

**GUIDANCE DOCUMENT No 19**  
**ON THE APPLICATION OF**  
**DIRECTIVE 2009/48/EC ON THE SAFETY OF TOYS**  
**Soother holders**

This Guidance document is a non-binding document intended to provide guidelines to help Member States and stakeholders making the distinction between different kinds of soother holders. It expresses the views of the majority of members in the Expert Group on Toy Safety.

The images appearing in the document constitute examples intended to facilitate the decision-making. They do not presuppose the conformity of the represented products<sup>1</sup>.

This Guidance document does not relieve national authorities from their obligation to determine for any individual product, on a case-by-case basis, whether it falls within the scope of application of the Toy Safety Directive 2009/48/EC or within the scope of application of other sectoral legislation. The Court of Justice of the European Union has repeatedly held that the national authorities, acting under the supervision of the courts, must proceed on a case-by-case basis, taking account of all the characteristics of the product. Therefore, this document shall not ‘prescribe’ which regulatory framework applies. Rather, it shall serve as one out of many elements supporting the national competent authorities in their case-by-case decision on individual products. In particular, this Guidance document does not prevent a national authority from consulting with colleagues from other regulated sectors concerned in order to reach a complete view on all aspects related to a given product.

## **1. Background**

Soother holders are commonly used products which come in many different types. The original purpose of these products was to keep the soother fastened to the child’s garment without the risk of strangulation. In former times there have been some accidents when so-called home-made cords were used for holding soothers. In the meantime many soother holders are designed in such a way that they also have a play value. In this case they are products with double-use: soother holders and toys at the same time.

Standard EN 12586 defines soother holder as ‘article that enables a soother to be secured to a child’s garment etc.’.

The term ‘soother holder’ is commonly used for all products to which a soother is connected, whether fastened to the child’s garment or not. There are various soother holders which are not intended to be fastened to a child’s garment, such as soother holder cloths and soother holders fastened to plush toys.

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<sup>1</sup> The views expressed in this document are not legally binding; only the Court of Justice of the European Union can give an authoritative interpretation of Union law.

## **Purpose of this guidance document**

This guidance document considers the different types of soother holders and intends to help differentiating between soother holders which are nothing but soother holders and those that are soother holders and toys at the same time.<sup>2</sup>

Soothers are used for newborns, infants and toddlers, this means they are used for children from the first month of life. Therefore, also soother holders will be used from the very beginning ('0 M+') and have to be safe for children of this age group.

**It must always be kept in mind that regardless of whether a soother holder is classified as a toy or not, it is a product for very young children that has to be safe.**

Examples see:

Annex 1: Soother holders intended to be fastened to garment

Annex 2: Soother holders not intended to be fastened to garment

## **2. Union legislation applicable to “soother holders”**

### **2.1 The General Product Safety Directive 2001/95/EC (GPSD)**

The General Product Safety Directive<sup>3</sup> defines a product as ‘any product - including in the context of providing a service - which is intended for consumers or likely, under reasonably foreseeable conditions, to be used by consumers even if not intended for them, and is supplied or made available, whether for consideration or not, in the course of a commercial activity, and whether new, used or reconditioned.’<sup>4</sup>

The Directive provides that ‘Each of its provisions shall apply in so far as there are no specific provisions with the same objective in rules of Community law governing the safety of the products concerned.’<sup>5</sup> Thus, soother holders without a play value fall within the scope of the GPSD.

### **2.2 The Toy Safety Directive 2009/48/EC**

The Toy Safety Directive<sup>6</sup> defines toys as ‘products designed or intended, whether or not exclusively, for use in play by children under 14 years of age’.<sup>7</sup>

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<sup>2</sup> It is not the aim of this guidance document to work out the differences between standards EN 12586 and EN 71-1.

<sup>3</sup> Directive 2001/95/EC on general product safety. OJ L 11, 15.1.2002, p. 4.

<sup>4</sup> Article 2(a) of the General Product Safety Directive 2001/95/EC.

<sup>5</sup> Article 1(2) of the General Product Safety Directive 2001/95/EC.

<sup>6</sup> Directive 2009/48/EC on the safety of toys. OJ L 170, 30.6.2009, p. 1.

<sup>7</sup> Article 2(1) of the Toy Safety Directive 2009/48/EC.

The Directive provides that ‘Toys, including the chemicals they contain, shall not jeopardise the safety or health of users or third parties when they are used as intended or in a foreseeable way, bearing in mind the behaviour of children.

The ability of the users and, where appropriate, their supervisors shall be taken into account, in particular, in the case of toys which are intended for use by children under 36 months or by other specified age groups. ...’<sup>8</sup>

Soother holders that have a play value fall within the scope of the Toy Safety Directive (for ‘play value’ see section 4 below).

### 3. Most important standards

The highest risks of soother holders lay in their mechanical and physical properties, thus the most important standards are:

- **EN 12586** Child use and care articles. Soother holder. Safety requirements and test methods<sup>9</sup>  
(The standard is not referenced in the Official Journal, versions EN 12586:1999 and EN 12586:1999/AC:2002 have been withdrawn in 2015.)
- **EN 71-1** Safety of toys - Part 1: Mechanical and physical properties<sup>10</sup>  
(This standard is referenced in the Official Journal<sup>11</sup> under the Toy Safety Directive.)

At the moment there are some inconsistencies between standards EN 12586 and EN 71-1 relating to requirements and test methods; there are also difficulties on how to interpret test results (see CEN/TR 16411<sup>12</sup>). This has led to uncertainties for all actors in the past years. However the basic rule is: Soother holders which are also classified as toys have to fulfil the requirements of the Toy Safety Directive.

It is important to consider Article 19(3) of the Toys Safety Directive 2009/48/EC stating that a toy shall be submitted to EC-type examination ‘where harmonised standards, the reference number of which has been published in the Official Journal of the European Union, covering all relevant safety requirements for the toy, do not exist’. This also applies to soother holders classified as toys.

EN 12586:2011, which applies to soother holders that are not toys, refers (among others) to chemical requirements of the superseded Toy Safety Directive 88/378/EEC and to the withdrawn standard EN 71-3:1994. Consideration should therefore be given to the chemical requirements of the currently applicable Toy Safety Directive 2009/48/EC, such as the chemical limits in Appendix C or the migration limits for elements, and to the currently applicable, referenced version EN 71-3:2013+A3:2018.

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<sup>8</sup> Article 10(2) of the Toy Safety Directive 2009/48/EC.

<sup>9</sup> Current version: EN 12586:2007+A1:2011.

<sup>10</sup> Current version: EN 71-1:2014+A1:2018.

<sup>11</sup> OJ C 282, 10.8.2018, p. 3.

<sup>12</sup> CEN/TR16411:2014 - Child use and care articles. 2014 compiled interpretations of CEN/TC 252 standards.

This Guidance document does not deal with standards on chemical properties. Of course soother holders classified as toys must also fulfil the chemical requirements of the Toy Safety Directive. Also other legislation such as REACH has to be considered for all soother holders.

#### **4. How to distinguish between soother holders that are toys and those that are not**

The definition of ‘toy’ in Article 2 (1), first subparagraph of the Toy Safety Directive 2009/48/EC provides the following criteria:

- Any product designed or intended
- whether or not exclusively
- for use in play
- by children under 14 years of age.

According to Guidance document No 4 ‘Grey zone problem: Is a specific product covered by the Toy Safety Directive 2009/48/EC or not?’<sup>13</sup> the main difficulty of this definition is the concept of ‘use in play’ or ‘play value’. Virtually everything has play value for a child, but this does not make every object fall into the definition of ‘toy’. In order to be considered as a toy for the purpose of the Directive, the play value has to be introduced in an intended way by the manufacturer.

The words ‘whether or not exclusively’ in the definition indicate that the product does not have to be exclusively intended for playing purposes in order to be considered as a toy, but it can have other functions as well. This is also referred to as double function. Thus, a product can be a soother holder and a toy at the same time, namely when the product has a play value.

This play value is not assumed if the soother holder only consists of a simple strap ([pictures 1 to 6](#)) or of coloured simple beads (made of wood, plastic, silicon or other materials) without further elements that could provide a play value ([pictures 7 to 15](#)). In this context, small elements such as a moon, stars or hearts are also considered as simple shaped elements ([see pictures 16 to 19](#)).

Also child appealing images printed on components of a soother holder provide no or only a low play value. Such products are not considered to be toys ([pictures 20, 21](#)).

Animal shaped fasteners are not considered to be toys as long as they are small and hard ([pictures 22, 23](#)), but a play value exists if the fasteners are designed as plush toys ([picture 24, 25](#)).

The following attributes (alone or in combination) can also add a play value, for example:

- Intended interaction (see [picture 26](#))
- Highly varying shaped elements (e.g. cars, flowers) in the same soother holder strap with beads (see [picture 27](#))

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<sup>13</sup> [http://ec.europa.eu/growth/sectors/toys/safety/guidance\\_en](http://ec.europa.eu/growth/sectors/toys/safety/guidance_en) .

- Rattle effect (see [picture 28](#))
- Three-dimensional figurine (animal, child, etc.) built of various elements (for example see [pictures 29 to 31](#))
- Plush toys attached to the strap (see [picture 32](#))

For further examples see [Annex 1](#) (soother holders intended to be fastened to garment) and [Annex 2](#) (soother holders not intended to be fastened to garment).

Guidance document No 4 also states that the declaration by the manufacturer of the intended use is a criterion to be considered. However, the reasonably foreseeable use shall prevail over the declaration of intended use by the manufacturer.

This means that, if it is reasonably foreseeable that the soother holder may be used as a toy, the product should be classified as toy.






Another basic rule is stated in section 10 (Annex I) of the Guidance Document on the Application of the Directive 2009/48/EC on the Safety of Toys: ‘Please note that if a consumer product does not fall under the Toys Directive, it still needs to be safe as regards the health and safety of consumers according to Directive 2001/95/EC on general product safety or any other applicable Community legislation containing specific health and safety requirements.’<sup>14</sup>





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<sup>14</sup> Guidance Document on the Application of the Directive 2009/48/EC on the safety of toys. 10.2.2016. [http://ec.europa.eu/growth/sectors/toys/safety/guidance\\_en](http://ec.europa.eu/growth/sectors/toys/safety/guidance_en)

**Annex 1.****Soother holders intended to be fastened to garment**






Examples of soother holders without play value versus soother holders with play value





No.	Products	Comments	Toy or not
<b><u>1</u></b>		Functional soother holder, no additional parts, not designed as toy  ➔ low / no play value	<b>NO</b>
<b>2</b>		Functional soother holder, no additional parts, not designed as toy  ➔ low / no play value	<b>NO</b>
<b>3</b>		Functional soother holder, no additional parts, not designed as toy  ➔ low / no play value	<b>NO</b>
<b>4</b>		Functional soother holder, no additional parts, not designed as toy  ➔ low / no play value	<b>NO</b>
<b>5</b>		Functional soother holder, no additional parts, not designed as toy  ➔ low / no play value	<b>NO</b>





6		<p>Functional soother holder, clip with printed image (e.g. frog)</p> <p>➔ low / no play value</p>	NO
7		<p>Simple wooden beads, monochrome, completely or almost completely uniform shapes of the beads</p> <p>➔ low / no play value</p>	NO
8		<p>Soother holder made of silicon beads</p> <p>➔ low / no play value</p>	NO
9		<p>Simple wooden beads in different colours completely or almost completely uniform shapes of the beads, singular printed image</p> <p>➔ low / no play value</p>	NO




10		<p>Simple wooden beads in different colours completely or almost completely uniform shapes of the beads, singular printed image</p> <p>➔ low / no play value</p>	NO
11		<p>Simple wooden beads in different colours completely or almost completely uniform shapes of the beads</p> <p>➔ low / no play value</p>	NO
12		<p>Simple wooden elements in different colours completely or almost completely uniform shapes of the elements</p> <p>➔ low / no play value</p>	NO


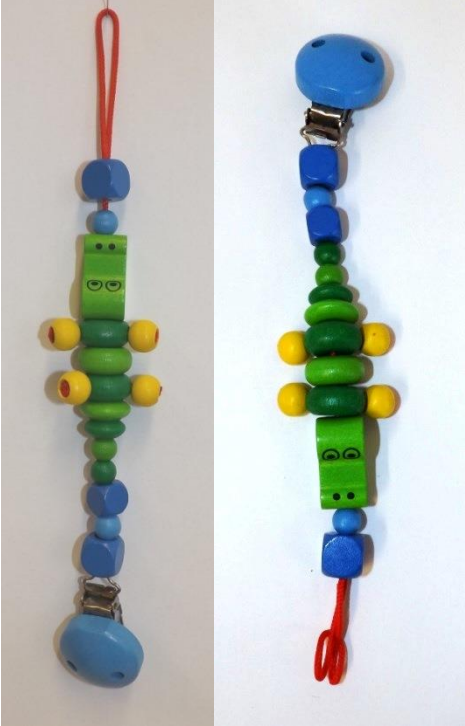






13		Simple beads and cubes made of plastic and/or silicon and/or wooden material  ➔ low / no play value	NO
14		Soothe holder with simple similar shaped beads made of plastic/silicon  ➔ low / no play value	NO
15		Simple wooden beads  ➔ low / no play value	NO
<a href="#"><u>16</u></a>		Soothe holder with different simple shaped elements, wooden beads and stars  ➔ low / no play value	NO
17		Wooden beads in different colours and various simple shapes  ➔ low / no play value	NO

18		Simple wooden beads in different colours/shapes/material (hard and soft) crocheted around beads  ➔ low / no play value	NO
19		Wooden beads in different colours and simple shapes (moon and star)  ➔ low / no play value	NO
<a href="#"><u>20</u></a>		Soother holder with different shaped elements with printed images symbolizing a “cow on the meadow”  ➔ low / no play value	NO
21		Soother holder designed as a toy train, printed images on wooden triangular prisms  ➔ low / no play value	NO



<p><u>22</u></p>		<p>Functional soother holder, with small clip designed as animal or head of an animal, hard, made of plastic or wood</p> <p>➔ low / no play value</p>	<p><b>NO</b></p>
<p>23</p>		<p>Simple wooden beads with small clip designed as animal or head of an animal, hard, made of plastic or wood , no great difference to clip with printed image</p> <p>➔ low / no play value</p>	<p><b>NO</b></p>
<p><u>24</u></p>		<p>Soother holder with clip designed as soft toy (soft filled plush)</p> <p>➔ play value</p>	<p><b>YES</b></p>
<p>25</p>		<p>Soother holder with clip designed with fabric owl (similar to plush toy)</p> <p>➔ play value</p>	<p><b>YES</b></p>

<u>26</u>		<p>Soothen holder with different shaped wooden beads and rings from plastic, movable parts, intended interaction</p> <p>→ play value</p>	<b>YES</b>
<u>27</u>		<p>Wooden beads in different colours and shapes (cars, flowers)</p> <p>→ play value</p>	<b>YES</b>
<u>28</u>		<p>Wooden beads in different colours and different shaped elements (owl, star), different materials; hanging elements, intended interaction, rattle effect</p> <p>→ play value</p>	<b>YES</b>

<p><b><u>29</u></b></p>		<p>Simple wooden beads in different colours, toy element (e.g. animal figure)</p> <p>→ play value</p>	<p><b>YES</b></p>
<p><b>30</b></p>		<p>Wooden beads in different colours and shapes, animal figure</p> <p>→ play value</p>	<p><b>YES</b></p>
<p><b>31</b></p>		<p>Simple wooden beads in different colours and simple wooden cubes, toy element (animal figure)</p> <p>→ play value</p>	<p><b>YES</b></p>

<p><u>32</u></p>		<p>Soother holder with duck made of fabric, soft filled</p> <p>→ play value</p>	<p><b>YES</b></p>
<p>33</p>		<p>Wooden toy, animal figure</p> <p>→ play value</p>	<p><b>YES</b></p>
<p>34</p>		<p>Soother holder on plush toy with clip to attach to the garment; dragon, 3-dimensional</p> <p>→ play value</p>	<p><b>YES</b></p>



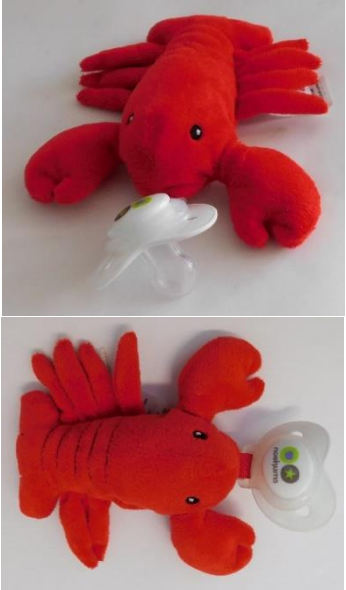


35		<p>Soother holder on plush toy with clip to attach to the garment; dog, 3-dimensional</p> <p>→ play value</p>	<b>YES</b>
36		<p>Any shaped soother holder with possibility to change soother to teether toy if it is sold as combi-product with the teether part</p> <p>→ play value</p>	<b>YES</b>

**Annex 2.****Soother holders not intended to be fastened to garment**

Examples of soother holders without play value versus soother holders with play value

No.	Products	Comments	Toy or not
37		Soother holder on simple cloth without child appealing elements/ appliqué  ➔ low / no play value	<b>NO</b>
38		Soother holder cloth with loops and child appealing appliqué, mainly 2-dimensional  ➔ low / no play value	<b>NO</b>
39		Soother holder cloth shaped as cloud, plush, mainly 2-dimensional  ➔ low /no play value	<b>NO</b>
40		Soother holder on plush toy, beetle, 3-dimensional  ➔ play value	<b>YES</b>



41		<p>Soother holder on plush toy, 3-dimensional</p> <p>➔ play value</p>	YES
42		<p>Soother holder on plush toy; rabbit, 3-dimensional</p> <p>➔ play value</p>	YES
43		<p>Soother holder on plush toy; bear with pocket, 3-dimensional</p> <p>➔ play value</p>	YES