg}/\text{kg}$	No requirements
Peroxide residue	Negative	Negative
Specific migration of heavy metals	Ba 1.2mg/kg ; Cu 4mg/kg ; Al 1mg/kg ; Zn 5mg/kg	No requirements



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Impurity residue	Pb、Cd、Sb、Hg and As shall not exceed 1mg/kg	No requirements
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Test conditions for specific migration and full migration:

Category	Type	Examples of objects involved	Test conditions*
A	Thermal contact, may require prolonged contact	Sealing ring of pressure cooker, sealing ring of sterilization tank	Test with water-based simulants , 121°C **1h or 100°C(or reflow temperature)4h If it is a long-term contact,121°C ** 1h,and then 40°C ***10 days
B	Long term contact	Seals for boxes and containers	40°C 10 days***
C	Medium duration	Pipes and valve parts that are still in working condition (static and dynamic) during two uses	40°C 24h***
D	Short term contact	Pipe and valve parts (static and dynamic), membranes, gloves, conveyor belts, sleeves, rollers	40°C 2h***
T	Oral contact****	bottle nipples and pacifier	40°C 24h

*When the actual use conditions are higher than the test conditions specified in the table, the test conditions should be similar to the actual use conditions.
 **If the contact temperature is greater than 121°C, the test temperature is equal to the contact temperature.
 ***If the contact temperature is greater than 40°C, the test temperature is equal to the contact temperature.
 ****See Annex IV of the Decree.

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