ETAD

Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers

SAFETY OF TOYS

ETAD RECOMMENDATION FOR "TOTAL" ELEMENT LIMITS FOR ORGANIC PIGMENT PRODUCTS SOLD INTO TOYS

August 13th, 2013

Regulatory background

In Europe, the comprehensive legislation addressing toy safety is the Toy Safety Directive (2009/48/EC) of the European Union, which replaces Directive 88/378/EEC. This directive applies to toy imports into or toys produced within the EU as of 20 July 2011, except for the chemical requirements of Annex II, which apply as of 20 July 2013.

The new Directive states that toys shall not present any risks of adverse effects on human health due to exposure to the chemical substances or mixtures contained in the toys. Compared to 88/378/EEC it brings, in particular, more references on certain chemicals by limiting their amount in materials used for toys; e.g.

- CMR (Carcinogenic, Mutagenic or toxic for Reproduction) substances are no longer allowed in accessible parts of toys
- certain heavy metals which are particularly toxic, like lead, may no longer be intentionally used in those parts of toys that are accessible to children
- And, as with the 1988 Directive there are limits on the amount of elements (heavy metals) that may migrate from the toy. These limits are now set for 19 elements and for 3 categories of toy materials and are more stringent.

Harmonised Toy Standards

A consequence of the new TSD was that the harmonised toy safety standards needed updating. The work of developing these new standards has been carried out by CEN/TC 52 WG5 "Safety of Toys, Chemical properties", of which ETAD is a member.

The new EN 71-3 "Migration of certain elements" has recently received a positive vote from the National Standards Bodies. The proposed method for determining migration from the final toy involves extraction of the soluble elements from *toy materials* using conditions which simulate the material remaining in contact with gastric juices for a period of time after swallowing. So in essence it uses the same principle as with the earlier version. However the new limit values require that significantly more sensitive methods are used for analysis of the migration solution. A recent Round Robin Trial showed that the proposed method lacked the required reproducibility. Further none of the analytical methods evaluated had the necessary sensitivity for Cr(VI) for Category I and Category II toys, also it has been shown that during migration Cr(VI) can transform to Cr(III). Work on a revision has been immediately launched.

Assessing conformity by testing according to EN 71-3 is not mandated by TSD. The standard now includes other ways of confirming compliance.by e.g. the use of suppliers' declarations.

However simply passing the onus on providing data up the supply chain does not solve the compliance problem. On one hand assessing migration into simulated gastric juice from a hydrophobic organic pigment raises some considerable experimental problems that would need to be solved e.g. complete wetting of hydrophobic powders, contact time etc. On the other hand the pigment's leaching properties in the final toy matrix can be influenced during processing especially by comminuting, chemical and thermal action as well as by the interaction of other components which could lead to an increased migration.

The TSD places that the responsibility for ensuring compliance rests with the economic operator

ETAD recommendation

ETAD member companies do their utmost to ensure that the necessary information is available for their products to allow purchasers to make informed decisions and to meet their obligations.

Having regard to the concerns outlined in the previous section regarding the migration of certain elements from colourants, ETAD is recommending limits on the total content of the elements specified in 2009/48/EC for the organic pigment products that are sold into toys.

The "Total Element Content" of a product comes from the presence of unavoidable trace impurities e.g. those ubiquitous heavy metals that are now present in the environment coming both from natural sources as well as from anthropogenic sources, and the presence of a metal as an inherent part of the molecular structure. Trace impurities will be present to a greater or lesser extent in every product.

These limits have been derived from the TSD migration limits for the final toy taking into account the usual colourant loadings in toys. This information can then be used by the toy manufacture to assess the conformity of his toy with the TSD requirements. It must clearly be emphasised again that it remains the responsibility of the economic operator placing the article on the market to ensure compliance with all aspects of the Toys Safety Directive.

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(These limits do not apply to products containing a listed element as an inherent part of the molecular structure or formula See Note 1)

ELEMENT	ETAD RECOMMENDED TOTAL LIMIT ppm
Aluminium	1000
Antimony	100
Arsenic	10
Barium	100
Boron	250
Cadmium	5
Chromium (III)	Not specified covered by Cr (III + VI)
Chromium (VI)	Not specified covered by Cr (III + VI)
Chromium (III and VI) (see note 2)	10
Cobalt	25
Copper	1000
Lead	50
Manganese	1000
Mercury	25
Nickel	100
Selenium	100
Strontium	1000
Tin	1000
Organic Tin	N/A covered by Tin metal entry.
Zinc	1000

Note 1**.** . This includes as examples but is not limited to:

- Copper Phthalocyanines, e.g. C.I. Pigment Blue 15, C.I .Pigment Green 7, C.I. Pigment Green 36
- Metal lakes based on Barium and Strontium, e.g.
  C.I. Pigment Red 48:1, C.I. Pigment Red 48:3, C.I. Pigment Red 49:1, C.I. Pigment Red 49:3, C.I. Pigment Red 53:1,

Note 2. The total limit value proposed here covers not only Cr(III) and Cr(VI) but all the possible oxidation states of Chromium as well as any trace chromium as metal which may result from the manufacturing equipment