

1 | General Information and Overview

Product	Risk assessor
<p>Product name: Soother holders</p> <p>Product category: Childcare articles</p> <p>Description: This is a risk assessment template for soother holders. It describes likely injury scenarios linked to non-conformities with the following clauses of EN 12586:2007 + A1:2011:</p> <p>Clause 5.1.4.2 - ventilation holes Clause 5.1.6 - length Clause 5.2.1 - impact resistance</p> <p>Please note that soother holders with play value are also assessed according to EN 71-1. If such a soother holder does not comply with EN 71-1, the risk assessment is carried out as if it was a toy. Please refer to the risk assessment template for toys for appropriate scenarios.</p> <p>How to use Users of the template should select the scenario(s) corresponding to the non-conformities identified for the product under assessment. All other scenarios can be deleted. The probabilities are estimated in the remaining scenarios. The scenarios presented in the template are likely scenarios. Users should ensure that the scenarios are suitable, that the steps are correct and that the injury level is appropriate.</p> <p>Disclaimer: The template has been developed by a Joint Action working group composed of market surveillance experts. The intention is to support market surveillance officials assessing the risk with a particular product as part of a</p>	<p>First name:</p> <p>Last name:</p> <p>Organisation:</p> <p>Address:</p>

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<p>market surveillance case. The template is not authorized or endorsed in any way and it is not binding for Member State market surveillance authorities. The contents of the original template is subject to change without notice.</p> <p>Disclaimer: This Risk Assessment Template arises from the Joint Market Surveillance Action on GPSD Products – JA2015, which received funding from the European Union in the framework of the ‘Programme of Community Action in the field of Consumer Policy (2014-2020)’. The content of this document represents the views of the author only and it is his sole responsibility; it cannot be considered to reflect the views of the European Commission and/or the Consumers, Health, Agriculture and Food Executive Agency or any other body of the European Union. The European Commission and the Agency do not accept any responsibility for use that may be made of the information it contains.</p>	

2 | Product risks - Overview

- Scenario 1 : To be determined - The child is playing with a soother holder with inadequate ventilation holes and puts the fastener in its mouth. The fastener gets stuck in the child's throat. The air flow is obstructed. The parents don't notice. The child is suffocated.
- Scenario 2 : To be determined - The child is sleeping using a soother attached to a soother holder that is too long. The child drops the soother in its sleep. The soother gets stuck to the surroundings of the child. The fastener remains attached to the child's clothes, so the soother holder gets twisted around the child's neck as the child moves and tumbles around while sleeping. The parents don't notice. The child is suffocated.
- Scenario 3 : To be determined - The child is playing with the soother. The fastener breaks. The child picks up a small part and puts it in the mouth. The parents do not notice. The small part get stuck in the larynx and the child suffocates.

Scenario 1 : Very young children - Product is impermeable to air

1 | Product hazard

Hazard Group: **Size, shape and surface**
 Hazard Type: **Product is impermeable to air**

2 | Consumer

Consumer type: **Very young children - 0 to 36 months (Very vulnerable consumers)**

3 | How the hazard causes an injury to the consumer

Injury scenario: **The child is playing with a soother holder with inadequate ventilation holes and puts the fastener in its mouth. The fastener gets stuck in the child's throat. The air flow is obstructed. The parents don't notice. The child is suffocated.**

4 | Severity of Injury

Injury: **Suffocation / Strangulation**
 Level: **4 Fatal suffocation / strangulation**

5 | Probability of the steps to injury

Step	Step(s) to Injury	Probability
1	The child is playing with a soother holder with insufficient ventilation holes.	1
2	The child puts the soother holder in the mouth.	0
3	The fastener gets stuck in the child's throat.	0
4	The air flow is obstructed. (The probability depends upon the actual size of the fastener and the ventilation holes if any.)	0
5	The parents don't notice.	0
6	The child is suffocated.	0

Calculated probability	Overall probability	Risk of this scenario
To be determined	To be determined	Risk to be determined

Scenario 2 : Very young children - High position of user

1 | Product hazard

Hazard Group: **Potential energy**
Hazard Type: **High position of user**

2 | Consumer

Consumer type: **Very young children - 0 to 36 months (Very vulnerable consumers)**

3 | How the hazard causes an injury to the consumer

Injury scenario: **The child is sleeping using a soother attached to a soother holder that is too long. The child drops the soother in its sleep. The soother gets stuck to the surroundings of the child. The fastener remains attached to the child's clothes, so the soother holder gets twisted around the child's neck as the child moves and tumbles around while sleeping. The parents don't notice. The child is suffocated.**

4 | Severity of Injury

Injury: **Suffocation / Strangulation**
Level: **4 Fatal suffocation / strangulation**

5 | Probability of the steps to injury

Step	Step(s) to Injury	Probability
1	The child is sleeping using a soother attached to a soother holder that is too long.	1
2	The child drops the soother in its sleep and the soother gets stuck to the surroundings of the child.	0
3	The fastener remains attached to the child's clothes.	0
4	The soother holder gets twisted around the child's neck as the child moves and tumbles around while sleeping.	0
5	The parents don't notice.	0
6	The child is suffocated.	0

Calculated probability	Overall probability	Risk of this scenario
To be determined	To be determined	Risk to be determined

Scenario 3 : Very young children - Product is or contains small part

1 | Product hazard

Hazard Group: **Size, shape and surface**
 Hazard Type: **Product is or contains small part**

2 | Consumer

Consumer type: **Very young children - 0 to 36 months (Very vulnerable consumers)**

3 | How the hazard causes an injury to the consumer

Injury scenario: **The child is playing with the soother. The fastener breaks. The child picks up a small part and puts it in the mouth. The parents do not notice. The small part get stuck in the larynx and the child suffocates.**

4 | Severity of Injury

Injury: **Suffocation / Strangulation**
 Level: **4 Fatal suffocation / strangulation**

5 | Probability of the steps to injury

Step	Step(s) to Injury	Probability
1	The child is playing with the soother holder. (If the soother holder has toy-like features, the probability will be 1. If it is a functional soother holder, the probability will be lower.)	1
2	The fastener breaks.	0
3	The child picks up a small part.	0
4	The child puts the small part in the mouth.	0
5	The parents do not notice.	0
6	The small part get stuck in the larynx and the child suffocates.	0

Calculated probability	Overall probability	Risk of this scenario
To be determined	To be determined	Risk to be determined