



## EN 71-9 ORGANIC CHEMICAL COMPOUNDS: How to comply ?

*The European Toy Directive (88/378/EC) also regulates the chemical safety of toys. The essential safety requirements on chemical safety are: toys must not contain dangerous substances or preparations within the meaning of Directive 67/548/EEC in amounts which may harm the health of children using them. In fact this means that a manufacturer should risk assess any not-regulated substance used in the production of toys.*

In order to regulate and specify some risks to health the European Commission mandated the standardisation bodies (CEN) to develop specific requirements for certain organic chemical compounds commonly found in toys.

This resulted in 3 new standards in addition to the EN 71-series:

- ◆ EN 71-9: 2005 safety of toys: organic chemical compounds: requirements
- ◆ EN 71-10: 2006 safety of toys: organic chemical compounds: sample preparation and extraction
- ◆ EN 71-11: 2005 safety of toys: organic chemical compounds: test methods

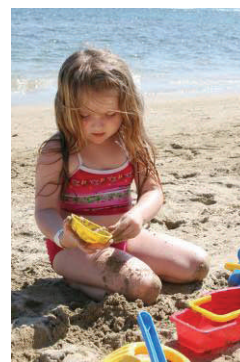
These standards outline the requirements for the usage of organic chemical compounds in toys.

### Legal status EN 71-9

A standard published by CEN does not automatically become a standard with reference to the Toy Directive. Only after publication in the Official Journal of the EU a standard is accepted as a way to show that essential requirements of the Toy Directive are met. Currently EN 71-9, -10 and -11 are "**voluntary standards**". This interim situation is confusing. Enforcement bodies in some Member States are known to have used EN 71-9 to withdraw products from the market, because EN 71-9 provides scientific evidence of dangerous substances.

Another discussion may influence the process as well.

At the moment the European Commission is reviewing the Toy Directive. The parts concerning the essential requirements on chemical safety are one of the major parts to be discussed and possibly changed.



### EN 71-9 standard

The standard EN 71-9 specifies the requirements for migration or content of certain hazardous organic chemical compounds from/in toys and toy materials by the following exposure routes:

- ◆ Mouthing
- ◆ Ingestion
- ◆ Skin contact
- ◆ Eye contact
- ◆ Inhalation

EN 71-9 regulates a total of 82 substances.

## What are the different ways to comply with the standard EN 71-9 ?

The standard EN 71-9 recognizes in annex B that there are different ways to comply with the standard. Not only sampling and testing in accordance to EN 71-9, EN 71-10 and EN 71-11, but also verification and assurance of conformity (supplier's declaration, certification); supported by the appropriate documentation can be used to assess conformity to the standard.

Below different ways of compliance are listed:

### 1) Sampling and testing in accordance with EN 71-9

This is the simplest to request for as it requires no more than samples to be sent in for analyses. The toy characteristics make out what testing is required. Some procedures will be simple and easy to comply with, but sometimes testing can be complicated, time consuming and costly.

### 2) Efficient compliance testing EN 71-9 (EC-9)

The standard is written bearing in mind a great variation of materials used in manufacturing toys. Efficient compliance testing is possible when information on the materials used can be provided. This can reduce the amount of testing enormously as only testing for relevant substances is needed.



### 3) Documentation review

To avoid testing of every single toy, the testing of raw material and processed material can be a solution. Documentation and tracking of every single material is not easy, but can reduce testing costs dramatically. The materials are tested at the lowest level of the production chain as possible. Review of renowned test reports and additional testing for missing information are part of the program.



### 4) Auditing

The auditing program gives full assurance setting up a 3<sup>rd</sup> party documentation, inspection, testing and tracking program. The full production process is reviewed, including supplier verification, material verification, document tracking, inspection, testing and process, product qualification systems are reviewed. The result is a certificate of compliance.

**SGS has full capability on EN 71-9 testing and services. For detailed information on the specific services developed for compliance with EN 71-9 please contact one of our toy labs.**

Please also refer to our SafeGuards 036/05 « EN71-9 organic chemical compounds in Toys » published in July 2005.

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