

Risk Assessment for RAPEX

General Information

Product

Product name: Toys intended for children under 36 months

Product category: Toys

Description: This is a PROSAFE risk assessment template for toys intended for children under 36 months. It describes likely injury scenarios linked to the following non-conformities with EN71-1:2011:

- §4.6 (Small parts originating from) Expanding materials (scenario 1)
- §4.11 (Small parts from) Mouth actuated toys (scenario 1)
- §4.18 (Small parts from) Aquatic toys and inflatable toys (scenario 1)
- §4.23.2 Small magnets from toys (scenario 1 and scenario 11)
- §4.25 (Small parts from) Toys attached to food (scenario 1)
- §5.1 General requirements (small parts) (scenario 1)
- §5.2 (Small parts from) Soft-filled toys (scenario 1)
- §5.4 Cords, chains and cables (scenario 5)
- §5.8 Shape and size (scenario 4)
- §5.10 Small balls (scenario 3)
- §5.13 Suction cups (scenario 10)
- §6 Packaging (scenario 8)
- §7 Warning (not for children below 36 months) (scenario 9)
- §8.11 Sharp edges (scenario 6)
- §8.12 Sharp points (scenario 7)

and with IEC 62115:2003

§14.6 Construction, accessibility of batteries (scenario 2)

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 then 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.

Disclaimer

The template has been developed by a PROSAFE

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.

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Product risks - Overview

- Scenario 1 : **Risk to be determined** - The child is playing with a toy with a detachable, small part. The child detaches the small part. The parents don't notice. The child puts the small part in its mouth. The small part goes into the child's airways and surgery is necessary to remove it.
- Scenario 2 : **Risk to be determined** - A child plays with a non-compliant toy with batteries. The child gets access to the battery compartment and pulls out one or more batteries. The parents don't notice in time. The child puts the battery in the mouth and swallows it. Hydroxide develops in the ingestinal channel and creates damages.
- Scenario 3 : **Risk to be determined** - The child is playing with a toy with a detachable, small ball. The child detaches the small ball. The parents don't notice. The child puts the small ball in its mouth. The ball goes into the child's throat and blocks the airways so it suffocates.
- Scenario 4 : **Risk to be determined** - A child plays with a toys with a non-compliant shape or size. The child puts a part of the toy into its mouth. The parents don't notice in time. The child falls on its face with the while biting the toy. The child suffers injuries to the teeth or phraynx area.
- Scenario 5 : **Risk to be determined** - A child is playing with a toy with a long cord, chain or cable. The child gets entangled in the cord. The parents don't notice in time. The string tightens around the child's neck. The oxygene flow to the child's brain is blocked for a period of time.

- Scenario 6 : **Risk to be determined** - A child plays with a toy that can have sharp edges. The sharp edge shows. The parents don't notice in time. The child gets in touch with the sharp edge. The child cuts its fingers, tongue or lips.
- Scenario 7 : **Risk to be determined** - A child plays with a toy that can have sharp points. A sharp point shows. The parents don't notice in time. The child gets in touch with the sharp point and suffers a deep, small cut.
- Scenario 8 : **Risk to be determined** - The child plays with the plastic packaging of a toy. The child places it over the mouth and nose. The parents don't notice in time. The child is unable to remove the plastic packaging. The airflow is temporarily blocked.
- Scenario 9 : **Risk to be determined** - The injury scenario will be similar to one of the above depending upon the risk with the product except that it will have one more step - step 1: The toy doesn't warn the parents that it shouldn't be given to children under 36 months, so the parent gives it to the small child. The injury level and the remaining steps can be copied from the scenario above that best fits the actual situation. (If the toy for instance also contains small parts, the injury and the steps in scenario 1 are copied to this scenario.)
- Scenario 10 : **Risk to be determined** - The child is playing with a toy with a detachable, small suction cup. The child detaches the suction cup. The parents don't notice. The child puts the suction cup in its mouth. The suction cup goes into the child's throat and blocks the airways temporarily.
- Scenario 11 : **Risk to be determined** - The child is playing with a toy with detachable, small magnets. (Cases with only one detachable magnet are covered by scenario 1.) The child detaches more than one magnet. The parents don't notice. The child puts the magnets in its mouth. The magnets go into the child's digestive system and causes internal wounds because they attract each other in the intestines.

Overall risk :

Risk to be determined

Scenario 1 : Very young children - Product is or contains small part

Product hazard

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

Consumer

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

How the hazard causes an injury to the consumer

Injury scenario: The child is playing with a toy with a detachable, small part. The child detaches the small part. The parents don't notice. The child puts the small part in its mouth. The small part goes into the child's airways and surgery is necessary to remove it.

Severity of Injury

Injury: Internal airway obstruction
 Level: 3 Oxygen flow to brain blocked without permanent consequences

Probability of the steps to injury

Step(s) to Injury	Probability
Step 1: The child is playing with a toy with a detachable, small part.	1
Step 2: The child detaches the small part. (Probability depends upon the accessibility and the force that is required to detach the small part.)	
Step 3: The parents don't notice in time.	
Step 4: The child puts the small part in its mouth.	
Step 5: The small part goes into the child's airways and surgery is necessary to remove it. (Probability depends upon shape, size and surface of small part.)	

Calculated probability:

To be determined

Overall probability:

To be determined

Risk of this scenario:

Risk to be determined

Scenario 2 : Very young children - Irritating or corrosive solid or fluid

Product hazard

Hazard Group: Toxicity
Hazard Type: Irritating or corrosive solid or fluid

Consumer

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

How the hazard causes an injury to the consumer

Injury scenario: A child plays with a non-compliant toy with batteries. The child gets access to the battery compartment and pulls out one or more batteries. The parents don't notice in time. The child puts the battery in the mouth and swallows it. Hydroxide develops in the ingestional channel and creates damages.

Severity of Injury

Injury: Ingestion
Level: 3 Internal organ injury (Refer also to internal airway obstruction in case the ingested object gets stuck high in the oesophagus.)

Probability of the steps to injury

Step(s) to Injury	Probability
Step 1: A child plays with a non-compliant toy with batteries.	1
Step 2: The child gets access to the battery compartment and pulls out one or more batteries. (The probability depends upon how easy it is to open the battery compartment and remove the batteries.)	
Step 3: The parents don't notice in time.	
Step 4: The child puts the battery in the mouth and swallows it. (The probability is fairly low. Often the child would spit out the battery, or the battery would create a "tickling experience" on the child's tongue.)	
Step 5: The battery creates burns in the ingestional channel. (Probability close to 100%. Probably depends upon the type of battery. Button-cell Li batteries are the most dangerous ones.)	

Calculated probability:

To be determined

Overall probability:

To be determined

Risk of this scenario:

Risk to be determined

Scenario 3 : Very young children - Product is impermeable to air

Product hazard

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

Consumer

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

How the hazard causes an injury to the consumer

Injury scenario: The child is playing with a toy with a detachable, small ball. The child detaches the small ball. The parents don't notice. The child puts the small ball in its mouth. The ball goes into the child's throat and blocks the airways so it suffocates.

Severity of Injury

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

Probability of the steps to injury

Step(s) to Injury	Probability
Step 1: The child is playing with a toy with a detachable, small ball.	1
Step 2: The child detaches the small ball. (Probability depends upon the accessibility and the force that is required to detach the ball.)	
Step 3: The parents don't notice.	
Step 4: The child puts the small ball in its mouth. (Probability is high. This is normal behaviour for small children.)	
Step 5: The ball goes into the child's throat and blocks the airways so it suffocates. (Probability depends upon size and surface of the ball.)	

Calculated probability:

To be determined

Overall probability:

To be determined

Risk of this scenario:

Risk to be determined

Scenario 4 : Very young children - Product is obstacle

Product hazard

Hazard Group: Size, shape and surface
 Hazard Type: Product is obstacle

Consumer

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

How the hazard causes an injury to the consumer

Injury scenario: A child plays with a toys with a non-compliant shape or size. The child puts a part of the toy into its mouth. The parents don't notice in time. The child falls on its face with the while biting the toy. The child suffers injuries to the teeth or phraynx area.

Severity of Injury

Injury: Fracture
 Level: 2 Extremities (finger, toe, hand, foot)
 Wrist
 Arm
 Rib
 Sternum
 Nose
 Tooth
 Jaw
 Bones around eye

Probability of the steps to injury

	Step(s) to Injury	Probability
Step 1:	A child plays with a toys with a non-compliant shape or size.	1
Step 2:	The child puts a part of the toy into its mouth. (The probability depends upon size and surface of the toy.)	
Step 3:	The parents don't notice in time.	
Step 4:	The child falls on its face while still biting the toy. (The probability depends upon the age of the child.)	
Step 5:	The child suffers injuries to the teeth or phraynx area. (The injury and the probability depends upon the shape, size and material of the toy.)	

Calculated probability:

To be determined

Overall probability:

To be determined

Risk of this scenario:

Risk to be determined

Scenario 5 : Very young children - Product is obstacle

Product hazard

Hazard Group: Size, shape and surface
 Hazard Type: Product is obstacle

Consumer

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

How the hazard causes an injury to the consumer

Injury scenario: A child is playing with a toy with a long cord, chain or cable. The child gets entangled in the cord. The parents don't notice in time. The string tightens around the child's neck. The oxygene flow to the child's brain is blocked for a period of time.

Severity of Injury

Injury: Suffocation / Strangulation
 Level: 3 Oxygen flow to brain blocked without permanent consequences

Probability of the steps to injury

	Step(s) to Injury	Probability
Step 1:	A child is playing with a toy with a long cord, chain or cable.	1
Step 2:	The child gets entangled in the cord. (The probability depends upon the length and mechanical strength of the wire.)	
Step 3:	The parents don't notice in time.	
Step 4:	The string tightens around the child's neck. (The probability depends upon the length and mechanical strength of the wire.)	
Step 5:	The oxygene flow to the child's brain is blocked for a period of time. (The probability depends upon the length and mechanical strength of the wire.)	

Calculated probability:

To be determined

Overall probability:

To be determined

Risk of this scenario:

Risk to be determined

Scenario 6 : Very young children - Sharp edge

Product hazard

Hazard Group: Size, shape and surface
Hazard Type: Sharp edge

Consumer

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

How the hazard causes an injury to the consumer

Injury scenario: A child plays with a toy that can have sharp edges. The sharp edge shows. The parents don't notice in time. The child gets in touch with the sharp edge. The child cuts its fingers, tongue or lips.

Severity of Injury

Injury: Laceration, cut
Level: 1 Superficial

Probability of the steps to injury

Step(s) to Injury	Probability
Step 1: A child plays with a toy that can have sharp edges.	1
Step 2: The sharp edge shows. (The probability depends upon the accessibility of the sharp edge - does the child have to break the toy to access the sharp edge or is it immediately accessible? The probability must be determined from an examination of the toy and the test report.)	
Step 3: The parents don't notice in time.	
Step 4: The child gets in touch with the sharp edge and cuts its fingers, tongue or lips. (The probability depends upon the accessibility, sharpness and material of the sharp edge.)	

Calculated probability:

To be determined

Overall probability:

To be determined

Risk of this scenario:

Risk to be determined

Scenario 7 : Very young children - Sharp corner or point

Product hazard

Hazard Group: Size, shape and surface
Hazard Type: Sharp corner or point

Consumer

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

How the hazard causes an injury to the consumer

Injury scenario: A child plays with a toy that can have sharp points. A sharp point shows. The parents don't notice in time. The child gets in touch with the sharp point and suffers a deep, small cut.

Severity of Injury

Injury: Piercing, puncturing
Level: 2 Deeper than skin
Abdominal wall (no organ involvement)

Probability of the steps to injury

Step(s) to Injury	Probability
Step 1: A child plays with a toy that can have sharp points.	1
Step 2: A sharp point shows. (The probability depends upon the accessibility of the sharp point - does the child have to break the toy to access the sharp point or is it immediately accessible? The probability must be determined from an examination of the toy and the test report.)	
Step 3: The parents don't notice in time.	
Step 4: The child gets in touch with the sharp point and suffers a deep, small cut. (The injury level and the probability depend upon the accessibility, geometry, dimensions and material of the sharp point.)	

Calculated probability:

To be determined

Overall probability:

To be determined

Risk of this scenario:

Risk to be determined

Scenario 8 : Very young children - Product is impermeable to air

Product hazard

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

Consumer

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

How the hazard causes an injury to the consumer

Injury scenario: The child plays with the plastic packaging of a toy. The child places it over the mouth and nose. The parents don't notice in time. The child is unable to remove the plastic packaging. The airflow is temporarily blocked.

Severity of Injury

Injury: Suffocation / Strangulation
 Level: 3 Oxygen flow to brain blocked without permanent consequences

Probability of the steps to injury

Step(s) to Injury	Probability
Step 1: The child plays with the plastic packaging of a toy.	1
Step 2: The child places it over the mouth and nose and is unable to remove it again. (The probability depends upon size and flexibility of the packaging.)	
Step 3: The parents don't notice in time.	
Step 4: The airflow to the brain is temporarily blocked. (The probability depends upon size and flexibility of the packaging.)	

Calculated probability:

To be determined

Overall probability:

To be determined

Risk of this scenario:

Risk to be determined

Scenario 9 : Very young children - Insufficient warning texts and symbols

Product hazard

Hazard Group: Product operating hazards
Hazard Type: Insufficient warning texts and symbols

Consumer

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

How the hazard causes an injury to the consumer

Injury scenario: The injury scenario will be similar to one of the above depending upon the risk with the product except that it will have one more step - step 1: The toy doesn't warn the parents that it shouldn't be given to children under 36 months, so the parent gives it to the small child. The injury level and the remaining steps can be copied from the scenario above that best fits the actual situation. (If the toy for instance also contains small parts, the injury and the steps in scenario 1 are copied to this scenario.)

Severity of Injury

Injury:
Level:

Probability of the steps to injury

Step(s) to Injury	Probability
Step 1: The toy doesn't warn the parents that it shouldn't be given to children under 36 months, so the parent gives it to the small child.	1

Calculated probability:

To be determined

Overall probability:

To be determined

Risk of this scenario:

Risk to be determined

Scenario 10 : Very young children - Product is impermeable to air

Product hazard

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

Consumer

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

How the hazard causes an injury to the consumer

Injury scenario: The child is playing with a toy with a detachable, small suction cup. The child detaches the suction cup. The parents don't notice. The child puts the suction cup in its mouth. The suction cup goes into the child's throat and blocks the airways temporarily.

Severity of Injury

Injury: Suffocation / Strangulation
Level: 3 Oxygen flow to brain blocked without permanent consequences

Probability of the steps to injury

Step(s) to Injury	Probability
Step 1: The child is playing with a toy with a detachable, small suction cup.	1
Step 2: The child detaches the suction cup. (Probability depends upon the accessibility and the force that is required to detach the suction cup.)	
Step 3: The parents don't notice.	
Step 4: The child puts the suction cup in its mouth.	
Step 5: The suction cup goes into the child's throat and blocks the airways temporarily. (The probability and the injury level depends upon size and surface of the suction cup.)	

Calculated probability:

To be determined

Overall probability:

To be determined

Risk of this scenario:

Risk to be determined

Scenario 11 : Very young children - Product is or contains small part

Product hazard

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

Consumer

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

How the hazard causes an injury to the consumer

Injury scenario: The child is playing with a toy with detachable, small magnets. (Cases with only one detachable magnet are covered by scenario 1.) The child detaches more than one magnet. The parents don't notice. The child puts the magnets in its mouth. The magnets go into the child's digestive system and causes internal wounds because they attract each other in the intestines.

Severity of Injury

Injury: Ingestion
 Level: 3 Internal organ injury (Refer also to internal airway obstruction in case the ingested object gets stuck high in the oesophagus.)

Probability of the steps to injury

Step(s) to Injury	Probability
Step 1: The child is playing with a toy with detachable, small magnets.	1
Step 2: The child detaches more than one magnet. (Probability depends upon the accessibility and the force that is required to detach the magnets.)	
Step 3: The parents don't notice.	
Step 4: The child puts the magnets in its mouth.	
Step 5: The magnets go into the child's digestive system and causes internal wounds because they attract each other in the intestines. (The probability depends upon the magnetic strength and size of the magnets.)	

Calculated probability:

To be determined

Overall probability:

To be determined

Risk of this scenario:

Risk to be determined