



General Product Safety Regulation (GPSR) Risk Analysis Template

Section 1 - Economic Operator Information

Indicate all the economic operators involved in the sale of the product.

Manufacturer:

- **Name:** [Enter Name]
- **Registered Trade Name / Trade Mark:** [Enter Trade Name]
- **Full Postal Address:** [Enter Address]
- **Electronic Address:** [Enter Email & Website]
- **Telephone Number:** [Enter Phone Number]
- **Primary Contact:** [Enter Contact Name / Role]

Importer:

- **Name:** [Enter Name]
- **Registered Trade Name / Trade Mark:** [Enter Trade Name]
- **Full Postal Address:** [Enter Address]
- **Electronic Address:** [Enter Email & Website]
- **Telephone Number:** [Enter Phone Number]
- **Primary Contact:** [Enter Contact Name / Role]

EU Authorised Representative / Responsible Person:

- **Name:** [Enter Name]
 - **Registered Trade Name / Trade Mark:** [Enter Trade Name]
 - **Full Postal Address:** [Enter Address]
 - **Electronic Address:** [Enter Email & Website]
 - **Telephone Number:** [Enter Phone Number]
 - **Primary Contact:** [Enter Contact Name / Role]
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Section 2 - General Product Description

Provide a detailed description of the product, its intended use, and key safety considerations. This section ensures a clear understanding of the product's nature and potential risks.

- **Product Name:** [Enter Product Name]
- **Description of the Product:** [Provide a brief overview, including intended function and target users]
- **Intended Use:** [Specify primary and any foreseeable secondary uses]
- **Essential Characteristics for Safety Assessment:**
 - [Describe key design features that impact safety, such as weight, dimensions, moving parts, or sharp edges]

- [Identify specific safety mechanisms, such as child-resistant locks, reinforced structures, or flame-retardant properties]
 - **Product Raw Materials:** [List materials used in production or attach Bill of Materials]
 - **Manufacturing Process Overview:** [Briefly outline key production steps that may affect safety]
 - **Age Grading:** [Specify intended age group and justify grading if applicable]
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Section 3 - Applicable Legal Requirements & Standards

Identify and apply all relevant legal requirements, harmonized standards, and additional reference standards applicable to the product.

- **Product Category:** [Specify product category]
 - **Applicable Legal Requirements:**
 - Example: General Product Safety Regulation EU/2023/988
 - Example: REACH Regulation 1907/2006/EC Annex XVII SVHCs
 - Example: Persistent Organic Pollutants EU/2019/1021
 - [Include other applicable EU directives, regulations, or national legislation]
 - **EU Harmonised Standards applied to meet General Safety Requirement:**
 - Example: EN 71 for child-appealing products
 - Example: EN 60335 for household electrical appliances
 - [Include additional harmonized standards relevant to the product]
 - **Other Reference Standards Applied:**
 - Example: Nearest appropriate non-harmonized standards
 - Example: Industry best practices, international safety standards
 - [List additional relevant technical specifications or guidelines used for compliance]
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Section 4 - Product Design Evaluation

Conduct a comprehensive hazard assessment evaluation to ensure the product's safety. Identify potential hazards, assess their severity, and document mitigation methods to reduce or eliminate risks. Each identified hazard should include a detailed description of the risk, applicable safety requirements, and preventive measures.

- **Physical and Mechanical Hazards:**
 - Identify risks such as sharp edges, small parts, instability, or entrapment hazards.
 - Assess compliance with relevant mechanical safety standards.
 - Specify design modifications, protective barriers, or labeling to mitigate risks.
- **Flammability / Thermal Hazards:**
 - Determine whether the product poses fire or burn risks.
 - Evaluate the use of flame-retardant materials and compliance with applicable fire safety regulations.
 - Implement labeling, warnings, or protective barriers where necessary.
- **Chemical Hazards:**
 - Identify hazardous substances such as lead, phthalates, or restricted chemicals.

- Confirm compliance with REACH, RoHS, or other applicable chemical safety regulations.
 - Outline testing procedures and risk mitigation strategies such as material substitution.
 - **Electrical Hazards (if applicable):**
 - Assess risks of electric shock, overheating, or short circuits.
 - Verify compliance with Low Voltage Directive (LVD) and other electrical safety standards.
 - Ensure appropriate insulation, grounding, and overload protection.
 - **Hygiene Hazards:**
 - Evaluate risks related to bacterial contamination, allergenic materials, etc.
 - Confirm compliance with hygiene-related safety standards.
 - Recommend materials, coatings, or cleaning instructions to reduce hygiene risks.
 - **Radiation Hazards (if applicable):**
 - Identify potential exposure to ionizing or non-ionizing radiation.
 - Ensure compliance with EMF (electromagnetic field) exposure limits.
 - Implement shielding, safety instructions, or usage restrictions.
 - **Mitigating Factors:**
 - Specify tests conducted to verify safety compliance (e.g., EN 71-1 for mechanical safety, REACH Annex XVII for chemical safety).
 - Outline protective design measures, user instructions, and warnings included to minimize risks.
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Section 5 - Risk Analysis / Assessment Findings

Conduct a structured risk analysis by categorizing hazards based on their severity and identifying control measures to mitigate or eliminate them. Each identified risk should be clearly described along with the preventive measures implemented.

- **Critical Risk:**
(e.g., Life-Threatening Hazard in foreseeable use)
 - Description of hazard: [Specify details]
 - Potential impact: [Describe consequences]
 - Control measures: [List measures taken, e.g., product tested, design modifications, material changes, safety features]
- **Major Risk:**
(e.g., Significant Injury or Significant Damage to Property Hazards in foreseeable use)
 - Description of hazard: [Specify details]
 - Potential impact: [Describe consequences]
 - Control measures: [List measures taken, e.g., product tested, reinforced construction, enhanced safety labeling, protective enclosures]
- **Minor Risk:**
(e.g., Minor Injury or Minor Damage to Property Hazards in foreseeable use)
 - Description of hazard: [Specify details]
 - Potential impact: [Describe consequences]
 - Control measures: [List measures taken, e.g., product tested, design refinements, warning labels, user instructions]
- **Manufacturing Concern(s) & Control Measure(s):**
(e.g., presence of foreign bodies from the manufacturing process)
 - Description of issue: [Specify details]
 - Potential impact: [Describe consequences]

- Control measures: [List measures taken, e.g., quality control checks, automated inspections, supplier audits]

Section 6 – Labelling Requirements

Ensure all necessary labeling and safety instructions are included in compliance with EU regulations.

- **Product Marking and Identification:**
 - CE marking (if applicable)
 - Manufacturer/importer details (name, address, contact information)
 - Batch number or serial number for traceability
- **Labelling / Instructions on the Product:**
 - Warnings and safety symbols relevant to the product
 - Usage instructions and assembly guidance
 - Age restrictions (e.g., "Not suitable for children under 3 years" if applicable)
- **Labelling / Instructions on the Packaging:**
 - Safe storage and transport guidelines
 - Hazard warnings in accordance with applicable EU directives (see below)
 - Disposal and recycling information
- **Specific Safety Information Included with the Product:**
 - User manual with step-by-step instructions
 - Maintenance and cleaning guidelines
 - Emergency procedures and first aid recommendations (if applicable)

Warnings

In the European Union, products that could be dangerous are required to have a hazard warning label using symbols or words like 'Warning' or 'Danger'. However, the specific format and wording of these warnings can vary depending on the product category and applicable regulations. For example, certain childcare articles are required to have warnings such as "⚠ WARNING - Never leave the child unattended" or "⚠ WARNING - Always use this product with adult supervision". Therefore, while it is common to use "⚠ WARNING!" to indicate hazards, it is not a universal requirement for all product categories in the EU. It is essential to consult the specific regulations and standards applicable to each product category to determine the appropriate warning labels.

Here are the top 20 warnings that are commonly required across multiple product categories to ensure compliance with the General Product Safety Regulation and other relevant EU directives:

1. ⚠ **WARNING!** Choking Hazard – Small parts. Not for children under 3 years.
2. ⚠ **WARNING!** Strangulation Hazard – Cords or straps may pose a risk to young children.
3. ⚠ **WARNING!** Risk of Electric Shock – Do not use near water or expose to moisture.
4. ⚠ **WARNING!** Fire Hazard – Keep away from open flames and high heat sources.
5. ⚠ **WARNING!** Contains hazardous substances. Use with adequate ventilation.
6. ⚠ **WARNING!** Flammability Risk – This product is flammable. Keep away from heat sources.
7. ⚠ **WARNING!** Burn Hazard – Hot surfaces may cause burns. Allow to cool before touching.
8. ⚠ **WARNING!** Suffocation Risk – Keep plastic bags away from babies and children.



9. ⚠ **WARNING!** Cutting Hazard – Sharp edges. Handle with care.
10. ⚠ **WARNING!** Risk of Eye Injury – Wear protective eyewear when using this product.
11. ⚠ **WARNING!** Hearing Damage Risk – Use hearing protection when exposed to loud noise.
12. ⚠ **WARNING!** Risk of Falling – Use only on a stable surface. Do not exceed weight limits.
13. ⚠ **WARNING!** May contain allergens such as latex, nickel, or fragrance.
14. ⚠ **WARNING!** Risk of Poisoning – Keep out of reach of children and pets.
15. ⚠ **WARNING!** Carbon Monoxide Risk – Do not use in enclosed or poorly ventilated areas.
16. ⚠ **WARNING!** Explosion Risk – Do not puncture or expose to extreme heat.
17. ⚠ **WARNING!** Risk of Radiation Exposure – Follow safety guidelines for use and disposal.
18. ⚠ **WARNING!** Entanglement Hazard – Loose parts may pose a risk to small children.
19. ⚠ **WARNING!** Risk of Serious Injury – Read and follow all safety instructions before use.
20. ⚠ **WARNING!** Not for use by children – Adult supervision required.

These warnings help ensure product safety and compliance with EU regulations.

Section 7 - Conclusion

The product compliance documentation has been assessed. Based on the review, the product is deemed safe in accordance with Regulation (EU) 2023/988 (GPSR). This document confirms that the product complies with the necessary product safety standards for the EU market.

Created by: [Enter Company Name], [Enter Location], [Insert Date]

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