

## **NATIONAL PRODUCT SAFETY GROUP.**

UK practitioner experts for product safety & compliance.

Supported by the Office for Product Safety & Standards.

### **Guidance Note on the safety enforcement of baby soother holders.**

#### **1. Scope.**

A soother holder's main purpose is to prevent a soother falling onto the floor and becoming contaminated when slipping out of a child's mouth. There have been a few accidents where home-made cords have been used. A functional soother holder is not to be considered as a toy. However many soother holders are now designed with added play value. In such cases they are consumer products with a double-use: being both a soother holder and a toy.

Soothers are used for new-borns, infants and toddlers, this means they are used for children from the first month of life. Therefore soother holders have to be safe for all children of this age group.

The main risks associated with this product involve:

- strangulation
- the release of small parts leading to choking hazards, and
- the migration of chemicals whilst being mouthed or chewed.

Whether a soother holder is classified as a toy or not, it is a product for very young children that has to be "safe".

#### **2. Legal compliance framework.**

Directive 2009/48/EC on the Safety of Toys, as amended (TSD) - implemented in the UK by the Toys Safety Regulations 2011 (TSR).

Soother holders that have a play value fall within the scope of the TSD. 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 TSD defines toys as, 'products designed or intended, whether or not exclusively, for use in play by children under 14 years of age'.

The TSD 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".

Directive 2001/95/EC on General Product Safety (GPSD) - implemented in the UK by the General Product Safety Regulations 2005 (GPSR).

Soother holders without play value fall within the scope of the GPSD and GPSR.

EU Guidance Document No 19 on the Application of Directive 2009/48/EC on the Safety of Toys. “Soother holders”. 26 September 2019. The note provides a gazetteer of suggested products based on the concept of “play value”.

EU Guidance Document No 4 on the application of Directive 2009/48/EC on the Safety of Toys. “Grey zone problem. Is a specific product covered by the Toy Safety Directive 2009/28/EC or not?” 15 October 2015.

These Guidance Notes provide assistance in distinguishing between soother holders that are toys and those that are not toys.

Commission Regulation (EC) No 1907/2006/1907 EC concerning the Registration etc of Chemicals (REACH), as amended.

### **3. Supporting voluntary standards**

EN 12586:2007+A1 Child use and care article – “Soother holder – Safety requirements and test methods”. Not harmonised.

Standard EN 12586 defines a soother holder as an, ‘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 holders fastened to plush toys.

“Although a soother holder is not intended to be mouthed it could be foreseen that the behaviour of infants for mouthing articles within reach of their mouths presents a risk. Therefore, materials used in the construction of soother holders could present chemical hazards due to mouthing by the child. This standard is intended to address those hazards that have been identified as specific problems but cannot encompass all chemical hazards or legislation.” EN 12586.

hEN 71-9:2005+A1:2007 Safety of toys- Part 9: “Organic chemical compounds – requirements for the migration or content of certain hazardous organic chemical compounds from/in certain toys and toy materials by the following exposure routes: - mouthing – ingestion - skin contact - eye contact – inhalation, when used as intended or in a foreseeable way, bearing in mind the normal behaviour of children and the function and design of the toy”. Harmonised.

In offering this advice NPSG wishes to make clear:

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- Independent legal advice should always be sought if appropriate.

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