

FRENCH REPUBLIC

Ministry of the Economy, Finance and
Industrial and Digital Sovereignty

Order of []

amending the Order of 8 September 1999 regarding products used for cleaning materials intended to come into contact with foodstuffs, the Order of 25 November 1992 on silicone elastomer materials and articles and the Order of 5 August 2020 on rubber materials and articles intended to come into contact with food and soothers for infants and young children and repealing the Order of 30 January 1984 on materials and articles containing vinyl chloride monomer and intended to come into contact with foodstuffs, food products and beverages

NOR: [...]

Public concerned: Manufacturers, importers and distributors of cleaning products for surfaces intended to come into contact with foodstuffs, professionals in the agri-food sector.

Manufacturers, importers and distributors of silicone elastomer materials and articles intended to come into contact with foodstuffs and their constituents.

Manufacturers, importers and distributors of rubber materials and articles intended to come into contact with food or soothers [also known as dummies] for infants and young children and the constituents thereof, and professionals from the agri-food industries that use these materials.

Subject: Authorisation of constituents in cleaning products of materials and articles intended to come into contact with food and of substances in silicone elastomer materials and articles intended to come into contact with food and correction of the rules applicable to rubber materials and articles intended to come into contact with food.

That order adds three constituents to the positive list annexed to the order of 8 September 1999, as amended following a favourable opinion from ANSES, corrects the restriction applicable to a constituent and adds a constituent withdrawn in error when the text was last amended.

This order adds a constituent to the positive list of the order of 25 November 1992 and updates the test conditions for the verification of the conformity of materials and articles made of silicone elastomers.

This order corrects a sentence of Article 6 of the order of 5 August 2020 and removes an erroneous reference to the restriction applicable to a constituent from the positive list of the order of 5 August 2020 and corrects an error in a calculation formula to interpret analytical results.

This order also repeals the order of 30 January 1984, the provisions of which have been incorporated into Regulation (EU) No of 14 January 2011 on plastic materials and articles intended to come into contact with foodstuffs.

Entry into force: The provisions of this order shall enter into force the day after its publication.

Application: This order is adopted for the implementation of decrees no of 12 February 1973 and no of 10 May 2007 concerning, respectively, the processes and products used for cleaning materials and articles intended to come into contact with foodstuffs and the placing on the market of those materials themselves.

The Minister for Labour, Health, Solidarity and Families, the Minister for the Economy, Finance and Industrial and Digital Sovereignty and the Minister for Agriculture and Food Sovereignty,

Having regard to Regulation (EC) No of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with foodstuffs and repealing Directives EEC and EEC;

Having regard to Regulation (EU) No of 14 January 2011 on plastic materials and articles intended to come into contact with foodstuffs, as amended;

Having regard to Directive EU of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services, together with Notification dated XXX sent to the European Commission;

Having regard to the Consumer Code, in particular Article L. 412-1 thereof;

Having regard to the Decree No of 12 February 1973 amendment implementing the Law of 1 August 1905 on the suppression of fraud with regard to chemicals in food and materials and articles in contact with foodstuffs, products and beverages intended for human and animal consumption and the processes and products used for the cleaning of such materials and articles, in particular Article 11 thereof;

Having regard to Decree No of 10 May 2007 as amended, implementing the Consumer Code as regards materials and articles intended to come into contact with foodstuffs, in particular Article 3 thereof;

Having regard to the Order of 25 November 1992 on silicone elastomer materials and articles brought or intended to be brought into contact with foodstuffs, food products and drinks;

With regard to the order of 8 September 1999 modified to apply Article 11 of Decree No of 12 February 1973 implementing the Law of 1 August 1905 to prevent deception and adulteration concerning processes and products used to clean materials and objects intended to come into contact with foodstuffs, products and drinks for human and animal consumption;

With regard to the order of 5 August 2020 on rubber materials and articles intended to come into contact with food and soothers for infants and young children;

Having regard to the opinion of the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) on 29 November 2019 and 8 August 2022,

Hereby order:

Article 1

The Annexes to the aforementioned order of 25 November 1992 are amended in accordance with Annex I to this order.

Article 2

The annex to the aforementioned order of 8 September 1999 is amended in accordance with Annex II to this order.

Article 3

The order of 5 August 2020 shall be amended as follows:

(1) In the fourth sub-paragraph of a) of (2 (II) of article 6, the words: 'specified in a or b' are replaced by the words: 'specified in (b) or (c)'

(2) Annex II and Annex VI are amended in accordance with Annex III to this order.

Article 4

The order of 30 January 1984 on materials and articles containing vinyl chloride monomer and intended to be brought into contact with foodstuffs, food products and beverages is repealed.

Article 5

Materials and objects made of silicone elastomers intended for contact with foodstuffs placed on the market for the first time before 1 July 2025 and which comply with the regulation in force before this date, may be marketed until stocks are exhausted.

Article 6

This order shall be published in the Official Journal of the French Republic.

Signed on

Minister of Labour, Health, Solidarity and Family

For and on behalf of the Minister:

The Director-General for Health

The Minister for the Economy, Finance and
Industrial and Digital Sovereignty

For and on behalf of the Minister:

The Director General for Competition Policy,
Consumer Affairs and Fraud Control

The Director General for Enterprises

The Minister for Agriculture and Food Sovereignty,

For and on behalf of the Minister:

The Director-General for Food

ANNEX I

The annexes to the aforementioned Order of 25 November 1992 are hereby amended

(1) In II of Annex I, the following rows are added:

'3,7,11-Trimethyldodecyne-3-ol (TMDDO, CAS no. :

Minimum purity 98.9 %, specific migration limit of 0.05 mg/kg of foodstuff. '

(2) Annex III is replaced by the following provisions:

'Annex III

Test conditions for verifying the conformity of silicone elastomeric materials and articles with this order

The global migration tests and the search for free organic volatile materials shall be carried out on the material or article in the state of finished product which has been vulcanised and annealed in accordance with good manufacturing practice, in accordance with the following protocol:

1. Determination of overall migration

The test conditions and food simulants used to carry out the migration tests shall be chosen in accordance with the provisions of the above-mentioned Regulation of 14 January 2011.

2. Determination of volatile organic compounds (VOC)

- Preparation of samples

Check that the samples are clean and free of any surface contamination (dust, etc.). The articles will not be washed.

For each test, cut around 10 g of the sample into pieces of around 1 x 1 cm.

Perform the test on at least 2 identical articles, one test per article.

- Operating procedure

Dry the crystallisers beforehand in an oven maintained at a temperature of between 105 °C and 110 °C.

Then place them in a desiccator and allow them to cool to room temperature.

Weigh at +/- 0.1 mg and note the mass of each dish (m0).

Place the previously cut samples into the crystallisers, leave them for 48 h at room temperature in a desiccator, enriched with an effective moisturising agent, and then weigh them together at ± 0.1 mg (m1).

Place the crystallisers in a ventilated oven maintained at 200 °C ± 5 °C for 4 hours.

Remove the crystallisers from the heated cabinet, place them in a desiccator and let them cool to room temperature. Weigh each crystalliser at ± 0.1 mg (m2).

For each test, the content of volatile organic compounds shall be expressed in % by mass and calculated using the following formula:

$$\frac{m_1 - m_2}{m_1 - m_0} \times 100$$

The results are expressed with 2 digits after the comma.

Compliance is based on the average of the tests.

3. Determination of peroxides in elastomers

Use the method described in the European Pharmacopoeia. '

ANNEX II

Section I a of the annex to the order of 8 September 1999 referred to above is amended as follows:

(1) Before paragraph 1, paragraphs 3 to 5 are replaced by the following provisions:

The constituents of this section shall not communicate toxicologically hazardous characteristics to marketed cleaning products due to their concentrations of contaminating chemical elements. In particular, the following general purity criteria shall apply to those constituents which are marked as having to comply with the provisions applicable to food additives:

- arsenic: no more than 1 mg/kg;
- lead: no more than 5 mg/kg;
- mercury: not more than 1 mg/kg;
- cadmium: no more than 1 mg/kg;

(2) In point 2, a new point 15 is added, worded as follows:

'15. Pyrithione Sodium ((bis[1-hydroxy-2(1H)-pyridinethionato-O,S]-(T-4)-zinc/pyridine-2-thiol 1- oxide, sodium salt) CAS No.) at a maximum use dose of 3 mg per litre of water used by the dishwasher. '

(3) Section E. of 3. is amended as follows:

(1) The provisions of point 12 shall be replaced by the following provisions:

'12. N,N-bis (carboxymethyl)-DL-alanine, trisodium salt ('Na₃MGDA' - CAS no.:).

For formulations with a maximum of 20.5 % Na₃MGDA and not more than 0.21 % Na₃MGDA after dilution in washing water. '

(2) After 13, an unnumbered paragraph is added as follows:

'14. Tetrasodium salt of glutamic N-N diacetic acid ('GLDA Na₄' - CAS No:) at a maximum application rate of 2.5 g/L. '

(4) In point B of point 4, a new point 4 is added, worded as follows:

'4. 1,2-benzisothiazoline-3-one (CAS No.).

The commercial substance shall have a minimum weight content of 90 % of 1,2-benzisothiazolin-3-one and 93 % of 1,2-benzisothiazolin-3-one and 2,2'-dithiobisbenzamide. Its maximum content by weight of 2,2'-dithiobisbenzamide shall not exceed 6 % and that of chlorobenzisothiazolone shall not exceed 1 %.

It can be used in preparations at the minimum concentration necessary to achieve the desired preservative effect. '

(5)(To A. of 4. is added a 15 worded as follows:

'15. Sodium peroxodisulphate ('Sodium persulphate', CAS no.),

This substance contains impurities not exceeding the following concentrations:

Sodium tetradecyl sulfate (CAS)	
Baryum (CAS)	mg/kg
Calcium (CAS)	mg/kg
Copper (CAS)	0.05 mg/kg
Magnesium (CAS)	mg/kg
Manganese (CAS)	mg/kg
Mercury (CAS)	mg/kg
Iron (CAS)	/kg
Chlorides (CAS)	
Water (CAS)	

Only for use as an auxiliary cleaning agent for organic membrane materials when clarifying beer.

For a maximum concentration of sodium peroxodisulphate of 5 g/L in the cleaning solution, with conditions of use providing for rinsing after use for the purpose of ensuring a residual content of less than 0.044 µg/L of beer. '

ANNEX III

The annexes to the order of 5 August 2020 are amended as follows:

(1) In the 3rd column of the 4th row of IX in Annex II, reference (1) is deleted.

(2) In the second indent of Annex VI, the formula for calculating the percentage of free volatile organic matter is replaced by the following formula:

$$\frac{m_1 - m_2}{m_1 - m_0} \times 100$$