

Risk Assessment for RAPEX

General Information

Product

Product name: Toys intended for children above 36 months

Product category: Toys

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

- §4.6 Expanding materials (scenario 10)
- §4.11 (Small parts from) Mouth actuated toys (scenario 1)
- §4.17.1 (Suction cups on) Projectile toys (scenario 8)
- §4.18 (Small parts from) Aquatic toys and inflatable toys (scenario 1)
- §4.23.2 Small magnets from toys (scenario 1 and scenario 11)
- §4.23.3 Small magnets from experimental sets (scenario 1 and scenario 11)
- §4.25 (Small parts from) Toys attached to food (scenario 1)
- §4.9 Protruding parts (scenario 4)
- §4.10.1 Folding mechanisms (scenario 5)
- §6 Packaging (scenario 6)
- §7 Warning (not for children below 36 months) (scenario 7)
- §8.11 Sharp edges (scenario 2)
- §8.12 Sharp points (scenario 3)

and with IEC 62115:2003

- §14.6 Construction, accessibility of batteries (scenario 9)

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 (e.g a mouth actuated toy or an inflatable toy). The small part comes off and the child accidentally swallows it. The parents don't notice. 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 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 3 : **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 4 : **Risk to be determined** - A child is playing with a toy with a protruding part (e.g. the end of a handle bar on a 3-wheeled bicycle). The child falls with the toy. The child falls on the protruding part. The child receives a puncture wound to the abdomen.
- Scenario 5 : **Risk to be determined** - A child is playing with a toy with a non-compliant folding mechanism. The child releases the folding mechanism and the toy folds. The child's fingers are trapped between the folding parts. One or more fingers break.
- Scenario 6 : **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 7 : **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 8 : **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 9 : **Risk to be determined** - A child plays with a non-compliant toy with button cell 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.
- Scenario 10 : **Risk to be determined** - The child is playing with a toy that contains expandable material. The child pull off some of this material. The parents don't notice. The child puts the expandable material in its mouth and swallows. The expandable material gets stuck in the upper airways and blocks them so the oxygen flow to the brain is blocked 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 : 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: Young children - Older than 36 months and younger than 8 years (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 (e.g a mouth actuated toy or an inflatable toy). The small part comes off and the child accidentally swallows it. The parents don't notice. 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 (e.g a mouth actuated toy or an inflatable toy).	1
Step 2: The small part comes off. (The probability depends upon the mechanical construction of the toy and can be determined from an examination of the toy and the test report.)	
Step 3: The parents don't notice.	
Step 4: The child accidentally swallows the small part. (The probability depends the shape, size and surface of the small part.)	
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 : Young children - Sharp edge

Product hazard

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

Consumer

Consumer Type: Young children - Older than 36 months and younger than 8 years (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 3 : Young children - Sharp corner or point

Product hazard

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

Consumer

Consumer Type: Young children - Older than 36 months and younger than 8 years (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 4 : Young children - Sharp corner or point

Product hazard

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

Consumer

Consumer Type: Young children - Older than 36 months and younger than 8 years (Vulnerable consumers)

How the hazard causes an injury to the consumer

Injury scenario: A child is playing with a toy with a protruding part (e.g. the end of a handle bar on a 3-wheeled bicycle). The child falls with the toy. The child falls on the protruding part. The child receives a puncture wound to the abdomen.

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 is playing with a toy with a protruding part (e.g. the end of a handle bar on a 3-wheeled bicycle).	1
Step 2:	The child falls with the toy. (The probability depends upon the toy and its use.)	
Step 3:	The child falls on the protruding part. (The probability depends upon the dimensions, geometry and accessibility of the protruding part.)	
Step 4:	The child receives a puncture wound to the abdomen. (The probability depends upon the dimensions, geometry and accessibility of the protruding part.)	

Calculated probability:

To be determined

Overall probability:

To be determined

Risk of this scenario:

Risk to be determined

Scenario 5 : Young children - Gap or opening between elements

Product hazard

Hazard Group: Size, shape and surface
 Hazard Type: Gap or opening between elements

Consumer

Consumer Type: Young children - Older than 36 months and younger than 8 years (Vulnerable consumers)

How the hazard causes an injury to the consumer

Injury scenario: A child is playing with a toy with a non-compliant folding mechanism. The child releases the folding mechanism and the toy folds. The child's fingers are trapped between the folding parts. One or more fingers break.

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 is playing with a toy with a non-compliant folding mechanism.	1
Step 2:	The child releases the folding mechanism and the toy folds. (The probability depends upon the toy and its intended use.)	
Step 3:	The child's fingers are trapped between the folding parts. (The probability depends upon the geometry and accessibility of the folding parts.)	
Step 4:	One or more fingers break. (The probability depends upon the geometry of the toy and the force, the child can apply to the folding mechanism.)	

Calculated probability:

To be determined

Overall probability:

To be determined

Risk of this scenario:

Risk to be determined

Scenario 6 : 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: Young children - Older than 36 months and younger than 8 years (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 7 : Young children - Insufficient warning texts and symbols

Product hazard

Hazard Group: Product operating hazards

Hazard Type: Insufficient warning texts and symbols

Consumer

Consumer Type: Young children - Older than 36 months and younger than 8 years (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.	

Calculated probability:

To be determined

Overall probability:

To be determined

Risk of this scenario:

Risk to be determined

Scenario 8 : 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: Young children - Older than 36 months and younger than 8 years (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 9 : Young children - Irritating or corrosive solid or fluid

Product hazard

Hazard Group: Toxicity

Hazard Type: Irritating or corrosive solid or fluid

Consumer

Consumer Type: Young children - Older than 36 months and younger than 8 years (Vulnerable consumers)

How the hazard causes an injury to the consumer

Injury scenario: A child plays with a non-compliant toy with button cell 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 button cell 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 10 : 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: Young children - Older than 36 months and younger than 8 years (Vulnerable consumers)

How the hazard causes an injury to the consumer

Injury scenario: The child is playing with a toy that contains expandable material. The child pull off some of this material. The parents don't notice. The child puts the expandable material in its mouth and swallows. The expandable material gets stuck in the upper airways and blocks them so the oxygen flow to the brain is blocked temporarily.

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 that contains expandable material.	1
Step 2: The child pull off some of this material. (Probability depends upon the accessibiliilty of the material.)	
Step 3: The parents don't notice.	
Step 4: The child puts the expandable material in its mouth and swallows.	
Step 5: The expandable material gets stuck in the upper airways and blocks them so the oxygen flow to the brain is blocked temporarily. (The probability and the injury level depends upon the amount of expandable material and the expansion factor - how easy it expands to dangerous volumes.)	

Calculated probability:

To be determined

Overall probability:

To be determined

Risk of this scenario:

Risk to be determined

Scenario 11 : 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: Young children - Older than 36 months and younger than 8 years (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 and swallows them.	
Step 5: The magnets goes 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