

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

PSR Number	SZTY1204007005TS
Version	1
Ref #	-
Date	12 April, 2012
Name	

SECTION 1 – General Information		<i>To be filled out by customer</i>	
Customer Name		Customer City	
Customer Street Address		Customer Country	
Customer City		Customer Phone Number	
Customer Country		Customer Primary Contact	
Customer Phone Number		Primary Contact Email	
Customer Primary Contact		Other Information	/
Primary Contact Email			
Other Information	/		

SECTION 2 – Description		<i>To be filled out by supplier or customer</i>		Name
Item/Concept Name	848			
Detailed Description	12 pcs in PVC blister bag , 30 pcs in bulk			
Materials Used	PE, PP, PVC			
Age Labelling on application form	-	Age Labelling on packaging or product	-	
Potential Quantity	-	Distribution Date	-	
Distribution Type (Premium/Retail/Other)	-			
Countries of Distribution	EUROPE	Country of Manufacture	China	
	Yes / No	Details		
Sample supplied to SGS?	Yes	-		
Prototype or Finished Sample	Finished	-		
With / without packaging	without	Blister and polybag		
Differences in final product?	No	-		



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Executive Summary

SECTION 3 – Age Grading

CR 14379 Classification of toys Guidelines	According to the table 4 Art and craft materials and related articles (Category C), this toy should be for the children over 3 years of old.
CEN Guidance Document	NA

SECTION 4 – Foreseeable Use

Intended/Foreseeable Use	They are water colour pencil for children over 3 yrs of age. Children could draw pictures or paint pictures by the pencil. Young children may drop it, throw it or mouth it.
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SECTION 5 – Mechanical/Physical Compliance Findings

EN71-1	<p>Europe</p> <p>The product should comply with the requirements for children over 36 months based on the play feature, construction and design.</p> <p>Non-conformity was not identified during this review, but the following requirements should be noted for the compliance</p> <ul style="list-style-type: none"> - No splinters can be found - Materials used in the toy shall be cleaned <p>Note: Above compliance requirements do not include labeling review.</p>
BS 7272	<p>This item shall comply with the voluntary BS standard-BS7272:2008.</p> <p>BS7272-1:2008-Specification for caps to reduce the risk of asphyxiation</p> <ul style="list-style-type: none"> - Pen caps shall permit a minimum air flow of 8 l/min, measured at room temperature, with a maximum pressure drop of 1.33 kPa. <p>BS7272-2:2008-Specification for end closures to reduce the risk of asphyxiation</p> <p>The end closure of pen shall withstand 10N tensile test.</p>

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>Airway obstruction</p> <p>The caps could pass through 1.5 in gauge and bear a critical length(less than 3 in) according to SGS Essential Safety Guidelines for Choking. Rigid objects bearing the size mentioned above could present airway obstruction hazard to children. The risk of the hazard could be increased as it's intended for young children to play. <i>The risk of the hazard could be reduced by increasing the length of the caps to more than 3in.</i></p> <p>Airway obstruction</p> <p>There could be an airway obstruction hazard if the pen caps cannot meet the requirement of BS7272-1:2008. The severity of this hazard is reduced as there are ventilation holes designed on the caps. Ensuring Pen caps shall permit a minimum air flow of 8 l/min, measured at room temperature, with a maximum pressure drop of 1.33 kPa could reduce the severity of hazard.</p> <p>The end closure is with a size which could cause airway obstruction hazard if it can be pulled out. Enhancing the security strength of end closure to withstand 10N tensile force test specified in BS7272-2:2008 could reduce the risk of this hazard.</p>

	<p>Chemical hazard The pen ink could present a chemical hazard as children may draw on their skin or lick the pen nib. Actions: Using only non-toxic and approved ingredients for the pen ink could reduce the chemical hazard from the ink.</p>
Critical Manufacturing Concerns	<p>Using only non-toxic and approved ingredients for the ink formulation throughout production may reduce the chemical hazard from the ink.</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>

SECTION 7 – Flammability

EN71-2 The item shall comply with the requirements of EN71 Part 2.

SECTION 8 – Hygiene

General According to New Toy Directive, 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.

SECTION 9 – Radioactivity

Toy shall comply with all relevant measures adopted under chapter III of the treaty establishing the European Atomic Community. Toys should be free from radioactive materials.

SECTION 10 – Chemical Assessment –

See Appendix B for details

Applicable Standards	<p>EU</p> <p>Toy Safety Directive (88/378/EEC & 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 <p>Regulation (EC) 552/2009 ANNEX XVII, REACH</p> <ul style="list-style-type: none"> - Phthalates (DEHP, DINP, DIDP, DBP, BBP & DNOP) - Cadmium content - Benzene <p>Regulation (EU) 276/2010 Annex XVII, REACH</p> <ul style="list-style-type: none"> - 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>Packaging Waste Directive (Pb + Cd + Hg + Cr VI) (94/62/EC)</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>Toxicological Risk Assessment</p> <p>BS7272-1:2008-Specification for caps to reduce the risk of asphyxiation</p> <p>BS7272-2:2008-Specification for end closures to reduce the risk of asphyxiation</p> <p>EN 71-9 Safety of toys – Organic chemical compounds The item will need to comply with EN71 Parts 9, 10 and 11 (Organic Chemical Compounds) when they are published in the Official Journal of the EU</p> <p>US California Proposition 65 Phthalates (DEHP, BBP, DBP, DIDP & DnHP)</p> <p>US Total lead content on substrate material</p>

	<p>Danish Statutory Order no. 858 of 5 September 2009, Cadmium content (Denmark)</p> <p><i>The requirements listed above do not cover possible additional national Member States (EU) legislation and Individual States (US & Canada) Regulation.</i></p>
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SECTION 11 – Labelling Assessment

CE Mark	<p>The height of the CE mark should be at least 5mm in height. No CE mark on the plastic bag packaging and the CE mark height on the blister card packaging is less than 5mm.</p> <p>Note: For the new Toy Directive the CE mark must be visible at point of sale.</p>
Labelling on Item	<p>All texts required shall be written in the official language of the country in which the toy is to be sold.</p> <p>Conclusion & Findings: The labelling on item can't comply with the requirement regulated in New Toys Directive-2009/48/EC and detailed in EN71-1. Following information was not found on toy it-self at time of assessment:</p> <p>EU New Toys Safety Directive (2009/48/EC) The following information shall be also placed on the packaging/instruction in final production if the toy is technically/economically not possible.</p> <ul style="list-style-type: none"> - Manufacturer name and address - Importer name and address - Product identification No.(such as item No., Batch No.etc)
Labelling on the packaging	<p>All texts required shall be written in the official language of the country in which the toy is to be sold.</p> <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> <p>EU New Toys Safety Directive (2009/48/EC) The following information shall be also placed on the packaging/instruction in final production if the toy is technically/economically not possible.</p> <ul style="list-style-type: none"> - Manufacturer name and address - Importer name and address - Product identification No.(such as item No., Batch No.etc)

SECTION 12 – SGS Review history

Initial reviewers:	Kelly Peng	Sample received date:	2 Apr, 2012
Comments:	kelly.peng@sgs.com	Review completion date:	19 Apr, 2012
Follow Up Review:		Sample received date:	
Comments:		Review completion date:	

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	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				
	Mechanical			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		
				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
				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			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	<i>Neurological (brain) damage, Leukaemia (children)</i>	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 gases 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 mouth; 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 mouth; 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 mouth; 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 mouth; 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		
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Appendix B

Chemical Risk Assessment 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 nitrosable substances with different requirements¹. 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 2.0² (2011), European Trade Union Priority List (Version 2.1)² (2010), Danish EPA Surveys on chemicals in consumer products (2003-2012), US Hazardous Substances Data Bank, RAPEX recall cases (2005 to 2012), survey reports performed by different countries and manufacturing guide books.

Remarks:

¹The chemical risk assessment of these substances is intended to prepare for the chemical requirements of Directive 2009/48/EC which will apply from Jul. 21, 2013. Until Jul. 20, 2013 assessments under the requirements of Directive 88/378/EEC are acceptable.

²The substances listed in the NGO priority lists that meet the criteria of Article 57 of REACH are considered as potential SVHCs.

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Company Address

Wenzho Kaiwen Stationery & Sports Manufacturing Co., Ltd.
135, Simingshan Road, Economy & Development Zone, Wenzhou
China



Product Photo

I. Product information:

Product Name	:	12pcs in PVC blister bag, 30pcs in bulk			
Product Style No.	:	848			
Product Composition	:	1-2, 4	<u>Component No.³</u>	<u>Product Composition</u>	<u>Color</u>
			Polypropylene (PP)	Multicolor	Pigment

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Polyethylene (PE) White NA
 Cotton White NA
 Ink Multicolor NA

Applicable Age	:	3+
Country of Origin	:	CHINA
Country of Destination	:	EUROPE

Remarks:

³Component No. is referred to the BOM in Appendix 1.

II. Product classification:

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

i: The PP and PE parts of the 12pcs in PVC blister bag, 30pcs in bulk are likely to be defined as **scraped-off toy materials**. These materials are **accessible** to children when the 12pcs in PVC blister bag, 30pcs in bulk is used as intended or in a foreseeable way, when taking into account the behavior of children

The Cotton parts of the 12pcs in PVC blister bag, 30pcs in bulk are **inaccessible** to children in any form, including inhalation, when the 12pcs in PVC blister bag, 30pcs in bulk is used as intended or in a foreseeable way, when taking into account the behavior of children.

The ink is likely to be defined as **liquid and sticky toy materials**.

Component No.	Material	Accessible as defined by EN 71-1?
1-2, 4	Polypropylene (PP)	Yes

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3	Polyethylene (PE)	Yes
5	Cotton	No
6	Ink	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 12pcs in PVC blister bag, 30pcs in bulk 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 12pcs in PVC blister bag, 30pcs in bulk will not be assessed for nitrosamines and nitrosable substances due to the following reasons:
 - (1) the 12pcs in PVC blister bag, 30pcs in bulk is **not designed for children under 36 months**;
 - (2) the 12pcs in PVC blister bag, 30pcs in bulk is **not intended to be placed in the mouth**⁴;
 - (3) the 12pcs in PVC blister bag, 30pcs in bulk **does not contain rubber or finger paints**⁴.

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

The 12pcs in PVC blister bag, 30pcs in bulk is likely to be defined as an **article with substances not intended to be released** under normal and foreseeable conditions of use.

Remark:

⁴Referring to the explanatory guidance document (rev 1.3) published by the European Commission of Apr. 05, 2011, "intended to be placed in the mouth" limits the application to such toys as balloons. For other materials, nitrosamines and nitrosable substances are relevant in particular for rubber and finger paints. (http://ec.europa.eu/enterprise/sectors/toys/documents/guidance/index_en.htm)

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III. Chemical requirements under new Toy Safety Directive and REACH:

<p>New Toy Safety Directive (2009/48/EC)⁵</p>	<p>CMR substances : Any substance that is classified as CMR categories 1A, 1B or 2 is prohibited to be used in the 12pcs in PVC blister bag, 30pcs in bulk unless the substance is below the concentration limit set in Regulation (EC) No 1272/2008⁶. The occurrence of CMR substances in the 12pcs in PVC blister bag, 30pcs in bulk is assessed in this report.</p> <p>19 Elements⁷ : The manufacturer of the 12pcs in PVC blister bag, 30pcs in bulk 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.</p> <p>55 Fragrances⁹ : Risk assessment on the migration of the 19 elements is not suggested⁸. 55 fragrances are banned (subject to concentration up to 100 mg/kg when their presence is technically unavoidable under good manufacturing practice). The 12pcs in PVC blister bag, 30pcs in bulk is non-scented toy. The likelihood of the occurrence of the fragrances is very low. Therefore, risk assessment of 55 fragrances is not performed.</p> <p>11 Fragrances⁹ : 11 fragrances are permitted but must be labeled if the concentration of each exceeds 100 mg/kg. Risk assessment of 11 fragrances is also not performed on the 12pcs in PVC blister bag, 30pcs in bulk as they are non-scented.</p> <p>Nitrosamines and nitrosable substances : Nitrosamines and nitrosable substances are banned in toys for children under 36 months or for toys that are intended to be placed in the mouth. As the 12pcs in PVC blister bag, 30pcs in bulk is not designed for children under 36 months nor intended to be placed in the mouth, the nitrosamines and nitrosable substances will not be assessed in this report.</p> <p>SVHCs : EU importer may obtain from the manufacturer of the 12pcs in PVC blister bag, 30pcs in bulk regarding SVHC information to pass along the supply chain if the 12pcs in PVC blister bag, 30pcs in bulk contains over 0.1% w/w of a SVHC on Candidate List¹⁰. The likelihood on the presence of SVHCs in the 12pcs in PVC blister bag, 30pcs in bulk is assessed in this report.</p> <p>Registration : EU importer may have to register the substance in the ink if the substance is equal or over 1 tonne per year.</p>
<p>REACH (Regulation (EC) No 1907/2006)</p>	

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Safety Data Sheet (SDS)

Since the ink is classified as mixture under REACH, EU importer or manufacturer may have to prepare a Safety Data Sheet (SDS) for supply chain communication according to Article 31 of REACH.

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 12pcs in PVC blister bag, 30pcs in bulk unless the restricted condition is complied.
The likelihood on the presence of restricted substances in the 12pcs in PVC blister bag, 30pcs in bulk is listed in this report.

Remarks:

- ⁵The chemical requirements of Directive 2009/48/EC will apply from Jul. 21, 2013. Until Jul. 20, 2013, the placing of the toy on the market will not be impeded if the toy complies with the chemical requirement of Directive 88/378/EEC.
- ⁶Maximum 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.
- ⁷The list of 19 elements is available in Part III (13) of Directive 2009/48/EC.
- ⁸According 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, i.e. before 2013. (www.nca.ie/eng/Business_Zone/Product_Safety_and_Recalls/Toy_Safety/toy-safety-seminar/NCA-toy-seminar-Maureen-Logghe-Standards-061010.pdf)
- ⁹The list of fragrances is available in Part III (11) of Directive 2009/48/EC.

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Table A. Classification of the substances as listed in the ink (Component No. 6)

Component No. 6	Name	CAS No.	Classification ¹¹
	Glycerin	56-81-5	NA
	Glycol	107-21-1	NA
	Formaldehyde	50-00-0	NA
	Nigagin (Methylparaben)	99-76-3	NA
	TX 10	9002-93-1	NA
	Water	7732-18-5	NA
	Colourants		
	1. Cation Bright Red	12217-48-0	NA
	2. Cation Orange	54060-92-3	NA
	3. Cation Yellow	4208-80-4	NA
	4. Cation Jade Green	55840-82-9	NA
	5. Acid Ink Blue	28983-56-4	NA
	6. Acetic Acid Glacial	64-19-7	NA
	7. Weak Acid Red A	17372-87-1	NA
	8. Rose	81-88-9	NA
	9. Acid Red	3734-67-6	NA
	10. Acid Black	1064-48-8	NA

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11.	Orange 7 (ATT)	633-96-5	NA
12.	Acid Light Yellow	6359-98-4	NA
13.	K-2 b p	70210-20-7	NA
14.	Alkaline Purple	548-62-9	Carc. 2 Acute Tox. 4 * Eye Dam. 1 Aquatic Acute 1 Aquatic Chronic 1
15.	Acid Black 2	3-6-8005	NA
16.	Alkaline Green	569-64-2	Repr. 2 Acute Tox. 4 * Eye Dam. 1 Aquatic Acute 1 Aquatic Chronic 1

Analysis:

Table A lists the classification of the substance in the ink.

Some of the substances are classified according to the Regulation (EC) No 1272/2008:

1. The substance, Alkaline Purple (CAS No. 548-62-9), is classified Carc. 2 (H351: Suspected of causing cancer), Acute Tox. 4 (H302: Harmful if swallowed), Eye Dam. 1 (H318: Causes serious eye damage), Aquatic Acute 1 (Very toxic to aquatic life) and Aquatic Chronic 1 (H410: Very toxic to aquatic life with long lasting effects).
2. The substance, Alkaline Green (CAS No. 549-64-2), is classified Repr. 2 (H361d: Suspected of damaging the unborn child), Acute Tox. 4 (H302: Harmful if swallowed), Eye Dam. 1 (H318: Causes serious eye damage), Aquatic Acute 1 (Very toxic to aquatic life) and Aquatic Chronic 1 (H410: Very toxic to aquatic life with long lasting effects).

According to **Table A**, the ink does not contain any hazardous substances fulfilling SVHC and CMR criteria.

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IV. Framework of product analysis:

The manufacturer of the 12pcs in PVC blister bag, 30pcs in bulk has to comply with the new Toy Safety Directive (2009/48/EC) and REACH (Regulation (EC) No 1907/2006). Since the 12pcs in PVC blister bag, 30pcs in bulk is likely to be defined as a non-scented toy and is not designed for children under 36 months nor intended to be placed in the mouth, the likelihood on the occurrence of 66 fragrances, nitrosamines and nitrosable substances will not be assessed in this report. Also risk assessment on the migration of 19 elements is not suggested. The analysis of hazardous chemicals is laid down in two parts.

- *Part I CMR & SVHC Assessment*
- *Part II Restricted Substances Assessment*

V. Scope of substances

The purpose of this report is to identify the possible occurrences of hazardous substances in the 12pcs in PVC blister bag, 30pcs in bulk. 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 limits⁵. CMR categories 1A and 1B is one of the SVHC selection criteria under REACH.

ii: PBT and vPvB substances

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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 2.0¹² and the Trade Union Priority List (Version 2.1)¹³ 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 2.0¹² and the Trade Union Priority List (Version 2.1)¹³;

iv: Restricted substances

Substances listed on Annex XVII of REACH with restricted conditions that are relevant to the 12pcs in PVC blister bag, 30pcs in bulk.

Remarks:

¹²SIN List 2.0 by the International Chemical Secretariat (<http://w3.chemsec.org/>)

¹³Trade Union Priority List (Version 2.1) by the European Trade Union Confederation (www.etuc.org/a/6023?var_recherche=SVHC)

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Part I CMR & SVHC Assessment

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Table 1.1 – Possible hazardous substances in accessible parts of the 12pcs in PVC blister bag, 30pcs in bulk (CMR & SVHC)

No.	Substance	Index no.	EC no./CAS no.	Classification ¹⁴	Concentration limit under Regulation (EC) No 1272/2008 ⁶	Directive 2009/48/EC	Regulation (EC) No 1907/2006 ¹⁵	Function		Material ¹⁶	
								PE	PP	PE	PP
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%	√	√	PE, PP: 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%	√	√	PE, PP: Plasticizer			
3	2,4-di-tert-butylphenol	NA	202-532-0/ 96-76-4	Ev. C	NA	√	√	PP: Antioxidant			
4	2-ethylhexanoic acid	607-230-00-6	205-743-6/ 149-57-5	Repr. 2	3.0%	√	√	PE, PP: Intermediate for plasticizers			
5	Alkanes, C 10-13, chloro (SCCP)* [▼]	602-080-00-8	287-476-5/ 85535-84-8	Carc. 2; PBT; vPvB	1.0%	√	√	PE, PP: Plasticizer			
6	Benzyl butyl phthalate (BBP)* [▼]	607-430-00-3	201-622-7/ 85-68-7	Repr. 1B	0.3%	√	√	PE, PP: Plasticizer			
7	Bis(2-ethylhexyl) phthalate (DEHP)* [▼]	607-317-00-9	204-211-0/ 117-81-7	Repr. 1B	0.3%	√	√	PE, PP: Plasticizer			
8	Cadmium and its compounds [▼]	NA	NA	Ev. C (Some Cadmium compounds are classified as Carc., Muta. and Repr.)	NA	√	√	PP: Stabilizer			
9	Diarsenic pentaoxide* [▼]	033-004-00-6	215-116-9/ 1303-28-2	Carc. 1A	0.1%	√	√	PE, PP: Polymerization inhibitor			
10	Dibutyl phthalate (DBP)* [▼]	607-318-00-4	201-557-4/ 84-74-2	Repr. 1B	0.3%	√	√	PE, PP: Plasticizer			
11	Diisobutyl phthalate (DIBP)* [▼]	607-623-00-2	201-553-2/ 84-69-5	Repr. 1B	0.3%	√	√	PE, PP: Plasticizer			
12	Lead and its compounds	NA	NA	Ev. C (Some lead compounds are	NA	√	√	PE, PP: Stabilizer			

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13	Organotin compounds [†]	NA	NA	classified as Carc., Muta. and Repr.) PBT (Some organotin compounds are classified as Carc., Muta. and Repr.)	NA	PE, PP: Stabilizer

Remarks:

¹⁴The 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

¹⁵For 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).

¹⁶Shaded box represents the possible occurrence of the substance in the corresponding material/ component.

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- Refers to list of SVHCs on the Candidate List as of Dec 19, 2011 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 as of May 20, 2011 (Commission Regulation (EU) No 552/2009, Commission Regulation (EU) No 276/2010, Commission Regulation (EU) No 207/2011 and Commission Regulation (EU) No 494/2011) 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 12pcs in PVC blister bag, 30pcs in bulk unless it complies with the conditions of that restriction.

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Table 1.2 – Possible routes of exposure to hazardous substances in accessible parts of the 12pcs in PVC blister bag, 30pcs in bulk (CMR & SVHC)

No.	Substance	Routes of exposure ¹⁷	
		Dermal	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	2,4-di-tert-butylphenol		
4	2-ethylhexanoic acid		
5	Alkanes, C10-13, chloro (SCCP)*		
6	Benzyl butyl phthalate (BBP)*		
7	Bis(2-ethylhexyl) phthalate (DEHP)*		
8	Cadmium and its compounds		
9	Diarsenic pentaoxide*		
10	Dibutyl phthalate (DBP)*		
11	Diisobutyl phthalate (DIBP)*		
12	Lead and its compounds		
13	Organotin compounds		

Remark:

¹⁷Shaded box represents the possible routes of exposure of the hazardous substance in accessible parts of the 12pcs in PVC blister bag, 30pcs in bulk.

Data Analysis:

Table 1.1 shows the possible hazardous substances¹⁸ that may be found in the accessible parts of the 12pcs in PVC blister bag, 30pcs in bulk. 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. The distribution of the possible hazardous substances in each toy material is shown in Fig. 1.1. Pursuant to Fig. 1.1, the plastic parts of the 12pcs in PVC blister

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bag, 30pcs in bulk are likely to contain the highest number of hazardous substances. Most of the possible hazardous substances in plastic parts of the 12pcs in PVC blister bag, 30pcs in bulk are used as plasticizers.

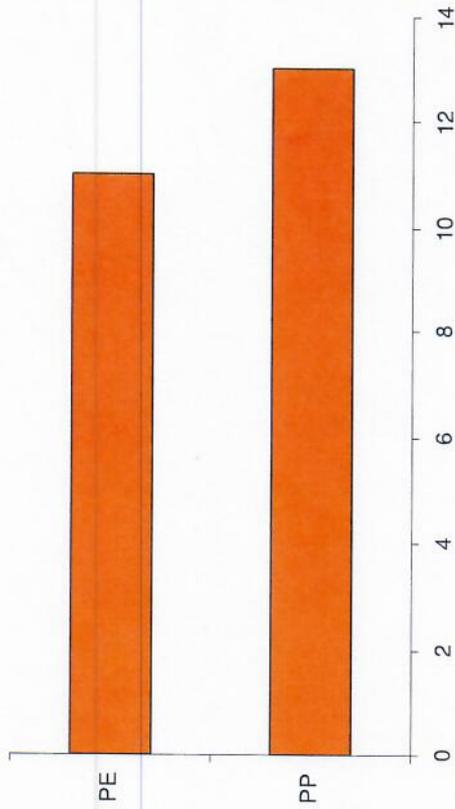


Figure 1.1. No. of substances in each accessible material

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 the 12pcs in PVC blister bag, 30pcs in bulk, the placing of the toy on the market may not be affected unless the concentration of that substance exceeds the corresponding limit.

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Remark:

¹⁸ Refer to the high risk substances which are likely to be found in the toy material.

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Table 1.3 – Possible SVHCs in inaccessible part of the 12pcs in PVC blister bag, 30pcs in bulk

No.	Substance	Index no.	EC no./CAS no.	Classification ¹⁴	Function	Material ¹⁶
1	Formaldehyde	605-001-00-5	200-001-8/50-00-0	Carc. 2; Ev.C	Cotton: Antiwrinkle agent	Cotton

Data Analysis:

Table 1.3 above shows the SVHC substances¹⁸ that may be found in the inaccessible parts of the 12pcs in PVC blister bag, 30pcs in bulk. Only the occurrence of SVHCs was assessed in this part as the restriction of CMR category 2 is not applicable if the substances or mixtures are inaccessible to children in any form. Materials that are present in both accessible and inaccessible parts would not be re-assessed.

The distribution of the possible hazardous substances in each inaccessible toy material is shown in Fig. 1.2. Most parts of the inaccessible part of the toy components are textiles, these components are likely to contain certain substances fulfill the SVHC criteria under 1907/2006/EC. Textiles are likely to contain large number of SVHC/ potential SVHC as they may contain plastic parts, such as PVC. SVHC in electronic components are also come from metal impurity, some of them may be used in soldering processing.

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Present of SVHC in the toy components will not impede the market availability. However, according to Article 33 of the REACH regulation, the manufacturer of articles containing SVHC with above 0.1% should provide the recipient with sufficient information to allow safe use, including as a minimum the name of that substance.

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Part II Restricted Substances Assessment

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Table 2.1 – Restricted conditions on restricted substances related to the 12pcs in PVC blister bag, 30pcs in bulk

Entry No. ^{1d}	Substance	EC No./ CAS No.	Classification ^{1,4}	Restriction conditions
5	Benzene	200-753-7/ 71-43-2	Carc. 1A Muta. 1B	Should not be used in toys or parts of toys where the concentration of benzene in the free state is greater than 5 mg/kg (0.0005%) of the weight of the toy or part of toy.
20	Tri-substituted organostannic compounds	N/A	N/A	Should not be used after 1 July 2010 in articles where the concentration in the article or part thereof, is greater than the equivalent of 0.1% by weight of tin.
	Dibutyltin (DBT) compounds	N/A	N/A	Should not be used after 1 January 2012 in mixtures and articles for supply to the general public where the concentration in the mixture or the article, or part thereof, is greater than the equivalent of 0.1% by weight of tin.
23	Cadmium and its compounds	231-152-8/ 7440-43-9	Carc. 1B Muta. 2 Repr. 2	Should not be placed on the market if their cadmium content (expressed as Cd metal) is greater than 0.01% by weight of the plastic material.
24	Monomethyl-tetrachlorodiphenyl methane Trade name: Ugilec 141	278-404-3/ 76253-60-6	NA	Articles containing the substance should not be placed on the market.

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25	Monomethyl-dichloro-diphenyl methane Trade name: Ugilec 121	NA	NA	Articles containing the substance should not be placed on the market.
26	Monomethyl-dibromo-diphenyl methane bromobenzylbromotoluene, mixture of isomers Trade name: DBBT	402-210-1/ 99688-47-8	NA	Articles containing the substance should not be placed on the market.
45	Diphenylether, octabromo derivative	N/A	N/A	Articles should not be placed on the market if they, or flame-retarded parts thereof, contain this substance in concentrations greater than 0.1% by weight.
51	Bis (2-ethylhexyl) phthalate (DEHP)	204-211-0/ 117-81-7	Repr. 1B	Should not be used as substances or in mixtures, in concentrations greater than 0.1% by weight of the plasticized materials, in toys and childcare articles. Toys and childcare containing these phthalates in a concentration greater than 0.1% by weight of the plasticized material should not be placed on the market
	Dibutyl phthalate (DBP)	201-557-4/ 84-74-2	Repr. 1B	
	Benzyl butyl phthalate (BBP)	201-622-7/ 85-68-7	Repr. 1B	
52	Di-"isononyl" phthalate (DINP)	249-079-5; 271-090-9/ 28553-12-0; 68515-48-0	N/A	Should not be used as substances or in mixtures, in concentrations greater than 0.1% by weight of the plasticized material, in toys and childcare articles which can be placed in the mouth by children. Such toys and childcare containing these phthalates in a concentration greater than 0.1% by weight of the plasticized material should not be placed on the market.
	Di-"isodecyl" phthalate (DIDP)	247-977-1; 271-091-4/ 26761-40-0; 68515-49-	N/A	

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	1		
Di-n-octyl phthalate (DNOP)	204-214-7/ 117-84-0	N/A	

Remark:

¹⁹The entry no. of restricted substances is according to Commission Regulation (EU) No 552/2009, Commission Regulation (EU) No 276/2010, Commission Regulation (EU) No 207/2011 and Commission Regulation (EU) No 494/2011.

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Table 2.2 – Restricted substances related to the 12pcs in PVC blister bag, 30pcs in bulk

No.	Material	Restricted substances on Table 2.1 ¹⁹											
		Entry 5	Entry 20	Entry 23	Entry 24	Entry 25	Entry 26	Entry 43	Entry 51	Entry 52			
1	Cotton												
2	PE												
3	PP												

Remark:

²⁰Shaded box represents the applicable restriction conditions of the restricted substances for the corresponding materials.

Data Analysis:

Table 2.2 lists the applicable restricted conditions of the restricted substances related to the 12pcs in PVC blister bag, 30pcs in bulk. Phthalates are probably used in the plastic parts of the 12pcs in PVC blister bag, 30pcs in bulk as plasticizers, while cadmium and its compounds may be added as colorants. In addition, flame retardants may also be added.

In order to place the product on the market, the manufacturer should confirm that the 12pcs in PVC blister bag, 30pcs in bulk complies with the restriction conditions listed in Annex XVII of REACH.

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VI. Conclusions and Suggestions

Conclusions:

- Plastic parts of the 12pcs in PVC blister bag, 30pcs in bulk may contain the highest number of hazardous substances. Most of the hazardous substances may be found as plasticizer in plastic parts.
- Restricted substances such as phthalates and flame retardants may be used in the 12pcs in PVC blister bag, 30pcs in bulk. The manufacturer should ensure that the toy components comply with the conditions of restriction under Annex XVII of REACH.

Comments and suggestions:

- The explanatory guidance document²¹ for the Toy Safety Directive stated that the testing obligation applies to the substances that can be expected to be present in the toy after risk assessment. The manufacturer of the 12pcs in PVC blister bag, 30pcs in bulk is suggested to conduct related testing in order to confirm that the product complies with the Directive.
- According to Article 33 of REACH, the manufacturer of an article containing a SVHC in a concentration of more than 0.1% should provide the recipient with sufficient information to allow the safe use of the article, including as a minimum the name of that substance.
- According to REACH, toys and childcare products containing restricted substances listed on Annex XVII should not be placed on the market or used unless they comply with the conditions of the restriction.
- The manufacturer has the obligation to make sure that the restricted substances listed in Table 2.1 should not be used in the 12pcs in PVC blister bag, 30pcs in bulk unless they comply with the conditions of these restrictions.
- To minimize the risk, appropriate preventive measure could be taken. Manufacturer should seek for the alternative for hazardous/ restricted substances that may be used in the 12pcs in PVC blister bag, 30pcs in bulk. This move will not only minimize the potential hazards to human health, environmental problems associated with disposal of the toy can also be reduced.

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Remark:

²¹TSD explanatory guidance document (rev 1.3) as of Apr. 05, 2011 (http://ec.europa.eu/enterprise/sectors/toys/documents/guidance/index_en.htm)

Appendices

Appendix 1 Bill of Material (BOM)

Component No.	Material	Color
1	Polypropylene (PP)	Multicolor
2	Polypropylene (PP)	Multicolor
3	Polyethylene (PE)	White
4	Polypropylene (PP)	White
5	Cotton	White
6	Ink	Multicolor

The possible hazardous substances (CMRs and SVHCs) in each toy material of the 12pcs in PVC blister bag, 30pcs in bulk 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 and inaccessible material are affixed in the following tables. The likelihood on the presence of the medium/ low risk substances in each material of the 12pcs in PVC blister bag, 30pcs in bulk is for reference only. User can decide whether the medium and low risk substances should be included in the scope of testing.

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Appendix 2 – Possible medium/ low risk substances in accessible parts of the 12pcs in PVC blister bag, 30pcs in bulk (CMR & SVHC)

No.	Substance	Index no.	EC no./ CAS no.	Classification ¹⁴	Concentration limit under Regulation (EC) No 1272/2008 ⁶	Directive 2009/48/EC	Regulation (EC) No 1907/2006 ¹⁵	Function		Material ²²	
								PE	PP	PE	PP
1	2,3-epoxypropan-1-ol	603-063-00-8	209-128-3/ 556-52-5	Carc. 1B; Muta. 2; Repr. 1B	0.1%	✓	✓	PE, PP: Stabilizer	L	L	
2	3,3'-dichlorobenzidine	612-068-00-4	202-109-0/ 91-94-1	Carc. 1B	0.0005%	✓	✓	PP: Intermediate of dyes		M	
3	3-amino-9-ethyl carbazole	612-280-00-7	205-057-7/ 132-32-1	Carc. 1B	0.1%	✓	✓	PP: Intermediate of dyes		L	
4	4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol	NA	209-218-2/ 561-41-1	Carc. 1B; Muta. 2	0.1%	✓	✓	PP: Colorant		L	
5	Acrylamide*	616-003-00-0	201-173-7/ 79-06-1	Carc. 1B; Muta. 1B; Repr. 2	0.1%	✓	✓	PE, PP: Cross-linking agents	M	M	
6	C.I. Direct Black 38	611-025-00-7	217-710-3/ 1937-37-7	Carc. 1B; Repr. 2	0.1%	✓	✓	PP: Colorant		L	
7	C.I. Pigment Red 104*	082-010-00-5	235-759-9/ 12656-85-8	Carc. 1B; Repr. 1A	0.1%	✓	✓	PP: Colorant		L	
8	C.I. Pigment Yellow 34*	082-009-00-X	215-693-7/ 1344-37-2	Carc. 1B; Repr. 1A	0.1%	✓	✓	PP: Colorant		M	
9	C.I. Solvent Blue 4	NA	229-851-8/ 6786-83-0	Carc. 1B; Muta. 2	0.1%	✓	✓	PP: Colorant		L	
10	Captan (ISO)	613-044-00-6	205-087-0/ 133-06-2	Carc. 2	1.0%	✓	✓	PE: Used in the manufacturing processes	L	L	
11	Dicyclohexyl phthalate (DCHP)	NA	201-545-9/ 84-61-7	Ev. C	NA	✓	✓	PE, PP: Plasticizer	L	L	
12	Diethyl phthalate (DEP)	NA	201-550-6/ 84-66-2	Ev. C	NA	✓	✓	PE, PP: Plasticizer	M	M	
13	Dihexyl phthalate (DHP)	NA	201-559-5/ 84-75-3	Ev. C	NA	✓	✓	PE, PP: Plasticizer	M	M	
14	Malachite green hydrochloride	602-096-00-5	209-322-8/ 569-64-2	Repr. 2	3.0%	✓	✓	PP: Colorant		L	
15	Molybdenum trioxide	042-001-00-9	215-204-7/ 1313-27-5	Carc. 2	1.0%	✓	✓	PE, PP: Catalyst	L	L	
16	n-hexane	601-037-00-0	203-777-6/ 110-54-3	Repr. 2; Ev. C	3%	✓	✓	PE, PP: Used in the manufacturing processes	L	L	
17	Nitrobenzene	609-003-00-7	202-716-0/ 98-95-3	Carc. 2; Repr. 2	1.0%	✓	✓	PP: Intermediate of dyes		M	
18	o-anisidine*	612-035-00-4	201-963-1/ 90-04-0	Carc. 1B; Muta. 2	0.0005%	✓	✓	PP: Intermediate of dyes		M	
19	o-dianisidine	612-036-00-X	204-355-4/ 119-90-4	Carc. 1B	0.0005%	✓	✓	PP: Intermediate of dyes		M	
20	o-phenylenediamine	612-145-00-2	202-430-6/ 95-54-5	Carc. 2; Muta. 2	1.0%	✓	✓	PP: Intermediate of dyes		L	
21	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%	✓	✓	PE, PP: Stabilizer	L	L	

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22	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	√	PE, PP: Plasticizer	L	L
23	α-chlorotoluene	602-037-00-3	202-853-6/ 100-44-7	Carc. 1B	0.1%	√	PE, PP: Used to synthetic BBP, which is a plasticizer	L	L
24	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%	√	PE, PP: Stabilizer	L	L

Remark:

²² Shaded box represents the possible occurrence of the substance in the corresponding material.

M Medium risk
L Low risk

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Appendix 3 – Possible medium/low risk SVHCs in inaccessible parts of the 12pcs in PVC blister bag, 30pcs in bulk

No.	Substance	Index no.	EC no./CAS no.	Classification ¹⁴	Function	Material ¹²
1	Acrylonitrile	608-003-00-4	203-466-5/ 107-13-1	Carc. 1B	Cotton: Cyanoethylation (to improve Dye, rot-resistance, and strength characteristics)	L
2	Arsenic acid ¹⁵	033-005-00-1	231-901-9/ 7778-39-4	Carc. 1A	Cotton: Desiccant	M
3	Benomyl (ISO)	613-049-00-3	241-775-7/ 17804-35-2	Muta. 1B; Repr. 1B	Cotton: Fungicide	L
4	Bis(tributyltin)oxide (TBTO) ¹⁶	NA	200-268-0/ 56-35-9	PBT	Cotton: Preservatives	L
5	Calcium arsenate ¹⁷	NA	231-904-5/ 7778-44-1	Carc. 1A	Cotton: Insecticide	L
6	Captan ¹⁸ (ISO)	613-046-00-7	219-363-3/ 2425-06-1	Carc. 1B	Cotton: Used as a seed treatment	L
7	Carbendazim (ISO)	613-048-00-8	234-232-0/ 10605-21-7	Muta. 1B; Repr. 1B	Cotton: Fungicide	L
8	Chlorocresol	604-014-00-3	200-431-6/ 59-50-7	Ev. C	Cotton: Preserving	L
9	Diarsenic pentaoxide ¹⁹	033-004-00-6	215-116-9/ 1303-28-2	Carc. 1A	Cotton: Herbicide	M
10	Fluazifop-butyl (ISO)	607-304-00-8	274-125-6/ 69806-50-4	Repr. 1B	Cotton: Herbicide	L
11	Flusilazole (ISO)	014-017-00-6	NA/ 85509-19-9	Carc. 2; Repr. 1B	Cotton: Pesticide	L
12	Linuron (ISO)	006-021-00-1	206-356-5/ 330-55-2	Repr. 1B; Carc. 2	Cotton: Herbicide	L
13	Metam sodium	006-013-00-8	205-293-0/ 137-42-8	Ev. C	Cotton: Herbicide	L

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14	N,N-dimethylformamide	616-001-00-X	200-679-5/68-12-2	Repr. 1B	Cotton: Fixing agent	M
15	Pentachlorophenol	604-002-00-8	201-778-6/87-86-5	Carc. 2; Ev. C	Cotton: Pesticide	M
16	Potassium dichromate* ^v	024-002-00-6	231-906-6/7778-50-9	Carc. 1B; Muta. 1B; Repr. 1B	Cotton: Fixing agent	M
17	Sodium dichromate* ^v	024-004-00-7	234-190-3/10588-01-9	Carc. 1B; Muta. 1B; Repr. 1B	Cotton: Fixing agent	M
18	Thiram	006-005-00-4	205-286-2/137-26-8	Ev. C	Cotton: Fungicide	L

** End of Report ***

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