



# Chemical safety assessment of toys

Guidance and inspiration for  
manufacturers, importers and distributors



**Ministry of Environment  
and Food of Denmark**  
Environmental  
Protection Agency



THE DANISH ASSOCIATION OF PLAY



# Contents

Section 1 of this guidance provides answers for manufacturers to a number of questions on how to make a chemical safety assessment.

Section 2 targets importers and distributors. However, if you are an importer or a distributor, you may benefit from reading about manufacturers' obligations as well, in order to prepare yourself for your dialogue with suppliers.

## Section 1: For manufacturers

1. What is a chemical safety assessment and what are the different stages involved?	4
2. What information do you need from your suppliers in order to make a chemical safety assessment?	5
3. How can you make sure that your bills of materials and bills of substances are adequate?	6
<u>Example 1:</u> BOM/BOS for a bottle of bubble solution.	6
4. Which chemical standards are relevant for toys?	7
5. How do you assess the quality of a test report?	8
6. What do you do if you are not able to obtain adequate information from your supplier?	8
7. How do you investigate whether a chemical substance is subject to restrictions or prohibitions, or whether the substance is undesirable?	9
<u>Example 2:</u> Search for Chloroacetamide in the ECHA databases and lists of substances	12
8. How do you assess chemical substances subject to restrictions in use?	14
9. How do you assess chemical substances not subject to restrictions in use?	14
10. How do you establish a realistic worst-case exposure scenario?	15
<u>Example 3:</u> Risk assessment of mineral oil in a magic wand	17
<u>Example 4:</u> Risk assessment of plasticisers in a football	18
<u>Example 5:</u> Risk assessment of chemicals emitted from a squishy	18
11. When should a chemical safety assessment be updated?	20

## Section 2: For importers and distributors

1. How can you assess whether a declaration of conformity is adequate?	21
<u>Example 6:</u> Declaration of conformity for a wooden toy	22
2. What do you do if you are not able to obtain a safety assessment from your supplier?	23

<b>List of abbreviations</b>	24
------------------------------	----



# Introduction

This guidance can help you assess whether the toys you sell comply with statutory chemical requirements and whether children can safely play with the toys.

If you are a manufacturer, you are responsible for making a chemical safety assessment of the toys you produce. This is part of the technical documentation and the declaration of conformity that you must be able to provide if so requested by the authorities.

If you are an importer, you must ensure that the manufacturer has made a safety assessment of the toys. If you are a distributor of toys, you do not have the same responsibility. Nevertheless, it is a very good idea to check that your supplier has the safety assessment under control, because it is your responsibility that the toys you market and sell are safe and comply with the law. If a product does not live up to statutory requirements, consumers may not necessarily think about who the manufacturer was, but rather who sold them the product. Moreover, if you sell toys that are not safe, this may severely damage your company's brand, even if you do not have ultimate responsibility. Note also that your legal responsibility is the same as that of the manufacturer, if you place your own trademark on the toy.

The legislation does not specify how comprehensive chemical safety assessments should be. Therefore, it is up to the manufacturer to assess what constitutes an appropriate level of detail. Under all circumstances, a chemical safety assessment requires that chemical competences are available at your company - either internally or from an external consultant.

This guidance takes as its point of departure the questions that may arise from the regulations on toys, and it is intended as a work of reference in which you can zoom in on any issues of relevance to you. However, it may also be a good idea to read the guidance in its entirety to get an overview of the regulations.

The guidance has been prepared by the Danish Environmental Protection Agency in collaboration with the Danish Association of Play, drawing on input from a number of Danish companies to reflect the needs of the companies. The guidance is based on the [EU guidelines on safety requirements on toys and technical documentation](#) and only serves to support companies in complying with the regulations on production and sale of toys, including the EU Toy Safety Directive and the Danish Statutory Order on safety requirements for toys, both of which are legally binding instruments.

## What is your role?

You are a **manufacturer** if you manufacture toys in Denmark, in another country in the EU or in a country outside the EU. You are also a manufacturer if someone else manufactures a toy for you, and you market the toy in your own name or under your own trademark.

You are an **importer** if you buy finished toys outside the EU, and you then re-sell the toys to another company, shop or directly to consumers in the EU.

You are a **distributor** if you sell toys that you have bought from Denmark or another country in the EU to a company, a shop or directly to consumers.

Read more about roles and obligations on [legetøjsregler.dk](http://legetøjsregler.dk) (in Danish)



## Section 1: For manufacturers

### 1. What is a chemical safety assessment and what are the stages involved?

A chemical safety assessment involves an assessment of the likelihood of toys containing chemicals that are prohibited or restricted. Since the legislation cannot take account of all substances that a toy or a new type of toy may contain, the manufacturer must also assess the likelihood of toys containing substances which are not prohibited or restricted, but which are nevertheless undesirable because they are known or suspected to be hazardous. The manufacturer must also assess whether substances in toys present a risk when children play with the toys. A toxicological risk assessment (TRA) may be included and, depending on scope, it may cover several stages in a chemical safety assessment.

The chemical safety assessment process includes three stages to be conducted by the manufacturer for each chemical substance:

#### 1. Identification

Review the documentation available in order to identify materials and substances contained in the toy.

#### 2. Characterisation

Examine each substance identified in order to clarify whether the substance is prohibited or subject to restrictions in use (total concentration or migration of the substance) or whether the substance is known or suspected to be hazardous.

#### 3. Assessment

Assessment of the likelihood that a material contains more than the permitted quantity of a restricted substance, or that it contains a non-regulated substance in quantities that will present a risk when children play with the toy.

If the assessment concludes that a material contains more than the permitted quantity of a restricted substance, or that a non-regulated substance will present a risk, the manufacturer must evaluate how to manage the risk. If the manufacturer decides to substitute the substance with another substance, this substance must be subject to the same assessment process.



## 2. What information do you need from your suppliers in order to make a chemical safety assessment?

You can only make an adequate safety assessment if you have information about the materials of which the final toy is made, and which chemical substances the materials contain. You must collect this information from your suppliers of raw materials, intermediates and components. This also applies to your supplier of the final toy, if you manufacture, import and sell the toy in your own name or under your own trademark.

### Ideally, relevant documentation will include:

- **Bill of materials (BOM):** List of raw materials, intermediates and components used to manufacture the final toy, stating the quantities used.
- **Bill of substances (BOS):** List of chemical substances in each material, stating the substance CAS numbers and the concentrations in which the substances are present.
- **Safety Data Sheet (SDS):** Safety data sheets for chemicals used in the manufacturing process if required under REACH.
- **Test reports:** Results of chemical analyses documenting that the toy complies with relevant regulation.

Toys consisting of many intermediates often have long supply chains, and in this case, it may be difficult to obtain information on chemicals used by suppliers further back in the chain. In other words, the amount of documentation available may differ considerably, and this may render it difficult to make a safety assessment.

### Examples of optimal and difficult conditions, respectively, for making a chemical safety assessment:

#### Optimal conditions

- All materials are traceable, for example via their tradenames or batch numbers
- All materials are supplied in a consistent and uniform quality
- Information about the used substances, substance CAS numbers and concentrations is available for all materials
- Tests documenting compliance with relevant regulations are available
- Safety data sheets for chemicals used in production are available if required under REACH
- No product changes are performed without new materials/substances being assessed

#### Difficult conditions

- Materials are not traceable
- It is not possible to ensure the same materials for each supply
- Materials are purchased on the basis of price, and not supplied by fixed suppliers
- Information about the used substances in materials is not available
- Safety data sheets for chemicals used are not available
- Product changes occur often
- Test results cannot be unambiguously linked to the toy/ material supplied



### 3. How can you make sure that your bills of materials and bills of substances are adequate?

The bill of materials (BOM) has to include all materials etc. used to manufacture the toy, and the bill of substances (BOS) has to include all the substances used. For intermediates purchased from suppliers, the BOM should indicate the documentation available, for example whether a supplier's declaration or a test report is available. The BOM should also indicate where in the toy different materials have been used, as this may be essential in order to assess the likelihood of children being exposed to the substances of the material.

#### Checklist to prepare or assess a BOM/BOS:

- Is there a unique identification number, so that there is no doubt that the BOM/BOS concerns the toy supplied?
- Is there a colour image of the toy, and is it good enough for you to confirm that the toy and the BOM/BOS match?
- Is it possible to identify all the different types of materials used in the toy?
- Is it possible to trace all materials back to named suppliers, for example on the basis of tradenames?
- Is it possible to trace all materials back to specific deliveries, for example on the basis of batch numbers?
- Is it stated where in/on the toy the different materials have been used/placed, for example whether they are accessible to the child?
- Have all substances been stated for all materials? And have CAS numbers and concentrations been stated for all substances?
- Has information been made available about substance impurity or reaction products that may have occurred during the manufacturing process?
- Is the detection limit stated for substances in connection with tests sufficiently low to enable an assessment of whether any limit value has been complied with?
- Is information about substances unambiguously linked to the materials in which they are present?
- Has the BOM/BOS been dated so that it can be assessed whether the list is still up to date?
- Has it been stated whether there is documentation that purchased intermediates comply with relevant chemical requirements, for example a test report or a supplier's declaration?

Example 1 shows a BOM/BOS for a bottle of soap-bubble solution. The soap-bubble solution is formulated by the manufacturer at the toy factory, and the manufacturer also moulds the cap, while the bottle and the sticker are purchased from a supplier.

#### Example 1: BOM/BOS for bottle of soap-bubble solution

Description	Part	Number used	Material/substance/component	CAS/EINECS/CI	Safety Data Sheet required (YES/NO)	Supplier's declaration/test report present (YES/NO)
Bottle	1	1	PVC with colourant/plasticiser	Not applicable		Y
Cap	2	100 mg	PVC resin	9002-86-2	N	
Cap		100 mg	Plasticiser	EC 229-176-9 CAS 6422-86-2	N	
Cap		1 mg	Colourant		N	Y
Sticker	3	1	Printed material on paper	Not applicable		Y
Wand	4	1	PE resin	9002-88-4	N	
Bubble solution	5	0.1 ml	Dodecanamide, N,N-bis(2-hydroxyethyl)	120-40-1	N	
Bubble solution		0.5 ml	Glycerol	56-81-5	N	
Bubble solution		0.5 ml	Sodium 2-[2-[2(tridecyloxy)ethoxy]ethoxy]ethyl sulphate	25446-78-0	N	
Bubble solution		0.5 ml	2-chloroacetamide	79-07-2	Y	
Bubble solution		15 ml	Distilled water	7732-18-5	N	



## 4. Which chemical standards are relevant for toys?

If you follow the chemical standards summarised in [the Official Journal of the European Union](#), you can assume that you comply with the chemical requirements in the Toy Safety Directive, but only with regard to the requirements covered by the standards. However, there is no statutory requirement to carry out analyses in accordance with the standards. An analysis may therefore be unnecessary if you can render it probable that a substance covered by a standard cannot be present in the toy material.

### List of relevant chemical standards for toys

Standard	Content
EN71-3: Migration of Certain Elements	Specifies requirements and test methods for the migration of aluminium, antimony, arsenic, barium, boron, cadmium, chromium (III), chromium (VI), cobalt, copper, lead, manganese, mercury, nickel, selenium, strontium, tin, organic tin and zinc.
EN71-4: Experimental sets for chemistry and related activities	Specifies requirements for the chemical substances and materials that may be used in experimental sets for chemistry and related activities, including maximum amount and concentration. This standard applies, for example, to carbon-dioxide-generating experimental sets and sets for chemical experiments within the fields of mineralogy, biology, physics, microscopy and environmental science. This standard also specifies requirements for labelling, a contents list, instructions for use, and safety equipment.
EN71-5: Chemical toys (sets) other than experimental sets	Specifies requirements for the chemical substances and materials that may be used in chemical toys other than chemical experimental sets, including maximum amount and concentration. The standard applies, for example, to plaster moulding sets, miniature sets with ceramic vitreous/enamelling materials, oven-hardening modelling clay, plastic moulding sets; photography sets as well as adhesives, paints, lacquers and varnishes for model sets. This standard also specifies requirements for marking, a contents list, instructions for use, and safety equipment.
EN71-7: Finger paints - Requirements and test methods	Specifies requirements and methods of analysis for substances and materials used in finger paints, including requirements for labelling and containers.
EN71-9: Organic chemical compounds - Requirements	Specifies requirements for the migration/emission or content of certain hazardous organic chemical compounds from/in certain toys and toy materials. Does not contain requirements for chemical toys, experimental sets or finger paints.
EN71-10: Organic chemical compounds - Sample preparation and extraction	Specifies sample preparation and extraction procedures for establishing the release or content of organic compounds from or content in those toys for which requirements exist in EN71-9.
EN71-11: Organic chemical compounds - Methods of analysis	Specifies methods for the analysis of extracts of toy and toy material prepared according to the sampling procedures in EN71-10.
EN71-12: N-nitrosamines and N-nitrosatable substances	Specifies requirements and test methods for N-nitrosamines and N-nitrosatable substances in toys made from elastomers and intended for use by children under 36 months or intended to be placed in the mouth, for example balloons. Also applies to finger paints.
EN71-13: Olfactory board games, cosmetic kits and gustative games	Specifies requirements for the chemical substances and materials that may be used in olfactory board games, cosmetic kits and gustative games, including maximum amount and concentration. The standard lists prohibited fragrances and labelling and marking requirements for certain fragrances.



## 5. How do you assess the quality of a test report?

There are no statutory requirements on which laboratories and methods should be used for testing. The quality of test reports therefore varies and the reports may be non-transparent. If you receive a test report as documentation from your supplier, you can use the checklist below to assess the quality of the test report.

### Checklist for assessing test reports:

- Does the report state the name and address of the laboratory performing the test?
- Has the laboratory been accredited to conduct the analyses in question? If the laboratory has been accredited, the accreditation number is always stated in the report.
- Can the report be uniquely identified, for example through a case number and a date of issue?
- Does the report contain unique identification of the material and the substance(s) that the test is designed to detect?
- Have the analyses been conducted on the final material or on raw materials? For example, tests of substances in raw materials are relevant when there is no chemical reaction when manufacturing the final product. Tests of raw materials may also be relevant if a raw material may contain a substance that is undesirable, even if it will be present in a very low concentration in the final product. An example of this is preservatives.
- Is the test relevant in relation to the respective toy/material and toy safety legislation, as well as the use of the toy? The test may concern legislation in other areas, for example food contact. The legislation may also not apply to the toy in question. For example, the RoHS Directive does not apply to non-electronic toys. Furthermore, legislation outside the EU is not relevant if the product is only sold in the EU.
- Does the test comply with the most recent legislation? For example, have new lower limit values for migration of substances been introduced or have new substances been added in Appendix C to the Toy Safety Directive?
- Has the product been changed since the test was performed? A change of a material is not always visible, and therefore, you may consider a new test to confirm the results of previous analyses. As a general rule, test reports should not be more than two years old.
- Have the sample preparation methods and methods of analysis applied been described with reference to applicable standards and any deviations from such standards?
- Does the report state the limit of detection (LOD) or limit of quantification (LOQ) for the test method?
- Has the test result uncertainty been stated? Generally, the uncertainty should be stated as it may influence the safety of the product. Accredited laboratories are obligated to calculate the uncertainty and disclose this on request.
- Has the report been signed, and possibly stamped, by a person authorised to do so?

## 6. What do you do if you are not able to obtain adequate information from your supplier?

It may be difficult to obtain the necessary information from your supplier if the information is confidential. The supplier is not under an obligation to disclose such information. However, this does not remove your obligation to make a safety assessment. In other words, if you are a manufacturer, obtaining a declaration of conformity from a supplier is not sufficient. You must always sign declarations of conformity yourself for products you place on the market.

Therefore, when making a safety assessment based on limited information, you will usually have to engage in closer dialogue with your supplier. You can use the knowledge already available about which



chemical substances could be present in different types of materials. For example, if a toy is made of soft PVC, you can assume, as a worst-case scenario, that phthalates have been used as plasticisers. Similarly, you can assume that toys made from metal alloys contain heavy metals; that aqueous materials contain preservatives; that electronics contain flame retardants; that textiles have been impregnated with fluorinated substances, etc. As many of these substances are subject to prohibitions or restrictions, you may request a supplier's declaration or an analysis report showing that no prohibited substances have been used, and that substances have only been used in permitted quantities.

If you do not trust the supplier's declaration or the analysis report from the supplier, you may arrange for targeted chemical analyses to be carried out. It is always a good idea to choose an accredited laboratory and to make sure that the laboratory is also accredited to perform tests according to the standards relevant for toys.

You can use the following list of examples of materials which could contain prohibited, restricted or undesirable substances in your dialogue with suppliers as well as test laboratories.

#### Examples of materials and the chemicals they can contain:

- **Soft plastics** can contain PAH (primarily present in black plastics), SCCP, phthalates, BPA, stabilisers (lead, cadmium and organic tin-compounds) and residual monomers such as phenol.
- **Hard plastics** can contain PAH (primarily present in black plastics), BPA, stabilisers (lead, cadmium and organotin compounds) and phenol.
- **Rubber** can contain zinc, PAH, nitrosamines and nitrosatable substances.
- **Textiles** can contain formaldehyde, anti-mildew agents, flame retardants, colouring agents and impregnation agents, such as PFAS.
- **Leather** can contain tanning substances such as chrome VI.
- **Metal alloys** can contain lead, iron, copper, mercury, aluminium, nickel, silver, tin and zinc.
- **Glass** can contain lead, arsenic or antimony.
- **Wood** can contain wood preservatives which in turn can contain chrome, arsenic, copper and creosote.
- **Paper** can contain colouring agents that may contain heavy metals.
- **Foam** can contain formamide and flame retardant such as TCEP, TDCP and TCPP.
- **Aqueous materials** can contain preservatives such as isothiazolinones, phenol and formaldehyde.

## 7. How do you investigate whether a chemical substance is subject to restrictions or prohibitions, or whether it is undesirable?

The Danish Statutory Order on safety requirements for toys is not the only piece of legislation that sets out restrictions and prohibitions on chemical substances in toys. Other legislation also contains a number of requirements on chemical substances that you must take into account in your safety assessment. For example, toy kitchen utensils which may be used to store food must comply with chemical requirements on food contact materials.

The list on the next page provides examples of EU legislation containing chemical requirements that may apply to toys. Note that EU regulations are directly applicable, while EU directives do not apply in Denmark until after they have been implemented in Danish legislation through an act or a statutory order.



### Examples of EU legislation containing chemical requirements on toys

<p><a href="#">Danish Statutory Order on safety requirements for toys no. 309 of 3 April 2017 (Legetøjsbekendtgørelsen) (in Danish)</a></p> <p><a href="#">Amended by Statutory Order no. 131 of 6 February 2019 (in Danish)</a></p>	<ul style="list-style-type: none"> <li>• Prohibition on CMR substances in accessible parts of toys in concentrations exceeding the classification limit</li> <li>• Migration limits for 19 elements - limits depend on the toy material</li> <li>• Migration limits for nitrosamines and nitrosatable substances as well as limit values for specific substances - apply to toys intended for use by children under three years or toys intended to be placed in the mouth</li> <li>• Prohibitions on, and requirements for, labelling certain fragrances</li> </ul>
<p><a href="#">REACH Regulation (EC) 1907/2006</a></p> <p><a href="#">List of amendments and consolidated versions</a></p> <p><a href="#">REACH Annex XVII</a></p> <p><a href="#">REACH Candidate List (SVHC)</a></p>	<ul style="list-style-type: none"> <li>• Restrictions on a number of substances - some apply to toys and materials used in toys</li> </ul>
<p><a href="#">POP Regulation (EU) 2019/1021</a></p>	<ul style="list-style-type: none"> <li>• Prohibition on a number of persistent substances</li> </ul>
<p><a href="#">RoHS Directive 2011/65/EU</a></p>	<ul style="list-style-type: none"> <li>• Prohibition on a number of substances in electrical and electronic toys</li> </ul>
<p><a href="#">Regulation on cosmetic products (EC) 1223/2009</a></p>	<ul style="list-style-type: none"> <li>• Regulation on a number of substances in toys which are also cosmetic products, for example positive lists of preservatives and annexes of substances not to be used in cosmetic products</li> </ul>
<p><a href="#">CLP Regulation (EC) 1272/2008</a></p>	<ul style="list-style-type: none"> <li>• Rules for classification and labelling of chemicals - apply to toys that are chemical mixtures, such as paints, finger paints, modelling clay and slime</li> </ul>
<p><a href="#">Regulation on food contact materials 1935/2004</a></p> <p><a href="#">Regulation on migration from plastic materials (EC) 10/2011</a></p>	<ul style="list-style-type: none"> <li>• Chemical requirements on packaging for consumer products, including toys</li> </ul>
<p><a href="#">Packaging Directive 94/62/EC</a></p>	<ul style="list-style-type: none"> <li>• Requirements on labelling and heavy metal content - apply to all batteries whether or not incorporated in appliances</li> </ul>
<p><a href="#">Batteries Directive 2006/66/EC</a></p>	<ul style="list-style-type: none"> <li>• Requirements on labelling and heavy metal content - apply to all batteries whether or not incorporated in appliances</li> </ul>
<p><a href="#">General Product Safety Directive 2001/95</a></p>	<ul style="list-style-type: none"> <li>• Requirements stipulating that only safe products are placed on the market, i.e. only products posing no risk, or products posing only a limited or acceptable risk, to consumer health and safety</li> </ul>



Additionally, there may be national regulations on toys that you will also have to take into account when selling toys in the respective countries. For example, [Danish Statutory Order no. 855 of 5 September 2009 on phthalates](#) prohibits and restricts a number of phthalates in toys made or intended for children under three years and products intended or likely to be placed in the mouth by children under three years.

It is recommended that you start by investigating whether the substance has a hazard classification. The EU has adopted binding harmonised classifications for health, environmental and/or physical hazards for more than 8,000 chemical substances, and restrictions and prohibitions can be based on this classification. Substances with hazard classifications can be found in the European Chemicals Agency (ECHA) database Classification and Labelling (C&L) Inventory.

The ECHA website includes a search function: [Search for chemicals](#). Here, you will find information about chemicals produced and imported into the European Union. The website offers a single point of access to search the C&L Inventory for information about hazardous properties, classification and labelling for a substance, and to search other relevant lists of substances. For example, you can find out whether the substance is subject to restrictions under REACH, whether it is on the REACH Candidate List or the list of substances that are currently being assessed or that are to be assessed over the next few years (Community Rolling Action Plan, CoRAP). However, the fact that a substance has been selected for assessment does not necessarily mean that the substance will be prohibited or restricted.

You may also search in the [Danish EPA database](#) of chemical substances in consumer products to find information as well as any assessments of chemicals investigated in various consumer products, including toys.

You cannot rule out that a substance is undesirable simply because it does not appear in searches in the Danish EPA database or on the ECHA website. Even though you cannot find information on the hazardous properties of a substance, as a manufacturer, you are still responsible to ensure that the substance does not affect children's safety and health. Other sources of information on undesirable substances include trade organisations and consumers' organisations. In Denmark, the Department of the Ministry of Environment and Food, the Danish Environmental Protection Agency, the Danish Safety Technology Authority and the Danish Association of Play organise an annual thematic day on toys to inform about new and coming rules in the chemicals area, among other things.

Example 2 shows a search for the substance 2-chloroacetamide on the ECHA website. 2-chloroacetamide is on the bill of materials in Example 1. 2-chloroacetamide is a preservative added to the soap-bubble solution in order to prevent bacterial growth.



## Example 2: Search for Chloroacetamide in the ECHA databases and lists of substances

You can search by substance name or by one of the numerical identifiers. The example shows a simple search on CAS number (79-07-2), but it is also possible to make a more advanced search, for example if you want to check whether use of the substance is restricted under REACH.

An agency of the European Union Sign In English (en)

**ECHA**  
EUROPEAN CHEMICALS AGENCY

About Us Contact Search the ECHA Website

LEGISLATION PUBLIC CONSULTATIONS INFORMATION ON CHEMICALS SUPPORT

ECHA > Information on Chemicals

**Search for Chemicals**

79-07-2 Search

I have read and I accept the legal notice ADVANCED SEARCH >

Please note that some of the information on chemicals may third parties. The use of such information may therefore require prior permission of the third party owners. Please consult the Legal notice for further information.

- > Cross regulation activities, other data, and data from previous legislation
- > REACH - Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation
- > CLP - Classification, Labelling and Packaging
- > BPR - Biocidal Products Regulation
- > PIC - Prior Informed Consent Regulation
- > POPs - Persistent Organic Pollutants Regulation

The search provides information about hazard classification and labelling of the substance. This example shows the overall conclusion that the substance is toxic if swallowed, is suspected of damaging fertility and may cause an allergic skin reaction.

An agency of the European Union Sign In English (en)

**ECHA**  
EUROPEAN CHEMICALS AGENCY

About Us Contact Search the ECHA Website

LEGISLATION PUBLIC CONSULTATIONS INFORMATION ON CHEMICALS SUPPORT

ECHA > Substance Information

Substance information

Infocards are automatically generated based on industry data. [What is an infocard?](#) See a problem or have feedback?

**2-chloroacetamide** RSS

Regulatory process names 2 Translated names 18 CAS names 1 IUPAC names 2 Trade names 8 Other identifiers 2 Print BIP

<p><b>Substance identity</b></p> <p>EC / List no.: 201-174-2</p> <p>CAS no.: 79-07-2</p> <p>Mol. formula: C<sub>2</sub>H<sub>4</sub>ClNO</p> <p></p>	<p><b>Hazard classification &amp; labelling</b></p> <p></p> <p><b>Danger!</b> According to the <b>harmonised classification and labelling (CLP00)</b> approved by the European Union, this substance is toxic if swallowed, is suspected of damaging fertility and may cause an allergic skin reaction.</p> <p><b>Additionally</b>, the classification provided by companies to ECHA in <b>REACH registrations</b> identifies that this substance is suspected of damaging fertility or the unborn child.</p>	<p><b>Properties of concern</b></p> <p><b>R</b> Possibly Toxic to Reproduction</p> <p><b>Ss</b> Skin sensitising</p> <p><b>How to use it safely</b></p> <ul style="list-style-type: none"> <li>■ <b>Precautionary measures</b> suggested by manufacturers and importers of this substance.</li> <li>■ <b>Guidance on the safe use of the substance</b> provided by manufacturers and importers of this substance.</li> </ul>
--	---	--

**About this substance**

This substance is manufactured and/or imported in the European Economic Area in 100 - 1 000 tonnes per year.

This substance is used in formulation or re-packing, at industrial sites and in manufacturing.

**Consumer Uses**

ECHA has no public registered data indicating whether or in which chemical products the substance might be used. ECHA has no public registered data on the routes by which this substance is most likely to be released to the



The C&L Inventory contains more information about hazard classes, classifications and concentration thresholds. Here, the substance is classified as Skin Sens. 1; H317 and may cause an allergic skin reaction at concentrations exceeding 0.1%.

In the soap-bubble solution in example 1, the concentration of the substance is 3%. It is permitted to add the substance as a preservative in order to prevent bacterial growth, but the product requires a hazard label and must carry the warning "May cause an allergic skin reaction".

#### Summary of Classification and Labelling

Harmonised classification - Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation)						
General Information						
Index Number	EC / List no.	CAS Number	International Chemical Identification			
616-036-00-0	201-174-2	79-07-2	2-chloroacetamide			
ATP Inserted / Updated: CLP00						
CLP Classification (Table 3)						
Classification		Labelling			Specific Concentration limits, M-Factors, Acute Toxicity Estimates (ATE)	Notes
Hazard Class and Category Code(s)	Hazard Statement Code(s)	Hazard Statement Code(s)	Supplementary Hazard Statement Code(s)	Pictograms, Signal Word Code(s)	Skin Sens. 1; H317: C ≥ 0,1 %	
Acute Tox. 3 *	H301	H301		GHS08 GHS06 Dgr		
Skin Sens. 1	H317	H317				
Repr. 2	H361F ***	H361F ***				
Signal Words		Pictograms				
Danger		 Health hazard  Skull and crossbones				



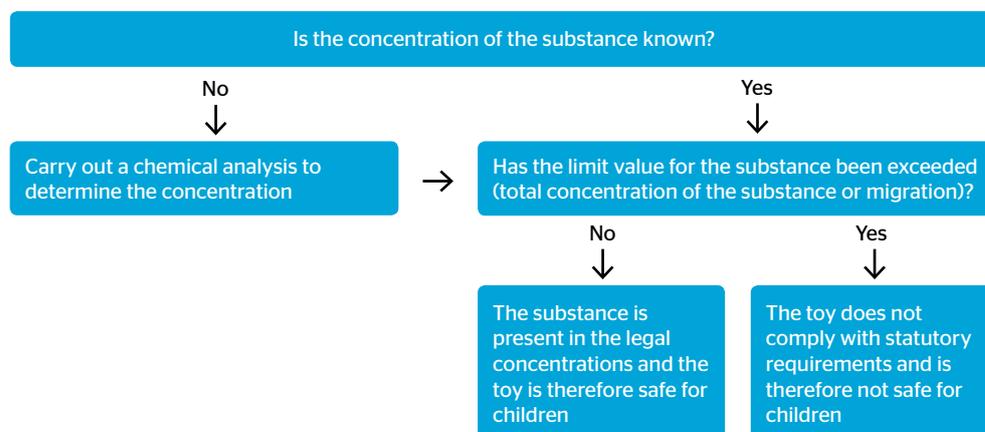
## 8. How do you assess chemical substances subject to restrictions in use?

If a limit value has been determined for a chemical substance that is part of the toy material, your task is to determine the likelihood that this limit value has been exceeded. The limit value may concern the content of the substance and migration or emission of the substance, and it is important that you do not mix up these limit values. In some cases, there may be requirements for both content and migration or emission.

If the concentration of the substance is stated in the bill of materials and bill of substances or in other documentation from your supplier, you determine whether the statutory requirement has been observed by comparing with the limit value of the total concentration of the substance. If you do not have information about the concentration of the substance, and you are not able to obtain additional information from your supplier, you will have to have a chemical analysis performed to clarify and document the concentration. If the concentration of the substance is higher than a possible migration limit, you will also have to have a migration test performed.

You should pay attention to whether the restriction in use only applies to accessible material and whether the substance you are to assess is present in inaccessible material. If a limit value for a substance only applies to accessible parts of the toy, it is permitted for the substance to be present in, for example, a component inside an electronic toy, provided it will not be in contact with the skin, and provided the substance does not migrate or emit from the toy.

### Procedure for chemical substances subject to restrictions in use:



## 9. How do you assess chemical substances not subject to restrictions in use?

If a chemical substance has a hazard classification, but is not subject to restrictions in use, the assessment of whether the substance poses a risk in the toy will depend on whether the child can be exposed to the substance. Your task is therefore to establish a realistic worst-case exposure scenario based on your knowledge about the use of the toy.

A chemical substance with no hazard classification can also be undesirable in toys, because it is suspected of posing a risk to health. If there is reason to believe that the substance is undesirable, a child's possible exposure to the substance should also be assessed on the basis of a realistic worst-case exposure scenario. See point 7 for how to investigate whether a substance is undesirable.

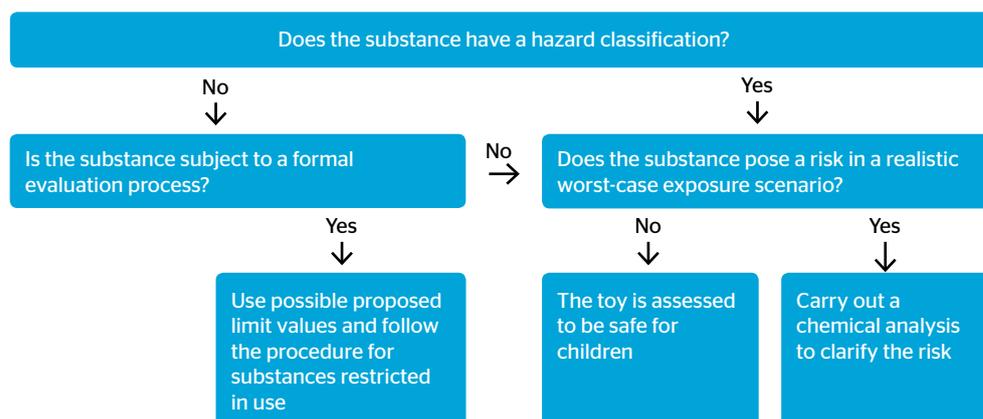
If a substance is subject to a scientific investigation or a formal evaluation process, there may be proposed limit values that can be included in the assessment. In such case, the assessment can be



carried out in the same way as for substances restricted in use. However, the fact that a substance is being investigated and assessed does not necessarily mean that the substance will be restricted.

If, on the basis of a realistic worst-case exposure scenario, you assess that there is only little likelihood that the substance poses a risk, you should document the assumptions underpinning your assessment. However, if you assess the substance poses a risk to health, you should carry out chemical analyses to clarify this risk.

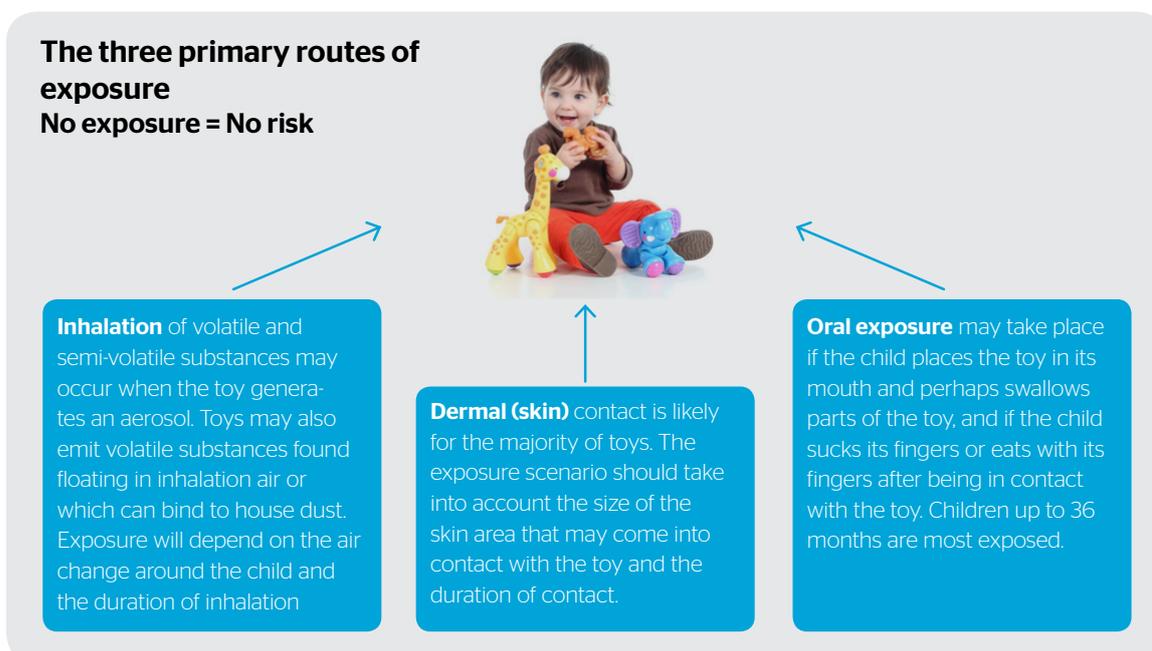
#### Procedure for chemical substances that are not restricted, but are undesirable in toys:



## 10. How do you establish a realistic worst-case exposure scenario?

An exposure scenario of a chemical substance is based on knowledge about the substance's routes of exposure, and on a number of assumptions on the age of the children playing with the toy, and how and in which situations the toy will be used. It is not sufficient to look at how the toy is intended to be used, it is also important to take account of how children are otherwise likely to use the toy.

As a starting point, you can consider a worst-case scenario, where the total content of the substance is assumed to migrate or be emitted and then absorbed 100% by the child. If the worst-case scenario shows that there is no risk, you can conclude that, similarly, a realistic worst-case scenario will not pose a risk, and therefore the toy is safe. If you conclude that there is a risk, you can establish a more realistic scenario by including knowledge about the migration and emission characteristics of the substance – perhaps from analyses – and repeat the calculation.





**When you establish a realistic worst-case exposure scenario, you should consider the following statements:**

- **Age - is the toy likely to be used by others than those of the age for which it is intended?**  
You should consider the intended and likely target group for the toy product, including whether the product is for children younger or older than three years. You can generally assume that parents will make sure that children younger than three years do not play with toys clearly appealing to children older than three years. However, if you are unsure about the age assessment, you should make sure the toy is safe for the youngest or most vulnerable age group relevant to account for in a realistic worst-case age assessment.
- **Use - is the toy likely to be used in other ways than intended or prescribed?**  
Typically, the child's age will also play an important role in how the toy is used. You should consider that children younger than three years will place toys in their mouth and may drink liquid toys such as soap-bubble liquid.
- **Exposure time - how long is the child likely to play with the toy?**  
How long and how often the child is exposed to the substance can be a very important factor. For example, it is very likely that exposure from a stuffed animal will be long and repeated if the child sleeps with the animal. In this case, it will be necessary to assume that inhalation of volatile substances and contact with skin will occur. The same applies to toys such as foam playmat puzzles for babies, where it is likely that the baby will be placed on the playmat for hours at a time every day with its nose and mouth close to the playmat.
- **Air change - does air change affect the exposure of the child?**  
Assumptions on air change around where the child is playing will be relevant if the toy emits volatile substances or generates an aerosol, for example a toy air brush. A worst-case air change may be a situation in which the child is playing with the toy under a duvet or in a tent.
- **Number of toys - how many toys does the child play with at a time?**  
If a toy emits a hazardous substance, the number of toys the child is playing with at a time or has in its room may affect the total amount to which the child is exposed. In this case, it may also be relevant to consider the likelihood that the child may also be exposed to the same substance or another substance with similar properties damaging to health. This could be plastic toys plasticised with phthalate(s). The number of toys may also be relevant if the toy is intended as a collector's item.
- **Temperature - is exposure dependent on temperature?**  
You should take into account whether temperature may play a role in migration of the substance. This may be the temperature in the room where the child is playing, in the bath water, outdoors when the sun is shining, etc.
- **Durability - does exposure change if the toy breaks?**  
You should consider the likelihood that children may be exposed to a hazardous substance if the toy breaks. This may be toys containing a liquid, for example a snow globe that could leak or break if dropped on the floor.



Below are examples of default values that you can use when establishing exposure scenarios. For more examples go [to the Danish EPA's surveys on chemicals in consumer products](#)

Variable	Default value	Source
Weight of child of 2-3 years	13,8 kg	<a href="#">Existing Default Values and Recommendations for Exposure Assessment, 2011</a>
Weight of child of 3-6 years	18,6 kg	<a href="#">Existing Default Values and Recommendations for Exposure Assessment, 2011</a>
Surface area of hands of child of 2-3 years	0,028 m <sup>2</sup>	<a href="#">Existing Default Values and Recommendations for Exposure Assessment, 2011</a>
Surface area of hands of child of 3-6 years	0,037 m <sup>2</sup>	<a href="#">Existing Default Values and Recommendations for Exposure Assessment, 2011</a>
Sleeping time for child of 1-3 years	12-14 hours/day	<a href="#">Guidelines on preventive healthcare services for children and adolescents, 2011 (in Danish)</a>
Sleeping time for child of 3-6 years	10-12 hours/day	<a href="#">Guidelines on preventive healthcare services for children and adolescents, 2011 (in Danish)</a>
Playtime for child under 3 years	4 hours/day	<a href="#">DS/CEN/TR 16918:2015</a>
Playtime for child older than 3 years	1 hour/day	<a href="#">DS/CEN/TR 16918:2015</a>
Size of child's room	7 m <sup>2</sup>	<a href="#">ISO 16000-9-Annex B og DS, 1994</a>

The following includes three different examples of chemical safety assessments of a magic wand, a football and a squishy. These assessments are product-specific, i.e. they only apply for the specific products and only for the time when the products were assessed. Results can therefore not be applied to other products, but they can serve as inspiration to what you should consider when carrying out a chemical safety assessment.

### Example 3: Risk assessment of mineral oil in a magic wand

A magic wand made of acrylic contains 90% mineral oil. The oil is classified as aspiration toxic category 1 and may be fatal if it is swallowed and enters the respiratory tract.

The product is intended for children of three years and older as it is used in role playing games. However, the product may be used by children of two years due to its simple design and colourful look.

As a worst-case scenario, the child drops the magic wand, so the acrylic breaks and the liquid seeps out. If this happens, the child will be exposed to a serious risk if the liquid is swallowed and enters the child's respiratory tract, as the mineral oil is classified as category Asp Tox 1; H304. Therefore, the oil in the magic wand must be replaced by water or some other liquid that does not pose a risk.

#### Conclusion

The risk associated with the product is too high, and the supplier is not able to find an alternative solution that could eliminate the risk. In addition, the product does not comply with REACH Annex XVII, entry 3. The magic wand must therefore not be sold.

### Example 4: Risk assessment of plasticisers in a football

A football of soft plastic contains 13% DIOP, a plasticiser. The ECHA Committee for Risk Assessment, RAC, has assessed that DIOP could have a teratogenic effect, and the substance was therefore [proposed classified in March 2018](#) as reprotoxic in category 1B; H360D. The proposal for harmonised classification has not yet been processed by the European Commission, but is expected to be included in Annex VI to the CLP Regulation (no. 1272/2008 of 16 December 2008).



The basis for the assessment by RAC is that toxicological studies show that DIOP resembles and behaves like the phthalate DBP. In terms of dose, the toxicological profiles of DIOP and DBP are similar at almost all endpoints (Saillenfait, 2013), with the same effects, for example testosterone production, embryo lethality and nipple retention. RAC therefore assesses that the categorisation principle for read across from DBP can be applied to DIOP.

#### Conclusion

RAC assesses DIOP to be reprotoxic. Although application of the categorisation principle for read across from DBP has not yet been adopted by the European Commission, current knowledge suggests that a ball containing 13% DIOP can constitute a risk for children. The ball may therefore not be sold.

#### **Example 5: Risk assessment of chemicals emitted from a squishy**

The risk assessment was conducted on the basis of information obtained in connection with the project [Analysis and risk assessment of fragrances and other organic substances in squishy toys](#).

The table below shows the substances released by the squishy, the concentration measured after one hour and three days, the applied DNEL value (Derived No Effect Level) and related critical effect of the DNEL value stated. However, there is no consensus on all DNEL values in the above project report.

Substance	Concentration [ $\mu\text{g}/\text{m}^3$ ] 1 hour/3 days	DNEL (10 hours) [ $\mu\text{g}/\text{m}^3$ ]	Critical effect of the DNEL applied
N,N-dimethylformamide	6500/3000	192	Mucous membrane irritation
N,N-dimethylaminoethanol	6800/3200	240	Affects the cornea and respiratory tract irritation
Triethylenediamine	3500/2900	17	Mucous membrane irritation
Bis(2-(Dimethylamino)ethyl) ether	280/340	5	Mucous membrane irritation
Triethylenediamine	5300/5600	984	Unspecified (most likely eye and respiratory tract irritation)

#### Hazard assessment

The DNEL values applied were established to protect against the most critical effects of the substances, i.e. effects that occur at the lowest exposure levels of the substances. This means that, because mucous membrane irritation is the most critical effect, the DNEL value for mucous membrane irritation will also protect against any other serious effects caused by higher exposure levels to the substance.

#### Exposure

The squishy is intended for children older than three years, but it is not unlikely that children younger than three years will also want to play with the squishy due to its appealing look and/or sensational experience. As a worst-case scenario, it is assumed that a child of three years will use the squishy. The size makes it unlikely that there will be oral exposure. The exposure will be greatest for contact with skin, for example when a child sleeps with the squishy in its arms. Moreover, exposure may take place through inhalation of substances released to the air.

On the basis of [Existing Default Values and Recommendations for Exposure Assessment](#), a realistic worst-case scenario is that a three-year-old child weighing 13.8 kg will sleep for ten hours a day with a squishy in its arms. It is also assumed that a resting/sleeping child will have an inhalation volume of 0.18  $\text{m}^3/\text{hour}$ . The surface area of the hands of a child of 2-3 years is 0.028  $\text{m}^2$ , and two hand palms therefore correspond to approx. 0.014  $\text{m}^2$ , i.e. 140  $\text{cm}^2$ . This is probably an underestimation, since the child is likely to sleep with the squishy in its arms, so that other skin areas will also be exposed.



The exposure calculations are based on the following:

Body weight: 13.8 kg  
 Exposure time: 10 hours/day  
 Surface area: 140 cm<sup>2</sup>  
 Inhalation volume: 0.18 m<sup>3</sup>/hour

Exposure is calculated as follows:

Exposure via inhalation (systemic uptake of N,N-dimethylformamide, 1 hour):

$$\frac{\text{concentration} \times \text{inhalation volume} \times \text{exposure time}}{\text{body weight}} = \text{exposure (inhalation, systemic)}$$

$$(6,5 \text{ mg/m}^3 \times 0,18 \text{ m}^3/\text{time} \times 10 \text{ hours/day})/13,8 \text{ kg} = \mathbf{0,8 \text{ mg/kg/day}}$$

Exposure via inhalation (locally eyes/respiratory tract of N,N-dimethylformamide, 1 hour): **6,5 mg/m<sup>3</sup>**

Total exposure (N, N-dimethylformamide, 1 hour): 0,8 mg/m<sup>3</sup> + 6,5 mg/m<sup>3</sup> = **7,3 mg/m<sup>3</sup>**

The table below shows the calculated exposures after 1 hour and 3 days:

Substance	Exposure [mg/m <sup>3</sup> ] 1 hour/3 days
N,N-dimethylformamide	7,3/3,4
N,N-dimethylaminoethanol	7,7/3,6
Triethylenediamine	4/3,3
Bis(2-(Dimethylamino)ethyl)ether	0,3/0,4
Cyclohexanone	6/6,3

#### Risk assessment

The risk is calculated using RCR, which is the ratio between exposure and DNEL. If RCR is above 1 and exposure therefore is higher than DNEL, there will be a risk.

$$\text{RCR} = \frac{\text{exposure}}{\text{DNEL}}$$

$$\text{RCR (N,N-dimethylformamide, 1 hour)} = \frac{7,3 \text{ mg/m}^3}{0,192 \text{ mg/m}^3} = 38$$

The table below shows the RCR values after 1 hour and after 3 days:

Substance	RCR 1 hour/3 days
N,N-dimethylformamide	38/17,7
N,N-dimethylaminoethanol	32,1/15
Triethylenediamine	235,3/194,1
Bis(2-(Dimethylamino)ethyl)ether	60/80
Cyclohexanone	6,1/6,4

#### Conclusion

It has been assessed that there is a serious risk of exposure to the substances in the squishy, if a 3-year-old child sleeps with the squishy in its arms for 10 hours a day for up to 3 days. The squishy must therefore not be sold.



## 11. When should a chemical safety assessment be updated?

A chemical safety assessment may need to be updated. As a manufacturer, you are obligated to repeat the assessment process for a toy, if you assess that the risk of chemical hazards may have changed.

### **The safety assessment must be updated when:**

- Changes are made to the materials of the toy and/or new chemical substances are used in the production of the toy, for example if a plastic material, a preservative or a colouring agent is replaced.
- The assessment of exposure to hazardous substances in the toy changes, for example if there is new knowledge that the child could come into contact with materials not previously assumed to be accessible, or if there is new knowledge about how the toy is used.
- New relevant legislation is introduced and you have to document that the toy complies with this.
- New toxicological data becomes available on the substances used, changing the hazard assessment.
- You receive complaints from consumers, for example that the toy has a chemical odour and easily breaks, so that the exposure changes.
- A similar product is withdrawn from the market, because a chemical risk has been assessed, for example a product made from the same materials.

It will be useful to set up a system for the work, for example procedures for how to collect and store documentation from your suppliers, how to monitor whether new legislation is issued or future legislation is in the pipeline, how to carry out a chemical safety assessment and when such assessment is to be updated.



## Section 2: For importers and distributors

### 1. How can you assess whether a declaration of conformity is adequate?

For all toy products placed on the market, the manufacturer must draw up a declaration of conformity, DoC, stating that the toy conforms with relevant EU legislation. The declaration of conformity must be written in either Danish or in English. Although this is not a requirement, it may be a good idea also to include relevant national legislation in the declaration.

If you are an importer, you should have declarations of conformity for all the toy products you import. It is sufficient for distributors to obtain declarations of conformity from their suppliers, if so requested by the authorities or customers.

Annex III to the Toy Safety Directive lists the eight points that the declaration of conformity must include, but it can still be difficult to assess whether a declaration is adequate. You can use the checklist below when assessing declarations of conformity. If you cannot answer yes to all the questions below, ask your supplier for a new declaration and/or documentation that supports the declaration, for example a test report.

#### Checklist for assessing declarations of conformity:

- Is there a unique identification number, so that there is no doubt that the declaration concerns the toy supplied?
- Is there a name and address of the manufacturer or some other person authorised to represent the manufacturer?
- Does the declaration of conformity state that the manufacturer is responsible for the declaration?
- Is there a colour image of the toy, and is it good enough for you to confirm that the toy and the declaration match?
- Is there a reference to the Toy Safety Directive (2009/48/EC with later amendments) and other relevant CE marking directives?
- Are there references to the relevant harmonised standards applied that support the relevant CE marking directives, or references to the specifications to which the declaration relates? Check the Official Journal of the European Union to make sure that reference is made to the existing version(s).
- Has the declaration been dated so that it can be assessed whether it is still up to date? Do you know whether any changes have been made to the production or product since the declaration was made, for example new materials, colours, sub-suppliers?
- If the toy has undergone EC-type examination, is there a name and address of the notified body that issued the certificate?
- Has the declaration been signed by the manufacturer, or has another person who you trust been authorised to sign on behalf of the manufacturer?

The manufacturer may prepare an overall declaration of conformity for a range of toy products made of the same materials but with different sizes or shapes, if the products are placed on the market simultaneously. Moreover, each product must still have its own unique identification number and colour image, and all products must be covered by the same EU harmonisation legislation and the same standards.

Example 6 shows a declaration for a wooden toy. The toy is considered as one product, although it contains three toys. If the three toys had been packaged and sold separately, they should have been marked with each their clear unique identification number. However, they could still have been covered by one overall declaration of conformity, because they had been made of the same materials and were covered by the same statutory requirements.



### Example 6: Declaration of conformity for a wooden toy

## EC declaration of conformity

**1. Unique identification: Ref. No.: 123456**

**2. Name and address of the manufacturer or his authorised representative:**

**Manufacturer:** Woodland toys ApS

**Address:** Plantagevej 1, 12941 Palmeby, Denmark

**3. This declaration of conformity is issued under the sole responsibility of the manufacturer:**

Woodland toys ApS, Plantagevej 1, 12941 Palmeby, Denmark

**4. Object of the declaration:**

Wooden stacking blocks, Ref. No: 123456



**5. The objects of the declaration described above are in conformity with the relevant EU harmonization legislation:**

Toy Safety Directive 2009/48/EC

**6. References to the relevant harmonised standards used, or references to the specifications in relation to which conformity is declared:**

Title	Reference
Safety of toys - Part 1: Mechanical and physical properties	EN 71-1:2014+A1:2018
Safety of toys - Part 2: Flammability	EN 71-2:2011+A1:2014
Safety of toys - Part 3: Migration of certain elements	EN 71-3:2013+A3:2018

**7. EC Type approval:** Not applicable

**8. Additional information:**

Palmeby 1/1-2019

\_\_\_\_\_ \_\_\_\_\_  
(place), (date)

Michael Woodland, CEO

\_\_\_\_\_ \_\_\_\_\_  
(name and function) (signature),



## 2. What do you do if you are not able to obtain a safety assessment from your supplier?

Whether you are an importer or a distributor, you are responsible for ensuring that the products you place on the market and sell are legal and safe. Importers should make sure that the manufacturer has made a safety assessment of the toy. However, distributors do not have the same responsibility. Nevertheless, if you are a distributor, it is also a good idea to check that your supplier has the safety assessment under control.

If you are an importer, you can ask the manufacturer whether you can have a look at the chemical safety assessment, even though the manufacturer is not obligated to provide this assessment. This applies in particular if you are uncertain as to whether a toy product complies with the chemical requirements. If you are not able to obtain the safety assessment from the manufacturer, you should ask specific questions regarding the substances in the materials of which you can see the product is made. You can also examine whether a material has a specific function and consider how this function has been achieved. For example, have chemicals been added to give the material a fragrance, preserve it, protect it against fire or against mould, make it soft, etc.? You can use the list in section 1, point 6, of examples of materials potentially containing prohibited, restricted or undesirable substances in your dialogue with your suppliers.

If you are not able to receive a satisfactory answer, you should consider choosing another supplier or have the product tested yourself. Below is a checklist of situations in which conducting your own tests is recommended.

### **Situations in which testing toys should be considered:**

- You are unsure whether you can trust the answers and documentation received from your supplier.
- Information about the substances in the materials used is not adequate.
- The supplier is new, and you therefore have no experience with this supplier.
- The toy has a "chemical" odour or oil-like "sweat".
- The toy is primarily used in children's inhalation zone.
- The type of toy is new, and you therefore have no experience with how this toy is used.

It may be useful to incorporate routine random checks of the supplied toy products into existing routines for quality control and supplier management. However, ultimately it is also about knowing your suppliers and having faith in them. It may also be useful to find out whether your suppliers have eco-management certifications or eco-labelling, as these could be good indicators for how well your suppliers manage their chemical safety assessments.



## List of abbreviations

**BOM:** Bill of materials

**BOS:** Bill of substances

**C&L Inventory:** Classification and Labelling Inventory (ECHA's inventory of classification and labelling of substances)

**CoRAP:** Community Rolling Action Plan

**DoC:** Declaration of conformity

**DNEL:** Derived No Effect Level (the level of a substance to which humans can be exposed with no effect)

**ECHA:** The European Chemicals Agency

**POP:** Persistent Organic Pollutants

**RAC:** The ECHA Committee for Risk Assessment

**RoHS:** Restriction of Hazardous Substances

**SDS:** Safety Data Sheets

**TRA:** Toxicological Risk Assessment

If you have any other questions or need guidance regarding the rules for chemicals in toys, please contact the Danish EPA at: [Legetoejpostkassen@mst.dk](mailto:Legetoejpostkassen@mst.dk)