

1 | General Information and Overview

Product	Risk assessor
<p>Product name: Soother</p> <p>Product category: Childcare articles</p> <p>Description: This is a risk assessment template for soothers. It describes likely injury scenarios linked to non-conformities with the following clauses of EN 1400:2013 + A1:2014:</p> <p>Clause 9.1.2 - impact resistance Clause 11 - teat protector</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 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</p>	<p>First name:</p> <p>Last name:</p> <p>Organisation:</p> <p>Address:</p>

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<p>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)’.</p> <p>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 - A child is using a soother. The child drops it and it 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 child's larynx and the child suffocates.

Scenario 2 :

To be determined - The child is playing with the teat protector and drops it. It 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 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: **A child is using a soother. The child drops it and it 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 child's 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	A child is using a soother.	1
2	The child drops the soother that 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 child's larynx and the child suffocates	0

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

Scenario 2 : 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 teat protector and drops it. It 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 teat protector.	1
2	The child drops the teat protector.	0
3	The protector breaks.	0
4	The child picks up a small part.	0
5	The child puts the small part it in the mouth.	0
6	The parents do not notice.	0
7	The small part get stuck in the child's larynx and the child suffocates	0

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