THE FRENCH REPUBLIC

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Ministry for Health and Prevention

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Decree on Information on Intimate Care Products

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Groups concerned: manufacturers, importers, distributors, consumers of these products

Purpose: Definition of the information which must appear on the packaging or leaflet of intimate care products.
Entry into force: the text enters into force on 1st January 2024

Leaflet: It defines the content of the information which must appear on the packaging of intimate care products placed on the market and the manner in which it is brought to the consumer's attention. Intimate care products include intimate care products for external use – such as absorbent towels, panty liners, menstrual panties – as well as intimate care products for internal use such as tampons, menstrual cups, menstrual sponges.

References: The provisions of the decree can be consulted, in their drafting resulting from this modification, on the Légifrance website (https://www.legifrance.gouv.fr).

The Prime Minister,
On the report of the Minister of Economy, Finance and Industrial and Digital Sovereignty and the Minister for Health and Prevention;
Having regard to Regulation (EU) 1007/2011 of the European Parliament and of the Council of 27 September 2011 on textile fibre names and related labelling and marking of the fibre composition of textile products and repealing Council Directive 73/44/EEC and Directives 96/73/EC and 2008/121/EC of the European Parliament and of the Council;
Having regard to the amended Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC;
Having regard to Directive (EU) 2015/1535 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;
In view of the consumer code, in particular articles L. 412-1, L. 423-1, R. 412-1 and R. 451-1;
Having regard to notification No 2022/0XXX/F addressed on XXXX to the European Commission;

Having regard to the scientific and technical support note of the National Agency for Food, Environmental and Occupational Health & Safety of 21 July 2022;
Having heard the Council of State (Finance section),

Hereby decrees

Article 1

The provisions of this Decree apply to intimate care products imported or introduced into French territory, held for sale or distribution free of charge, offered for sale, or distributed free of charge.

The following definitions apply: “Intimate care products” means single use or reusable products, intended to absorb or retain body fluids and to be put in contact with the internal or external genitourinary system of the pubescent human body.

The provisions of this Decree shall not apply to medical devices as defined in Regulation (EC) No 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing the Council Directives 90/385/EEC and 93/42/EEC referred to above.

Article 2

I. – The packaging of intimate care products shall bear the following information:

(1) the composition of the product, in the form of a list containing all the components that are present and for each of these components, the details of the substances and materials that each includes intentionally incorporated during the manufacturing process of the finished product. This provision does not apply to textile products, subject to the specific provisions of Regulation No 1007/2011 of the European Parliament and of the Council of 27 September 2011 on textile fibre names and related labelling and marking of the fibre composition of textile products and repealing Council Directive 73/44/EEC and Directives 96/73/EC and 2008/121/EC of the European Parliament and of the Council referred to above;

(2) the terms and precautions of use, in particular those specified in the annex to this Decree;

(3) the health risks associated with the composition or use of the product (in particular irritations, intolerances, allergies, micro-trauma). In particular, for intimate care products for internal use, this information contains the information detailed in the annex to this Decree on menstrual toxic shock syndrome and on the symptoms that should lead to prompt medical consultation.

The information mentioned from (1) to (3) shall be in indelible, visible, legible and comprehensible characters in the French language.

II. – When intimate care products are offered for sale by means of distance communication, the information referred to in I shall be provided before the completion of the purchase and shall appear on the distance selling medium.

III. – When several intimate care products are distributed in the same packaging designed to constitute a sales or distribution unit for the end user or the consumer, certain information referred to in I may appear on an accompanying leaflet. In this case, the packaging shall indicate:

(1) at least the following information: the risk of menstrual toxic shock syndrome related to the use of intimate care products for internal use, the maximum wear period for these products, the recommendation for wearing intimate care products for external use at night, the appropriate choice of protection in relation to the menstrual flow and the composition as defined in (1) of I.

(2) that details of the terms and precautions of use as well as the health risks associated with the composition or use of the products are set out in the leaflet.

IV. – When intimate protective products are intended to be sold or distributed free of charge individually or in bulk in accordance with the provisions of Article D.120-5 of the Consumer Code, or where the size of the product and its packaging makes it manifestly impossible to comply with the requirements of I, the information required shall be contained in a leaflet accompanying the product.

Article 3

The provisions of this Decree shall not prevent the placing on the market in France of intimate care products lawfully manufactured or marketed in another Member State of the European Union or in Turkey, or lawfully manufactured in a State party to the Agreement establishing the European Economic Area, in so far as they are accompanied by information ensuring a level of safety equivalent to that required by this Decree.

Article 4

This Decree shall enter into force on 1st January 2024. Products which do not comply with the provisions of this Decree placed on the market before this date may continue to be offered for sale or distributed free of charge for six months from this date.

Article 5

The Minister of Economy, Finance and Industrial and Digital Sovereignty, the Keeper of the Seals, the Minister of Justice, the Minister for Health and Prevention, the Minister Delegate attached to the Prime Minister, responsible for gender equality, diversity and equal opportunities, the Minister Delegate attached to the Minister of Economy, Finance and Industrial and Digital Sovereignty, responsible for small and medium-sized enterprises, trade,

small-scale industry and tourism, shall each be responsible for his part for the implementation of this Decree, to be published in the Official Journal of the French Republic.

Dated

By the Prime Minister:

The Minister of Economy, Finance, and Industrial and Digital Sovereignty

Bruno LE MAIRE

The Keeper of the Seals, Minister of Justice,

Éric DUPONT-MORETTI

The Minister for Health and Prevention,

François BRAUN

The Minister Delegate attached to the Prime Minister, responsible for gender equality, diversity and equal opportunities,

Isabelle ROME

Minister Delegate attached to the Minister of Economy, Finance and Industrial and Digital Sovereignty, responsible for small and medium-sized enterprises, trade, small-scale industry and tourism

Olivia GRÉGOIRE

ANNEX: Terms and precautions for the use of intimate care products

These relate to:

- washing of hands before use or insertion of the product and its removal;
- washing or disinfection of reusable products before their use;
- information on the positioning of the product, how to remove it;
- regular change of the product;

- **For intimate care products for internal use,**

- the indication of using only one product at a time;
- the maximum recommended wear period, which may not exceed 6 hours;
- the recommendation on wearing the product only during menstruation and the use of a product adapted to the menstrual flow of the person, who must have access to an explicit indication of the absorption capacity of the product;
- information that menstrual toxic shock syndrome is a serious, potentially life-threatening infectious disease related to wearing an intimate care product for internal use for too long during menstruation, the complete description of possible symptoms of menstrual toxic shock syndrome (fever that is sudden and above 39°C, vomiting, diarrhoea, skin rashes resembling sunburn, sore throat, dizziness and/or fainting, specifying that not all of them may occur at the same time);
- the recommendation to consult a doctor immediately if the symptoms of menstrual toxic shock syndrome appear, remove the product and, if possible, store it for analysis, inform the doctor of current menstrual periods and the possibility of having a menstrual toxic shock syndrome linked to the use of an intimate care product for internal use;
- the recommendation to people who have already developed menstrual toxic shock syndrome not to use intimate care products for internal use;
- the recommendation to use intimate care products for external use at night, given the maximum wear period indicated, in order to reduce the risk of developing menstrual toxic shock syndrome.