



**New EU Toys Directive
(2009/48/EC)**

TECHNICAL FILE

Item No. : 52733

Item Name: Cactus Oasis Sprinkler

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Date: FEB 08,2024

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Part I: Physical Safety Assessment

SECTION 1 – Description	
Item/Concept Name:	52733
Detailed Description:	Cactus Oasis Sprinkler
Materials Used:	PVC
Age Grading:	Over 2 years
	

Executive Summary

SECTION 2 – Foreseeable Use

Intended/Foreseeable Use	Children will play the item as intended.
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SECTION 3 – Mechanical/Physical Compliance Findings

Mechanical & physical

Europe

The product is likely to comply with the requirements for children over 2 years based on the play feature, construction and design.

Non-conformity was not identified during this review, but the following requirements should be noted for the compliance.

- Mold flash shall not be present
- No sharp point/edge can be found
- Materials used in the toy shall be clean.

SECTION 4 – Product Design Evaluation

Risk Assessment Recommendations:

Major Concerns

Tip over

While using the item in outdoor, children playing inside the product may tip over if there is a strong wind, or if children lean on the inflate wall as the item doesn't has any anchor to fix it on the floor.

Action: this hazard can be reduced by reminding consumer this hazard, adult supervision is always needed.

Airway obstruction

There may present an airway obstruction hazard if stopper and plastic film became detached. However, the hazard is slightly reduced as no small component was detached after test.

	<p><i>Action: this hazard can be reduced by:</i></p> <ul style="list-style-type: none"> - <i>making sure all stoppers are well attached and be capable of being pushed into the toy in order to protrude length less than 5mm from the surface of the toy when inflated.</i> - <i>Making sure over-flow rims are well treated to shorten protruding length less than 2 mm.</i>
<p>Minor Concerns</p>	<p><u>Suffocation</u></p> <p>The plastic film of ball pit present suffocation hazard if it is too thin. However, this hazard is minor as the thickness is more than 0.038mm.</p> <p><i>Action: this hazard can be reduced by making sure all the plastic film's average thickness is greater than 0.038mm.</i></p> <p><u>Impact</u></p> <p>The ocean balls may present impact hazard to face or other parts of body when children throw it. However, this hazard is inherent for these similar products, and it's reduced as these components are relatively soft.</p> <p><i>Action: this hazard can be reduced by adding a warning to alert users not to throw the ball to others' face or body.</i></p>
<p>Critical Manufacturing Concerns</p>	<p>Heavy elements content and raw materials should be controlled, especially phthalates, Nitrosamine.</p> <p>Mould flash and process splinter should be well controlled throughout production in order to minimize the laceration hazard from sharp points on the items.</p> <p>The item should be manufactured in a clean environment and this should be closely monitored throughout production to avoid external contamination.</p> <p>Well processing the inflaming retarding for the product, it's better to use inflammable materials.</p>

SECTION 5 – Flammability	
EN71-2	This product is likely to comply with the requirements of EN71 Part 2.

SECTION 6 – Hygiene

Hygiene	Toys must be designed and manufactured in such a way as to meet hygiene and cleanliness requirements in order to avoid any risk of infection, sickness or contamination (New Toy Safety Directive 2009-48-EC).
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SECTION 7 – Radioactivity

Radioactivity	This product has no characteristic related to this hazard.
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SECTION 8– Applicable European Directives, Regulations and Harmonized Standards

Applicable Standards	<p>EU Toy Safety Directive (2009/48/EC)</p> <ul style="list-style-type: none"> - EN 71-1 Safety of toys - Mechanical and physical properties - EN 71-2 Safety of toys - Flammability - EN 71-3 Safety of toys - Migration of certain elements (19 elements) <p>EN 71-12 Safety of toys – N-Nitrosamines and N-nitrosatable substances Flame Retardant-TCEP & TCPP & TDCPP Content (Directive 2014/79/EU, amendment of 2009/48/EC) Migration BPA-(Directive 2014/81/EU, amendment of 2009/48/EC)</p> <p>REACH Annex XVII – Restrictions</p> <ul style="list-style-type: none"> - Cadmium - Organotins - Phthalates - PAHs - Azocolourants <p>Regulation (EC) 1907/2006, REACH, Article 33</p> <ul style="list-style-type: none"> - Substances of very high concern (SVHCs) on the current candidate list <p>Regulation (EU) No 519/2012</p> <ul style="list-style-type: none"> - Short Chain Chlorinated Paraffin (SCCP) Content <p>Packaging Waste Directive (Pb + Cd + Hg + Cr VI) (94/62/EC)</p>
Other Test Recommendations	<p>EN 71-9 Safety of Toys - Organic Chemical Compounds DIN 53160 Germany AfPS GS 2019:01 – PAHs Denmark Statutory Order No. 1082-Lead German Chemikalien Verbotverordnung - Pentachlorophenol (PCP)</p>
	<p>Gulf Countries</p> <ul style="list-style-type: none"> - GSO EN 71-1 Safety of toys - Mechanical and physical properties - GSO EN 71-2 Safety of toys - Flammability - GSO EN 71-3 Safety of toys - Migration of certain elements

SECTION 9 – Labelling Assessment

CE Mark	<p>Yes for EU Note: For the new Toy Directive the CE mark must be visible at point of sale.</p>
Labeling	<p>All texts required shall be written in the official language of the country in which the toy is to be sold.</p> <p>New Toys Safety Directive (2009/48/EC) The following information can be placed on the packaging/instruction only if it is not technically or economically feasible to place it on the toy itself.</p> <ul style="list-style-type: none"> - Batch/Serial/Model Number - Manufacturer name and address - Importer name and address <p>The CE marking must be affixed visibly, legibly and indelibly to the toy, to an affixed label or to the packaging. It must be visible at the point of sale.</p>  <p>The packaging shall be marked the following warning, as long as the warning is clearly visible at the time of purchase: "Warning. Use only under adult supervision"</p>
Instructions	<p>A detailed instruction booklet shall be accompanied with the item. In which contains:</p> <ul style="list-style-type: none"> - Warnings - Product description - Maintenance - Cleaning & Storage - Repair <p>An instruction of repair patch was found and accompanied with supervision contents.</p> <p>It is suggested to print warning statement to alert the parent / adult to use the patch correctly (repair the damaged pool by adult only and frequent check the used patch stuck on the item.</p>

SECTION 10 – Recall Case Study

<p>Slovenia</p>	<p>Category: Toys</p> <p>Product: Play tent "Pop-Up Tent with 100 Balls"</p> <p>Brand: Outdoor Active</p> <p>Name:</p> <p>Type/number of model: Product code: art.16200; EAN 4022498572629, lot 03/10</p> <p>Batch number/Barcode:</p> <p>OECD Portal Category:</p> <p>Description: Toy pop-up tent with 100 balls.</p> <p>Country of origin: China</p> 	<p>Injuries, Cuts</p> <p>The product poses a risk of injuries because the metallic wires of the tent can break and sharp points can protrude through the tent fabric causing cuts and injuries to children playing with the tent. The product does not comply with the Toys Safety Directive and with the relevant European standard EN 71-1.</p>	<p>Voluntary measures: Voluntary recall from consumers by the distributor.</p>
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. Part II: Chemical Safety Assessment

Summary and Recommendation

None of the materials listed in the submitted BOM is identified from the substances that are classified as CMR of categories 1A, 1B or 2 under Regulation (EC) No. 1272/2008, substances which are Persistent, Bioaccumulative and Toxic (PBT) and very Persistent and very Bioaccumulative (vPvB), restricted substances listed on Annex XVII of REACH and SVHCs on Candidate List. It is also recommended to review the manufacture process to ensure these substances are not added.

The test listed in the table “**Applicable European Directives, Regulations and Harmonized Standards**” are recommended for compliance testing, in order to reduce unintentional chemical risk such as contamination of material during production process.

Chemical management from incoming material to finish product throughout the supply chain is an important part for fulfilling complex and ever-changing chemical requirements. The “**Universal Chemical Safety Assessment**” provided additional information to assist manufacturer in reviewing the manufacturing process, it is to ensure the chemical properties of a toy manufactured through such process is consistence to the BOM stated.

Universal Chemical Safety Assessment

The following assessment was based on worst case scenario by assessing the possibility of existing of hazardous chemical in the material given in the BOM submitted.

Product classification:

A. New Toy Safety Directive (2009/48/EC)

i: The PVC, PE and paper parts of the **Cuddly Cub Ball Pit** (SAMPLE) are likely to be defined as **scraped-off toy materials**. These materials are **accessible** to children when the SAMPLE is used as intended or in a foreseeable way, when taking into accounts the behavior of children.

Component No.	Material	Accessible as defined by EN 71-1?
1-2	PVC	Yes
3	Polyethylene (PE)	Yes
4	Paper	Yes

The CMR substances in categories 1A, 1B and 2 and the 19 elements should fulfill the chemical requirements of Part III, Annex II of 2009/48/EC unless they are **inaccessible**.

ii: The SAMPLE is likely to be defined as a **non-scented** toy. The likelihood of the occurrence of 66 allergenic fragrances will not be assessed.

iii: The SAMPLE is designed for children under 36 months and contains accessible/inaccessible rubber parts¹. The manufacturer have the obligation to ensure that the migration of nitrosamines and nitrosatable substances is below the limit 0.05 mg/kg and 1 mg/kg, respectively.

B. REACH (Regulation (EC) No 1907/2006)

i: The SAMPLE is likely to be defined as an **article with substances not intended to be released and substance** under normal and foreseeable conditions of use.

Remark:

¹Referring to the explanatory guidance document (**rev 1.9**) published by the European Commission of **Feb 10, 2016**, nitrosamines and nitrosatable substances are relevant in particular for rubber and finger paints.

(http://ec.europa.eu/growth/sectors/toys/safety/guidance/index_en.htm)

Chemical requirements under new Toy Safety Directive and REACH:

New Toy Safety Directive (2009/48/EC)	CMR substances :	Any substance that is classified as CMR categories 1A, 1B or 2 is prohibited to be used in the SAMPLE unless the substance is below the concentration limit set in Regulation (EC) No 1272/2008 ² . The occurrence of CMR substances in the ABC is assessed in this report.
	19 Elements ³ :	The manufacturer of the SAMPLE has to confirm that the migration levels of the restricted elements are under the defined maximum permitted levels in pliable and scraped-off toy materials. Safety assessment on the migration of the 19 elements is not suggested ⁴ .
	55 Fragrances ⁵ :	55 fragrances are banned (subject to concentration up to 100 mg/kg when their presence is technically unavoidable under good manufacturing practice). The SAMPLE is non-scented toy. The likelihood of the occurrence of the fragrances is very low. Therefore, safety assessment of 55 fragrances is not performed.
	11 Fragrances ⁵ :	11 fragrances are permitted but must be labeled if the concentration of each exceeds 100 mg/kg. Safety assessment of 11 fragrances is also not performed on the SAMPLE as they are non-scented.
	Nitrosamines and nitrosatable substances :	Nitrosamines and nitrosatable substances are banned in toys for children under 36 months or for toys that are intended to be placed in the mouth. As the SAMPLE is designed for children under 36 months and contains accessible/ inaccessible rubber parts, the manufacturer is obligated to ensure the migration of nitrosamines and nitrosatable substances is below the limit 0.05 mg/kg and 1 mg/kg, respectively.
REACH (Regulation (EC) No 1907/2006)	SVHCs :	EU importer may obtain from the manufacturer of the SAMPLE regarding SVHC information to pass along the supply chain if the SAMPLE contains over 0.1% w/w of a SVHC on Candidate List ⁶ . The likelihood on the presence of SVHCs in the ABC is assessed in this report.
	Restricted substances :	Restricted substances for which Annex XVII of REACH contains a restriction relevant to toy materials and children's products should not be used in the SAMPLE unless the restricted condition is complied. The likelihood on the presence of restricted substances in the SAMPLE is listed in this report.

Remarks:

²Maximum concentration of the substance regulated under the new Toy Safety Directive (2009/48/EC), CMR categories 1A, 1B and 2, that can be present in toys, components of toys or micro-structurally distinct parts of toys. Referring to Appendix B(2) of Directive 2009/48/EC, the relevant concentration for the classification of mixtures containing the substances should be those established in accordance with Regulation (EC) No 1272/2008 (with amendment referring to Commission Regulation (EU) No 286/2011) from Jun. 1, 2015.

In case the limit for a substance is set in EN 71-9 and this limit is lower than the specific concentration and the generic limit for a CMR substance in accordance with Regulation (EC) No 1272/2008 (with amendment referring to Commission Regulation (EU) No 286/2011), the limit in EN 71-9 will be used.

³The list of 19 elements is available in Annex II Part III (13) of Directive 2009/48/EC.

⁴According to EN 71-3, there is no relationship between the total element content of a toy material and the soluble migration of that element under standard test conditions. Therefore, measuring the total element content and converting the result to give a soluble element figure is not an answer to this problem.

As presented by Maureen Logghe from the European Commission on the topic of European Commission Toys Standards, the timeframe for the European Committee for Standardization (CEN) to revise EN 71-3 to meet the requirements of Directive 2009/48/EC is four years from his presentation, ie. before 2013.

(http://corporate.nca.ie/eng/Business_Zone/Product_Safety_and_Recalls/Toy_Safety/toy-safety-seminar/NCA-toy-seminar-Maureen-Logghe-Standards-061010.pdf)

⁵The list of fragrances is available in Annex II Part III (11) of Directive 2009/48/EC.

⁶SVHCs on Candidate List is updated by the European Chemicals Agency (ECHA) on a periodic basis.

(http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp)

Conclusion:

Although the data indicates a number of injures and a number of fatalities involving inflatable pool and toy, given the exposure of these items to the population it is thought that there may be a relatively low probability of injury resulting from their use and that injuries may be unlikely to be severe.

BOM (Bill of Materials)

Product Name: Cactus Oasis Sprinkler					
Date: 2023-2-8					
Item No: 52733					
Description or level number	Part Number	Number Used (g)	Material, Substance, Component	CAS or Einecs	MSDS Required Y/N
AIR VALVE	1	19	PVC 60.4%	9002-86-2	Y
			DOTP 36.2%	6422-86-2	Y
			ESO 1.8%	8013/7/8	Y
			Organic Tin compounds Heat Stabilizer 0.6%	13463-67-7	Y
			Barium zinc Heat Stabilizer 1.0%	/	Y
CONNECTOR	2	7	PP	/	N
TUBE		39			
SPRAY HEADER		2			
NUT		82.5			
ORANGE PVC SHEET	3	916	PVC 60.3%	9002-86-2	Y
YELLOW-GREEN PVC SHEET			DOTP 32.3%	6422-86-2	Y
			ESO 1.2%	8013/7/8	N
RED PVC SHEET			Barium zinc Heat Stabilizer 0.8%	/	Y
			CaCO3 5.4%	471-34-1	Y
COATING	4	6.3	Polymerization of the prepolymer 50%	/	N
			photosensitive monomer 30%	/	N
			photoinitiator 15%	/	N
			pigments 5%	/	N



Addresses of the places of manufacture and storage:

Bestway (Europe) s.p.a. (Via Resistenza, 5, 20098 San Giuliano Milanese (Milano), Italy) license to Bestway inflatables and material corp. (No. 208 Jin Yuan Wu Road, Shanghai, 201812, China) for production and storage of Bestway (Jiang Su) Plastics Corp. (No.8 Garden Road, Funing Economic Development Zone, Jiang Su, 224400, China)