

# Publication of new French Order for rubber materials and articles.

## Customer information 09/2020.

French Order of 5 August 2020 relating to rubber materials and articles intended to come into contact with foodstuffs and pacifiers for infants and young children has been published in August. It repeals French Order November 9, 1994 and will become effective on July 1, 2021.

### MAJOR UPDATES ARE:

#### 1. Definition of rubber:

Article 2 clarifies the scope of rubber, which also covers vulcanized thermoplastic elastomer, but does not cover silicone elastomers due to having already its own enforced French Order.

#### 2. Update on approved list of substances:

The list of approved substances has been updated. The setup is divided and categorized in the following annexes:

- Annex I for monomers, starting substances and modifying agents
- Annex II for additives
- Annex VII for purity criteria of colorants and pigments
- Annex VIII for temporary approved substances that can be used until July 1, 2025
  - Substances in Annex VIII are not fully toxicologically evaluated and a safety assessment dossier should be submitted before July 1, 2025 for authorization
  - Rubber materials and articles in which the substances listed in the table within Annex VIII have been incorporated and for which no authorization application dossier has been submitted before July 1, 2025, may be marketed until stocks are exhausted

#### 3. Consideration of chemical safety, including non-intentionally added substances (NIAS):

According to Article 5, the following substances must not present a risk to human health within the meaning of Article 3 of Regulation (EC) No 1935/2004.

- Decomposition or reaction products, reaction intermediates

- The oligomers and the impurities of the monomers, starting substances, modifying agents and additives used to obtain the synthetic polymers for manufacturing rubber materials and articles
- Free volatile organic substances

#### 4. Changes in rules for verifying the conformity:

The new Order also holds some changes in terms of testing requirements. Most notable are:

- Free volatile organic substances shall be tested according to the conventional gravimetric method as well as an identification method using analytical instrument (HS-GCMS screening)
- Inclusion of specific migration limit (SML) and maximum residual content (QM) for certain heavy metals

#### 5. Inclusion of specific measure for declaration of compliance (DoC):

According to Article 12, a written DoC should be available at the marketing stages other than sale or distribution free of charge to the final consumer. A description of information that is needed to be declared in the DoC is specified in Annex V. This is a completely new part in the new Order and hence the DoC is now also a legal national requirement for rubber food contact materials and articles in France.

This new French Order shall come into force on July 1, 2021. Rubber materials and articles placed on the market for the first time before July 1, 2021, can be marketed until stocks are exhausted. With the update above, TUV Rheinland Group can support customers finding the right approach and testing for the compliance requirements. Please feel free to contact your local TUV Rheinland for further information.

Reference link:

<https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000042225149>

**FOR FURTHER TECHNICAL INFORMATION,  
PLEASE CONTACT US:**

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