

**RISK/SAFETY ASSESSMENT TO TOY SAFETY DIRECTIVE
2009/48/EC**

PSR Number	T31820210004SA
Version	0
Ref #	-
Date	Apr 19, 2018
Name	-

SECTION 1 – General Information		<i>To be filled out by customer</i>	
Customer Name	Safari Ltd.		
Customer Street Address	5960 Miami Lakes Drive, Miami Lakes, FL 33016, USA		
Customer City	Miami	Customer City	Miami
Customer Country	USA	Customer Country	USA
Customer Phone Number	305-621-1000	Customer Phone Number	305-621-1000
Customer Primary Contact	Ceny Kindred		
Primary Contact Email	pd@safariltd.com		
Other Information	-		

SECTION 2 – Description		<i>To be filled out by supplier or customer</i>		Name
Item/Concept Name	INCREDIBLE CREATURES - ALLIGATOR WITH BABIES, AMAZON TREE BOA, AMERICAN BULLFROG, ARMADILLO, BALD EAGLE, BEARDED DRAGON, BLUE CRAB, CLOWN ANEMONEFISH, COBRA, CORAL SNAKE, DUCKLING, EASTERN CHIPMUNK, EASTERN COTTONTAIL RABBIT BABY, EASTERN DIAMONDBACK RATTLESNAKE, EASTERN SCREECH OWL, FLYING FISH, FLYING SQUIRREL, FROGFISH, GALAPAGOS SALLY LIGHTFOOT CRAB, GOLDFISH, GROUNDHOG, HAMMERHEAD SHARK BABY, HEDGEHOG, HERMIT CRAB, HONEY BEE, HORNED LIZARD, KEMP'S RIDLEY SEA TURTLE, KEMPS RIDLEY SEA TURTLE BABY, LARGEMOUTH BASS, MORAY EEL, PANDA BABY, PIGLET, POT-BELLIED PIG, RED-EARED SLIDER TURTLE, SALTWATER CROCODILE, SEA TURTLE, SEA TURTLE BABY, TORTOISE, TORTOISE, TORTOISE BABY, VEILED CHAMELEON, VEILED CHAMELEON BABY			
Style/Item No.	259629, 257629, 268729, 262829, 251029, 263129, 269729, 261829, 260329, 257429, 265829, 263029, 262129, 269329, 263429, 263529, 250229, 100070, 261729, 263629, 100118, 267929, 261129, 267529, 268229, 156605, 262429, 267429, 265629, 261529, 263229, 265429, 266029, 269529, 262629, 260429, 268129, 258629, 260729, 260829, 267829, 261029			
Materials Used	Plastic			
Age Labelling on application form	--	Age Labelling on packaging or product	--	
Potential Quantity	-	Distribution Date	-	
Distribution Type (Premium/Retail/Other)	-			
Countries of Distribution	EU	Country of Manufacture	China	
	Yes / No	Details		
Sample supplied to SGS?	Yes	-		
Prototype or Finished Sample	-	-		
With / without packaging	With	-		
Differences in final product?	-	-		

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Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.

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SGS Hong Kong Ltd. Office: 5F & 8F, Manhattan Centre, 8 Kwai Cheong Road, Kwai Chung, H.T. t (852) 2334 4481f (852) 2764 3126 e mktg.hk@sgs.com



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Executive Summary

SECTION 3 – Age Grading

ISO / TR 8124-8 Age Determination Guidelines	< 36 months
CEN Guidance Document	-

SECTION 4 – Foreseeable Use


Intended/Foreseeable Use	Plastic figurine intended for children under 3 years old.
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SECTION 5 – Mechanical/Physical Compliance Findings

EN71-1		<p>Europe The product should comply with the requirements for children under 36 months based on the play feature, construction and design.</p> <p>The following requirements should be noted,</p> <ul style="list-style-type: none"> - Mold flash shall not be present - Materials used in the toy shall be clean <p>Note: Above compliance requirements do not include labeling review.</p>
EN62115		N/A
RED Directive		N/A

SECTION 6 – Product Design Evaluation - *Refer to Appendix A for details*

Risk Assessment Recommendations:

Critical Concerns	No critical concern was identified
Major Concerns	No major concern was identified
Minor Concerns	<p><u>Airway Obstruction</u></p> <p>Those figurines as shown below could pass through 1.5" gauge; which may pose the airway obstruction according with SGS Essential Safety Guidelines for Choking. However, the risk of this hazard is reduced since the figurines does not have critical shape and size. <i>This risk of hazard can be enlarging the figurines with sizes larger than the gauge</i></p> <div style="text-align: center; margin-top: 20px;">  </div>

Critical Manufacturing Concerns	<p>Heavy elements content and raw materials should be controlled, especially lead in paint and phthalates, which are involved large number of US CPSC and REPAX recall cases.</p> <p>Mould flash and process burrs should be well controlled throughout production in order to minimize the laceration hazard from sharp points or edges on the items.</p> <p>Moulding quality of plastics hardness and property should be well controlled to ensure strengthen of the shape and housing steady.</p>
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SECTION 7 – Flammability	
Critical Concerns	No critical concern was identified
Major Concerns	No major concern was identified
Minor Concerns	The toy can comply with the requirement according to the EN 71-2. The risk of flammability hazard is reduced.

SECTION 8 – Hygiene	
Critical Concerns	This product has no characteristic related to this hazard
Major Concerns	This product has no characteristic related to this hazard
Minor Concerns	This product has no characteristic related to this hazard

SECTION 9 – Radioactivity	
Critical Concerns	This product has no characteristic related to this hazard
Major Concerns	This product has no characteristic related to this hazard
Minor Concerns	This product has no characteristic related to this hazard

SECTION 10 – Applicable European Directives, Regulations and Harmonized Standards	
Applicable Standards	<p>EU</p> <p>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 - 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>REACH Regulation (EC) ANNEX XVII,</p> <ul style="list-style-type: none"> - Phthalates (DEHP, DINP, DIDP, DBP, BBP & DNOP) - Cadmium content - PAHs - Organotin (expressed as tin) <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 and its amendments)</p> <p><i>The requirements listed above represent our best efforts to include the applicable requirements for the countries in which these products will be distributed.</i></p>

Other Test Recommendations	<p>Germany ZEK-01.4-08 – PAHs EN 71-9 Safety of Toys - Organic Chemical Compounds</p> <p><i>The requirements listed above do not cover possible additional national Member States (EU) legislation.</i></p>
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SECTION 11 – Applicable Safety Labelling

CE Mark	<p>Yes for EU Note: For the new Toy Directive the CE mark must be visible at point of sale.</p>
Labelling	<p>All texts required shall be written in the official language of the country in which the toy is to be sold.</p> <p>EU 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>CE mark and age related warnings should be present on the toy or packaging as long as they are visible at the point of sale, along with a description of the hazard/harm either on the item/packaging or in a leaflet.</p>
Instructions	<p>All texts required shall be written in the official language of the country in which the toy is to be sold.</p> <p>EU Toys Safety Directive (2009/48/EC) The following information can be placed on the packaging/instruction if the toy is technically/economically not possible.</p> <ul style="list-style-type: none"> - Batch/Serial/Model Number - Manufacturer name and address - Importer name and address

SECTION 12 – SGS Review history

Initial reviewers:	Ken Tsai	Sample received date:	April 9, 2018
		Review completion date:	April 19, 2018
Comments:			

Appendix A – Mechanical and Physical Assessment

Hazard	Remark		Hazard Property	Typical injury scenario	
Physical / Mechanical	Asphyxiation	Airway Obstruction	Aspiration, choking, ingestion and insertion into nose	Product is or contains small part	Person (child) swallows small part, the part gets stuck in larynx and blocks airways
		Suffocation	Mechanical resistance to air flow or increase of CO ₂ , (e.g. external blocking of mouth and nose, chest compression preventing breathing, or restrained in a closed space).	Product is impermeable to air	Product covers mouth and/or nose of a person (typically a child), or covers internal airway
		Strangulation	External constriction in the neck area causing blockage of the airway or circulatory system	Gap or opening between elements	Person puts a limb or body in opening and is trapped with finger, arm, neck, head, body or clothing; injury occurs due to gravity or movement
		Submersion / Drowning	Lack of oxygen caused by submersion into liquid or other substance		
	Kinetic Energy	Impact	Struck by/against moving objects (e.g. in the face/eye or body).	Moving product	Person in the line of movement of the product is being hit by the product or run over
	Flying objects			Person is hit by the flying object and depending on the energy sustains injuries	
	Elastic element or spring			Elastic element or spring under tension is suddenly released; person in the line of movement is hit by the product	
	Falls	Falls	e.g. fall on same level from slipping/tripping/collision, fall on/from stairs/steps/elevated surface, fall from/out of building/structure, fall into hole or other opening in surface, etc.	Low mechanical stability,	Product tips; person on top of product falls from height, or person near product is hit by the product; electrical product tips, breaks and gives access to live parts, or continues to work heating nearby surfaces.
				Low mechanical strength,	Product collapses by overloading; person on top of product falls from height, or person near product is hit by the product electrical product tips, breaks and gives access to live parts, or continues to work heating nearby surfaces.
				High position of user	Person at high position on the product loses balance, has no support to hold on to and falls from height
				Product is obstacle	Person trips over product, falls and hits the floor; or person bumps into product

				Slippery surface	Person walks on surface, slips and falls hitting the floor
				Acceleration	Person on the accelerating product loses balance, has no support to hold on to and falls with some speed
		Explosion	Mechanical or pressure related explosion (i.e. non-chemical or non-electrical explosion)	Pressurised liquid or gas, or vacuum	Liquid or gas under pressure is suddenly released; person in the vicinity is hit; or implosion of the product produces flying objects
	Mechanical	Laceration	Cut/tear by sharp edges or sharp points.	Sharp edge	Person touches sharp edge; this lacerates skin or cuts through tissues
		Puncture	Puncture by sharp point(s), projection(s), or spike(s) to external or internal body parts (e.g. ear drum)	Sharp corner or point	Person hits sharp corner or is hit by moving sharp object; this causes a puncture or penetration injury
		Abrasion	Damage to skin	Rough surface	Person slides along rough surface; this causes friction and/or abrasion
		Entrapment	Entrapment of body part into object (e.g. finger, hand, head)	Gap or opening between elements	Person puts a limb or body in opening and is trapped with finger, arm, neck, head, body or clothing; injury occurs due to gravity or movement
				Rotating parts Rotating parts close to one another	A body part, hair or clothing of a person is entangled by the rotating part; this causes a pulling force A body part, hair or clothing of a person is drawn in by the rotating parts; this causes a pulling force and pressure on the body part
		Pinching/Crushing/Amputation	Pinch/crush between moving surfaces or from tourniquet action	Parts moving against one another	Person puts a body part between the moving parts while they move together; the body part gets trapped and put under pressure (crushed)
		Foreign Body	Foreign body into any non-airway body part(s) (e.g. eye, ear, skin)	Sharp corner or point	Person hits sharp corner or is hit by moving sharp object; this causes a puncture or penetration injury
		Strain	Acute overexertion of muscles.		
	Other	Vibration/Noise	Include sound-induced hearing loss (include loss of hearing sensitivity and immediate physical damage, e.g. ruptured eardrums) and the blockage of blood vessels from the use of vibrating tools.	Vibration	Person holding the product loses balance and falls; or prolonged contact with vibrating product causes neurological disorders, osteo-articular disorder, trauma of the spine, vascular disorder
				Noise	Person is exposed to noise from the product. Tinnitus and hearing loss may occur depending on sound level and distance
		Interference with Safe Activity	Include any condition that reduce normal senses/functions, such as vision, hearing, walking, etc.		

		Magnets	Intestinal perforations if swallowed		
Physical / Other	Radiation	High Intensity Visible Light	e.g. high intensity lights, lasers, LEDs		
		Ultraviolet Light	Either from the sun or man-made (e.g. UV lamps, electric arc welding, plasma torches, high-intensity lights, sources of 'black light', and certain types of lasers, etc.) Can cause thermal or photochemical injury.	Ultraviolet radiation, laser	Skin or eyes of a person are exposed to radiation emitted by the product
		Infrared Radiation			
		Microwave Radiation	Neurological (brain) damage, Leukaemia (children)	High intensity electromagnetic field (EMF) source; low frequency or high frequency (microwave)	Person is close to the electromagnetic field (EMF) source, body (central nervous system) is exposed
		Ionizing Radiation	Can be caused by x rays, gamma rays, alpha particles, beta particles, neutrons, and other nuclear particles.		
	Thermal Effect	Flammability and Fires	e.g. conflagration, ignition of clothing or other flammable material.	Open flames	A person near the flames may sustain burns, possibly after clothing catches fire
		Thermal Burn	Burn by hot object/appliance/surface, or by fire/flame.	Heat production	Product becomes hot; a person touching it may sustain burns; or the product may emit molten particles, steam etc. that hits a person
				Hot surfaces	Person does not recognise the hot surface and touches it; the person sustains burns
				Flammable substances	Person is near the flammable substance; an ignition source sets the substance to fire; this causes injuries to the person
				Explosive mixtures	Person is near the explosive mixture; an ignition source causes an explosion; the person is hit by the shock wave, burning material and/or flames
				Ignition sources	The ignition source causes a fire; a person is injured by flames, or intoxicated by gases from the house fire
				Overheating	Product overheats; fire, explosion
	Scalding Burn	Burn by hot liquid/steam/gas.	Hot liquids	Person handling a container of liquid spills some of it; the liquid falls on the skin and causes scalds	

				Hot gasses	Person breathes in the hot gasses emitted from a product; this causes lung burn; or prolonged exposure to hot air causes dehydration	
		Hypothermia / Cold Burn	Include but is not limited to frostbite or cryogenic burns.	Cold surfaces	Person does not recognise the cold surface and touches it; the person sustains frostbite	
		Electrical	Electrical Shock	The stimulation of the body's nervous system by an electric current or discharge.	High/low voltage	Person can touch part of the product that is at high voltage; the person receives an electric shock and may be electrocuted
			Electrical Fire	Include but not limited to ignition of combustibles caused by sparks and arcs or heat from electrical components.		
			Electrical Burn	Burn caused by an electric current passing through or near the body		
			Electrical Explosion	Include but is not limited to explosion from short circuiting, or from the presence of liquid or its contaminants which disassociate violently when current passes through.		
Chemical	Toxic Effect	Toxic solid or fluid	Person ingests substance from product, e.g. by mouthing; and/or substance gets onto skin Person aspirates (breathes in) solid, fluid or emetic mass (pulmonary aspiration)	Acute poisoning; irritation, dermatitis, Acute poisoning in lungs (aspiration pneumonia); infection		
		Toxic gas, vapour or dust	Person inhales substance from product; and/or substance gets onto skin	Acute poisoning in lungs; irritation, dermatitis		
		Sensitising substance	Person ingests substance from product, e.g. by mouthing; and/or substance gets onto skin; and/or person inhales gas, vapour or dust	Sensitisation; allergic reaction		
		Irritating or corrosive solid or fluid	Person ingests substance from product, e.g. by mouthing; and/or substance gets onto skin or in eyes	Irritation, dermatitis; skin burn; eye injury, foreign body in eye		
		Irritating or corrosive gas or vapour	Person inhales substance from product; and/or substance gets onto skin or in eyes	Irritation, dermatitis; skin burn; acute poisoning or corrosive effect in lungs or in eyes		
		CMR substance	Person ingests substance from product, e.g. by mouthing; and/or substance gets onto skin; and/or person inhales substance as gas, vapour or dust	Cancer, mutation, reproductive toxicity		
	Other Chemical Effects	Chemical Explosion	Reaction of energetic substances			

Chemical Safety Assessment Report

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.

Applicable European Directives, Regulations and Harmonized Standards

Applicable Standards	<p>EN 71-3 Safety of toys - Migration of certain elements 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 <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 Germany AfPS GS 2014:01 – PAHs Denmark Statutory Order No. 1082-Lead</p>

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 and ABS parts of the sample are 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	Poly(vinyl chloride) (PVC)	Yes
2	Acrylonitrile butadiene styrene (ABS)	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: Referring to the explanatory guidance document¹, nitrosamines and nitrosatable substances are relevant in particular for rubber or finger paints. Since the sample does not contain these materials, assessment for nitrosamines and nitrosatable substances in the sample will not be necessary.

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:

<p>New Toy Safety Directive (2009/48/EC)</p>	<p>CMR substances :</p>	<p>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 1272/2008². The occurrence of CMR substances in the sample is assessed in this report.</p>
	<p>19 Elements³ :</p>	<p>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 suggested⁴.</p>
	<p>55 Fragrances⁵ :</p>	<p>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.</p>
	<p>11 Fragrances⁵ :</p>	<p>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.</p>
	<p>Nitrosamines and nitrosatable substances :</p>	<p>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 does not contain rubber or finger paints, nitrosamines and nitrosatable substances are normally of real concern, thus these substances will not be assessed in this report.</p>
<p>REACH (Regulation (EC) No 1907/2006)</p>	<p>SVHCs :</p>	<p>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 List⁶. The likelihood on the presence of SVHCs in the sample is assessed in this report.</p>
	<p>Restricted substances :</p>	<p>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.</p>

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)

Scope of substances

The purpose of this report is to identify the possible occurrences of hazardous substances in the sample. This report aims to include substances regulated under the new Toy Safety Directive and REACH. Selected potential SVHCs from NGOs are also included. These include:

i: CMR categories 1A, 1B & 2

According to the new Toy Safety Directive, substances that are classified as CMR of categories 1A, 1B or 2 under Regulation (EC) No 1272/2008 should not be used in toys, in components of toys or in micro-structurally distinct parts of toys unless the substances are within the prescribed limits⁷. CMR categories 1A and 1B is one of the SVHC selection criteria under REACH.

ii: PBT and vPvB substances

Substances which are persistent, bioaccumulative and toxic (PBT), very persistent and very bioaccumulative (vPvB) in accordance with the criteria set out in Annex XIII of REACH may be included in the list of SVHCs. The substances identified as PBTs and vPvBs in the SIN List 2.1⁸ and the Trade Union Priority List (Version 2.2)⁹ are included.

iii: Substances of equivalent level of concern

Potential SVHCs regarded as of equivalent level of concern to i and ii above are on the SIN List 2.1⁸ and the Trade Union Priority List (Version 2.2)⁹;

iv: Restricted substances

Substances listed on Annex XVII of REACH with restricted conditions that are relevant to the sample.

Remarks:

⁷The chemical requirements listed in Directive 2009/48/EC.

⁸SIN List 2.1 by the International Chemical Secretariat (<http://w3.chemsec.org/>)

⁹Trade Union Priority List (Version 2.2) by the European Trade Union Confederation (<http://www.etuc.org/trade-union-priority-list>)

Table 1.1 – Possible hazardous substances in accessible parts of the sample (CMR & SVHC)

No.	Substance	Index no.	EC no./ CAS no.	Classification ¹⁰	Concentration limit under Regulation (EC) No 1272/2008 ²	2009/48/EC Directive	(EC) No 1007/2006/11	Function	Material ¹²	
									ABS	PVC
1	1,2-benzenedicarboxylic acid; di-C6-8-branched alkylesters, C7-rich*	607-483-00-2	276-158-1/71888-89-6	Repr. 1B	0.3%	v	v	ABS, PVC: Plasticizer		
2	1,2-benzenedicarboxylic acid; di-C7-11-branched and linear alkylesters*	607-480-00-6	271-084-6/68515-42-4	Repr. 1B	0.3%	v	v	ABS, PVC: Plasticizer		
3	2-ethylhexanoic acid	607-230-00-6	205-743-6/149-57-5	Repr. 2	3.0%	v		ABS, PVC: Intermediate for plasticizers		
4	4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated*	NA	NA	Ev. C	NA		v	PVC: Blowing agent		
5	4-Nonylphenol, branched and linear*	NA	NA	Ev. C	NA		v	ABS: Used in the manufacturing processes PVC: Stabilizer		
6	Alkanes, C10-13, chloro (SCCP)* [■]	602-080-00-8	287-476-5/85535-84-8	Carc. 2; PBT; vPvB	1.0%	v	v	ABS, PVC: Plasticizer		
7	Benzyl butyl phthalate (BBP)* [▼]	607-430-00-3	201-622-7/85-68-7	Repr. 1B	0.3%	v	v	ABS, PVC: Plasticizer		
8	Bis(2-ethylhexyl) phthalate (DEHP)* [▼]	607-317-00-9	204-211-0/117-81-7	Repr. 1B	0.3%	v	v	ABS, PVC: Plasticizer		
9	Bisphenol A	604-030-00-0	201-245-8/80-05-7	Repr. 2; Ev. C	3.0%	v	v	PVC: Chain terminator; antioxidant		
10	C,C'-azodi(formamide)*	611-028-00-3	204-650-8/123-77-3	Ev. C	NA		v	PVC: Blowing agent		
11	C.I. Solvent Yellow 14	611-056-00-6	212-668-2/842-07-9	Carc. 2; Muta. 2	1.0%	v		ABS: Colorant		
12	Cadmium and its compounds [▼]	NA	NA	Ev. C	NA	v	v	ABS, PVC: Stabilizer		
13	Dibutyl phthalate (DBP)* [▼]	607-318-00-4	201-557-4/84-74-2	Repr. 1B	0.3%	v	v	ABS, PVC: Plasticizer		
14	Dibutyltin dichloride (DBTC)* [▼]	050-022-00-X	211-670-0/683-18-	Muta. 2; Repr. 1B	0.3%	v	v	PVC: Stabilizer		

			1							
15	Diethyl phthalate (DEP)	NA	201-550-6/ 84-66-2	Ev. C	NA	v		PVC: Plasticizer		
16	Diisobutyl phthalate (DIBP) *	607-623-00-2	201-553-2/ 84-69-5	Repr. 1B	0.3%	v	v	ABS, PVC: Plasticizer		
17	Isophorone	606-012-00-8	201-126-0/ 78-59-1	Carc. 2	1.0%	v		PVC: Solvent in printing ink		
18	Lead and its compounds ▼	NA	NA	Ev. C	NA	v	v	ABS, PVC: Stabilizer		
19	Naphthalene	601-052-00-2	202-049-5/ 91-20-3	Carc. 2; Ev. C	1.0%	v	v	PVC: Used in printing ink		
20	Nonylphenol ▼	601-053-00-8	246-672-0/ 25154-52-3	Repr. 2; Ev. C	3.0%	v	v	PVC: Stabilizer		
21	Organotin compounds ▼	NA	NA	PBT	NA	v	v	ABS, PVC: Stabilizer		
22	Phenol	604-001-00-2	203-632-7/ 108-95-2	Muta. 2	0.001%	v		ABS, PVC: Used in the manufacturing processes		
23	Styrene	601-026-00-0	202-851-5/ 100-42-5	Ev. C	NA		v	ABS: Raw material		
24	Toluene ▼	601-021-00-3	203-625-9/ 108-88-3	Repr. 2; Ev. C	3.0%	v	v	PVC: Used in printing ink		
25	Tributyl phosphate	015-014-00-2	204-800-2/ 126-73-8	Carc. 2	1.0%	v		PVC: Plasticizer		

Remarks:

¹⁰The classification of CMR substances is according to the Regulation (EC) No 1272/2008.

Carc. 1A : Carcinogenic category 1A

Carc. 1B : Carcinogenic category 1B

Carc. 2 : Carcinogenic category 2

Muta. 1A : Mutagenic category 1A

Muta. 1B : Mutagenic category 1B

Muta. 2 : Mutagenic category 2

Repr. 1A : Toxic for reproduction category 1A

Repr. 1B : Toxic for reproduction category 1B

Repr. 2 : Toxic for reproduction category 2

PBT : Substances which are persistent, bioaccumulative and toxic in accordance with the criteria set in Annex XIII of REACH

vPvB : Substances which are very persistent and very bioaccumulative in accordance with the criteria set in Annex XIII of REACH

Ev. C : Equivalent level of concern. Substances which fulfill the criteria set in Article 57(f) of REACH

NA : Not applicable

¹¹For substances regulated by both the new Toy Safety Directive (2009/48/EC) and REACH (Regulation (EC) No 1907/2006), apart from the maximum concentration of the substances that can be present in toys, components of toys or micro-structurally

distinct parts of toys, the manufacturer also has the obligation to pass SVHC information along the supply chain if the whole toy contains over 0.1% w/w of a SVHC on the Candidate List (Article 33 of REACH).

¹²Shaded box represents the possible occurrence of the substance in the corresponding material/ component.

* Refers to list of SVHCs on the Candidate List that are of particular importance at the time this report is prepared. (http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp)

▼ Refers to list of restricted substances on the Annex XVII of REACH (Commission Regulation (EC) No 552/2009, Commission Regulation (EU) No 276/2010, Commission Regulation (EU) No 207/2011, Commission Regulation (EU) No 336/2011, Commission Regulation (EU) No 494/2011, Commission Regulation (EU) No 109/2012, Commission Regulation (EU) No 412/2012, Commission Regulation (EU) No 835/2012, Commission Regulation (EU) No 836/2012, Commission Regulation (EU) No 847/2012, Commission Regulation (EU) No 848/2012, Commission Regulation (EU) No 126/2013 and Commission Regulation (EU) No 1272/2013) that are of particular importance at the time this report is prepared. Manufacturer has the obligation to make sure that the restricted substance should not be used in the SAMPLE unless it complies with the conditions of that restriction.

▼ Refers to list of restricted substances on the Annex I of POPs (Regulation (EC) No 850/2004) as of Jun 19, 2012 (Commission Regulation (EU) No 757/2010, Commission Regulation (EU) No 519/2012 and Commission Regulation (EU) No 2015/2030) that are of particular importance at the time this report is prepared. Manufacturer has the obligation to make sure that the restricted substance should not be used in the toy unless it complies with the conditions of that restriction.

Table 1.2 – Possible routes of exposure to hazardous substances in accessible parts of the sample (CMR & SVHC)

No.	Substance	Routes of exposure ¹³		
		Dermal	Oral§	Inhalation
1	1,2-benzenedicarboxylic acid; di-C6-8-branched alkylesters, C7-rich*			
2	1,2-benzenedicarboxylic acid; di-C7-11-branched and linear alkylesters*			
3	2-ethylhexanoic acid			
4	4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated*			
5	4-Nonylphenol, branched and linear*			
6	Alkanes, C10-13, chloro (SCCP)*■			
7	Benzyl butyl phthalate (BBP) *▼			
8	Bis(2-ethylhexyl) phthalate (DEHP)*▼			
9	Bisphenol A			
10	C,C'-azodi(formamide)*			
11	C.I. Solvent Yellow 14			
12	Cadmium and its compounds▼			
13	Dibutyl phthalate (DBP)*▼			
14	Dibutyltin dichloride (DBTC)*▼			
15	Diethyl phthalate (DEP)			
16	Diisobutyl phthalate (DIBP) *			
17	Isophorone			
18	Lead and its compounds▼			
19	Naphthalene			
20	Nonylphenol▼			
21	Organotin compounds▼			
22	Phenol			
23	Styrene			
24	Toluene▼			
25	Tributyl phosphate			

Remark:

¹³Shaded box represents the possible routes of exposure of the hazardous substance in accessible parts of sample.

§ Referring to the EN71-3, all the accessible parts and components of toys intended for children up to 6 years of age may come into contact with the mouth. The likelihood of mouth contact with parts of toys intended for older children is not considered significant in most cases.

Data Analysis:

Table 1.1 shows the possible hazardous substances¹⁴ that may be found in the accessible parts of sample. Substances are ranked according to their occurrence from the references and experts' comments. The possible routes of exposure to these hazardous substances are shown in **Table 1.2**.

Materials in the toy may have the possibility to contain certain substances regulated under Directive 2009/48/EC and Regulation (EC) No 1907/2006. Most of the possible hazardous substances in plastic parts of the sample are used as plasticizers.

The report only identifies the possible CMRs & SVHCs that may be used in the manufacturing processes and any treatments. It does not take the amount or the concentration into consideration. According to Tables 3.5.2, 3.6.2 and 3.7.2 in Regulation (EC) No 1272/2008, CMR substances have different concentration limits according to their classifications. Thus, even in case any CMR or SVHC is found in sample, the placing of the toy on the market may not be affected unless the concentration of that substance exceeds the corresponding limit.

Remark:

¹⁴Refer to the high risk substances which are likely to be found in the toy material.

The possible hazardous substances (CMRs and SVHCs) in each toy material of the sample are listed in **Table 1.1** of this report. These possible hazardous substances refer to the high risk substances which are likely to be found in toy. Medium and low risk substances of accessible material are affixed in the following tables. The likelihood on the presence of the medium/ low risk substances in each material of the sample is for reference only. User can decide whether the medium and low risk substances should be included in the scope of testing.

Table 1.3 – Possible medium/ low risk substances in accessible parts of the sample (CMR & SVHC) – No further action is necessary. The list is provided for reference during manufacture process control.

No.	Substance	Index no.	EC no./ CAS no.	Classification ¹⁰	Concentration limit under Regulation (EC) No 1272/2008 ²	2009/48/EC Directive	(EC) No 1907/2006	Function	Material ¹⁵	
									ABS	PVC
1	1,2-dichloroethane	602-012-00-7	203-458-1/107-06-2	Carc. 1B	0.1%	v	v	ABS: Solvent PVC: Used in printing ink	L	L
2	2,3-epoxypropan-1-ol	603-063-00-8	209-128-3/556-52-5	Carc. 1B;Muta. 2;Repr. 1B	0.1%	v	v	ABS, PVC: Stabilizer	L	L
3	3,3'-dichlorobenzidine [▼]	612-068-00-4	202-109-0/91-94-1	Carc. 1B	0.0005%	v	v	ABS, PVC: Intermediate of dyes	M	M
4	3,4-dinitrotoluene	609-051-00-9	210-222-1/610-39-9	Carc. 1B;Muta. 2;Repr. 2	0.1%	v	v	ABS: Precursor	L	
5	3-amino-9-ethyl carbazole	612-280-00-7	205-057-7/132-32-1	Carc. 1B	0.1%	v	v	PVC: Intermediate of dyes		L
6	3-propanolide	606-031-00-1	200-340-1/57-57-8	Carc. 1B	0.1%	v	v	PVC: Stabilizer		L
7	4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol*	NA	209-218-2/561-41-1	Carc. 1B; Muta. 2	0.1%	v	v	PVC: Colorant		L

8	4-aminoazobenzene*▼	611-008-00-4	200-453-6/60-09-3	Carc. 1B	0.001%	v	v	ABS: Colorant	M	
9	6-Methoxy-m-toluidine*▼	612-209-00-X	204-419-1/120-71-8	Carc. 1B	0.1%	v	v	PVC: Intermediate of dyes		L
10	Acrylamide*▼	616-003-00-0	201-173-7/79-06-1	Carc. 1B;Muta. 1B;Repr. 2	0.1%	v	v	ABS, PVC: Cross-linking agents	M	M
11	Acrylonitrile	608-003-00-4	203-466-5/107-13-1	Carc. 1B	0.1%	v	v	ABS: Used in the manufacturing processes	M	
12	Benzene▼	601-020-00-8	200-753-7/71-43-2	Carc. 1A; Muta. 1B	0.1%	v	v	ABS: Used in the manufacturing processes	L	
13	Benzophenone-1	NA	205-029-4/131-56-6	Ev. C	NA		v	PVC: Photostabilizer		M
14	Benzophenone-3	NA	205-031-5/131-57-7	Ev. C	NA		v	PVC: Photostabilizer		M
15	Bis(2-methoxyethyl) phthalate*	607-228-00-5	204-212-6/117-82-8	Repr. 1B	0.3%	v	v	PVC: Plasticiser		L
16	Bis(chloromethyl) ether	603-046-00-5	208-832-8/542-88-1	Carc. 1A	0.001%	v	v	ABS: Used in the manufacturing processes	L	
17	Butyl glycidyl ether	603-039-00-7	219-376-4/2426-08-6	Carc. 2; Muta. 2	1.0%	v		PVC: Stabilizer and plasticizer		L
18	C.I. Direct Black 38*	611-025-00-7	217-710-3/1937-37-7	Carc. 1B;Repr. 2	0.1%	v	v	PVC: Colorant		L
19	C.I. Pigment Red 104*	082-010-00-5	235-759-9/12656-85-8	Carc. 1B; Repr. 1A	0.1%	v	v	PVC: Colorant		M
20	C.I. Pigment Yellow 34*	082-009-00-X	215-693-7/1344-37-2	Carc. 1B; Repr. 1A	0.1%	v	v	ABS, PVC: Colorant	L	M
21	C.I. Solvent Blue 4*	NA	229-851-8/6786-83-0	Carc. 1B; Muta. 2	0.1%	v	v	PVC: Colorant		L
22	C.I. Solvent Yellow 14	611-056-00-6	212-668-2/842-07-9	Carc. 2; Muta. 2	1.0%	v		PVC: Colorant		M
23	Cadmium (pyrophoric)*▼	048-	231-	Carc. 1B; Muta.	0.1%	v	v	PVC: Stabilizer		L

		011-00-X	152-8/ 7440-43-9	2; Repr. 2						
24	Cadmium oxide (non-pyrophoric)* [▼] [1]; cadmium (non-pyrophoric)* [▼] ; [2]	048-002-00-0	NA/ 1306-19-0 [1] 7440-43-9 [2]	Carc. 1B; Muta. 2; Repr. 2	0.1%	v	v	PVC: Stabilizer		L
25	Diarsenic pentaoxide* [▼]	033-004-00-6	215-116-9/ 1303-28-2	Carc. 1A	0.1%	v	v	ABS, PVC: Polymerization inhibitor	L	L
26	Dibutyl phthalate (DBP)* [▼]	607-318-00-4	201-557-4/ 84-74-2	Repr. 1B	0.3%	v	v	ABS, PVC: Used in printing ink	L	L
27	Dicyclohexyl phthalate (DCHP)	NA	201-545-9/ 84-61-7	Ev. C	NA		v	ABS, PVC: Plasticizer	L	L
28	Diethyl phthalate (DEP)	NA	201-550-6/ 84-66-2	Ev. C	NA		v	ABS: Plasticizer	M	
29	Dihexyl phthalate (DHP)*	607-702-00-1	201-559-5/ 84-75-3	Repr. 1B	0.3%	v	v	ABS, PVC: Plasticizer	M	M
30	Dimethylnitrosoamine	612-077-00-3	200-549-8/ 62-75-9	Carc. 1B	0.001%	v	v	ABS: Plasticizer	M	
31	Fentin acetate (ISO)	050-003-00-6	212-984-0/ 900-95-8	Carc. 2; Repr. 2	1.0%	v		PVC: Stabilizer		L
32	Formamide*	616-052-00-8	200-842-0/ 75-12-7	Repr. 1B	0.3%	v	v	ABS: Spinning agent	L	
33	Hexamethylphosphoramide	015-106-00-2	211-653-8/ 680-31-9	Carc. 1B; Muta. 1B	0.01%	v	v	PVC: Stabilizer		L
34	Hydroxylamine sulfate (2:1)	612-123-00-2	233-118-8/ 10039-54-0	Carc. 2	1.0%	v		ABS: Polymerization inhibitor	L	
35	Isophorone	606-012-00-8	201-126-0/ 78-59-1	Carc. 2	1%	v		ABS: Solvent in printing ink	M	
36	Malachite green hydrochloride	602-096-00-5	209-322-8/ 569-64-2	Repr. 2	3.0%	v		PVC: Colorant		L
37	Molybdenum trioxide	042-001-00-9	215-204-7/ 1313-27-5	Carc. 2	1.0%			ABS: Catalyst PVC: Catalyst; flame retardant	L	M
38	N-methyl-2-pyrrolidone*	606-021-00-7	212-828-1/ 872-50-4	Repr. 1B	5.0%	v	v	PVC: Spinning agent		M
39	Nitrobenzene	609-003-	202-716-0/	Carc. 2; Repr. 2	1.0%	v		PVC: Intermediate of		M

		00-7	98-95-3					dyes		
40	o-anisidine* [▼]	612-035-00-4	201-963-1/90-04-0	Carc. 1B; Muta. 2	0.0005%	v	v	ABS, PVC: Intermediate of dyes	M	M
41	o-dianisidine [▼]	612-036-00-X	204-355-4/119-90-4	Carc. 1B	0.0005%	v	v	PVC: Intermediate of dyes		M
42	o-phenylenediamine	612-145-00-2	202-430-6/95-54-5	Carc. 2; Muta. 2	1.0%	v		PVC: Intermediate of dyes		L
43	Solvent naphtha (petroleum), light arom.	649-356-00-4	265-199-0/64742-95-6	Carc. 1B; Muta. 1B	0.1%	v	v	ABS, PVC: Solvent in printing ink	M	M
44	Strontium chromate* [▼]	024-009-00-4	232-142-6/7789-06-2	Carc. 1B	0.1%	v	v	PVC: Colorant		L
45	TGIC (1,3,5-tris(oxiranylmethyl)-1,3,5-triazine-2,4,6-(1H,3H,5H)-trione)*	615-021-00-6	219-514-3/2451-62-9	Muta. 1B	0.1%	v	v	ABS, PVC: Stabilizer	L	L
46	Toluene [▼]	601-021-00-3	203-625-9/108-88-3	Repr. 2; Ev. C	3.0%	v	v	ABS: Used in printing ink	M	
47	Trichloroethylene*	602-027-00-9	201-167-4/79-01-6	Carc. 1B; Muta. 2	0.1%	v	v	PVC: Used to control relative molecular mass		M
48	Trilead bis(orthophosphate)	082-006-00-3	231-205-5/7446-27-7	Repr. 1A	0.3%	v	v	ABS: Stabilizer	L	
49	Xylenol	604-006-00-X [1] 604-037-00-9 [2]	215-089-3 [1] 203-606-5 [2]/ 1300-71-6 [1] 108-68-9 [2]	Ev. C	NA		v	ABS, PVC: Plasticizer	L	L
50	α-chlorotoluene	602-037-00-3	202-853-6/100-44-7	Carc. 1B	0.1%	v	v	ABS, PVC: Used to synthetic BBP, which is a plasticizer	L	L
51	β-TGIC (1,3,5-tris[(2S and 2R)-2,3-epoxypropyl]-1,3,5-triazine-2,4,6-(1H,3H,5H)-trione)*	616-091-00-0	423-400-0/59653-74-6	Muta. 1B	0.1%	v	v	ABS, PVC: Stabilizer	L	L

Remark:

¹⁵Shaded box represents the possible occurrence of the substance in the corresponding material.

M Medium Risk

L Low Risk

Appendix - Bill of Material (BOM)

Component No.	Material	Color
1	Poly(vinyl chloride) (PVC)	Multicolor
2	Acrylonitrile butadiene styrene (ABS)	Brown and yellow

*** End of Report ***

The purpose of this assessment report is to assist clients to manage hazardous substances in toy materials by evaluating their possible occurrence under the scope of the new Toy Safety Directive (2009/48/EC) and REACH (Regulation (EC) No 1907/2006). The hazardous substances in the new Toy Safety Directive include Carcinogenic, Mutagenic and Toxic for reproduction (CMR) substances Categories 1A, 1B and 2, migration of 19 elements, 66 allergenic fragrances, nitrosamines and nitrosatable substances with different requirements¹⁶. Substances regulated under REACH include restricted substances and Substances of Very High Concern (SVHC) which is a collective term for CMR substances Categories 1A and 1B, Persistent, Bioaccumulative and Toxic (PBT), very Persistent and very Bioaccumulative (vPvB) and Substances of Equivalent level of Concern. Clients should also note that the toy should comply with applicable Community requirements.

This report includes analysis of potential occurrence and uses of substances and comparison of risks in different materials. Information in this report comprises of currently available literature data plus experts' comments on consumer products. Literature data include non-governmental organizations (NGOs) priority list - SIN List 2.1¹⁷(2013), European Trade Union Priority List (Version 2.2)¹⁷ (2011), Danish EPA Surveys on chemicals in consumer products (2001-2012), US Hazardous Substances Data Bank, RAPEX recall cases (2005 to 2013), survey reports performed by different countries and manufacturing guide books.

Remarks:
¹⁶The chemical safety assessment of these substances is intended to prepare for the chemical requirements of Directive 2009/48/EC.

¹⁷The substances listed in the NGO priority lists that meet the criteria of Article 57 of REACH are considered as potential SVHCs.

Disclaimer

This chemical safety assessment report is intended for guidance only. While the information contained in this report is provided in good faith and has been based on reliable sources available at the time this report is prepared, it is to be relied upon at Applicant's own discretion. No representation or warranty is made with regards to the completeness of the findings in this report and no liability will be accepted for damages or consequential loss whatsoever resulting from the use of this report directly or indirectly, or reliance on the information provided. This report shows only the results of document review and no actual testing on product(s) has been conducted.