Verband der
Mineralfarben-
industrie e. V.

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Position Paper
of Verband der Mineralfarbenindustrie e. V. (VdMi)
on the Toys Directive:
Use of Pigments in Toys

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Directive 2009/48/EC of 18 June 2009 on the safety of toys, which are manufactured or imported in the EU, already applies as from 20 July 2011. A transitional period of four years was granted for chemical requirements; that transitional period ended on 20 July 2013. At the same time, the "old" standard EN 71-3:1994 was repealed.
Since that date, solely the new requirements are applicable.

Pigments – both inorganic and organic – are used for colouring toys or components of toys. According to the New Toys Directive, toys are understood to mean *"products designed or intended, whether or not exclusively, for use in play by children under 14 years of age"* (Article 2).
In the past, it was common practice to transfer the limit values – as laid down for toys in the "old" standard EN 71-3:1994 – also to colourants (e.g. pigments) and fillers.

Chemical requirements to toys

Toys and their components must not contain any substances that are classified as carcinogenic, mutagenic or toxic for reproduction (CMR) under the CLP Regulation (EC) 1272/2008 or Directive 1999/45/EC.

The New Toys Directive 2009/48/EC tightens – partly considerably – the chemical requirements to toys and their components.

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Annex II Particular safety requirements, III chemical requirements of Directive 2009/48/EC, migration limits from toys or components of toys (as compared with EN 71-3:1994)

Element	ppm in dry, brittle, powder-like or pliable toy material (category I)	ppm in liquid or sticky toy material (category II)	ppm in scraped-off toy material (category III)	ppm in toy material EN 71-3:1994
Aluminium	5625	1406	70000	
Antimony	45	11,3	560	[60]
Arsenic	3,8	0,9	47	[25]
Barium	4500	1125	56000	[1000]
Boron	1200	300	15000	
Cadmium*	1,3	0,3	17	[75]
Chromium (III)	37,5	9,4	460	[60]
Chromium (VI)	0,02	0,005	0,2	
Cobalt	10,5	2,6	130	
Copper	622,5	156	7700	
Lead	13,5	3,4	160	[90]
Manganese	1200	300	15000	
Mercury	7,5	1,9	94	[60]
Nickel	75	18,8	930	
Selenium	37,5	9,4	460	[500]
Strontium	4500	1125	56000	
Tin	15000	3750	180000	
Organic tin compounds	0,9	0,2	12	
Zinc	3750	938	46000	

* Lower limit values for cadmium according to Directive 2012/7/EC amending Directive 2009/48/EC

Now the New Directive on the safety of toys (2009/48/EC) contains – for three categories of toys or toy components – maximum migration limits, namely for 19 elements (inter alia, heavy metals). They are intended to minimize the exposure of children to these elements. The maximum limits (in mg/kg) refer to the toy or to the toy component.
The permitted maximum migration limits depend on the type of toy material (category I: dry, brittle, powder-like or pliable toy material; category II: liquid or sticky toy material; category III: scraped-off toy material).

These extended requirements to the chemical properties of toys or toy components are described in Annex II part III of Directive 2009/48/EC; they apply as from 20 July 2013.
Another lowering of limit values (e.g. for barium) is currently under discussion.

Scope of Application of the Toy Standard

Under the “old” Toys Directive 88/348/EEC (fully repealed as from 20 July 2013), the detailed requirements for the safety of toys were laid down in the standard series EN 71- (safety of toys). This standard series needed to be revised recently in the light of the New Toys Directive 2009/48/EC.

The new EN 71-3 (date of issue: July 2013; EN 71-3:2013) has been published, describing the requirements to and the test methods for the migration of the 19 elements for the three categories of toys or toy components.

The limit values for the migration of these elements are stated in mg/kg of toy or toy component. Thus, the limit values do not refer to the colouring component (pigment). In the further processing stages, pigmentation is usually between 0.1 and 40%, depending on the use (e.g. master batch, coating, printing ink).

In the past, pigment manufacturers tested numerous products directly as regards the earlier named eight maximum migration limits of EN 71-3:1994, even though that "old" version of EN 71-3 only provided for testing in the finished product. On that basis, processors obtained a declaration of compliance with the standard, ensuring use in the downstream supply chain.

The following should be noted: Also in the past, the mentioned testing of pigments did not release the manufacturers of finished products (here: manufacturers of toys or toy components) from their testing obligation under the Toys Directive.

Conclusions

According to the New Toys Directive 2009/48/EC, now maximum limits are applicable for the migration of 19 elements (inter alia, heavy metals), each for three categories of toys. Therefore, it will be no longer possible to transfer the relevant requirements to pigments in the same way as it was done in the past.

It has already emerged that this large number of elements cannot be analysed without very sophisticated effort and, in some cases, the methods laid down in the standard EN 71-3:2013 cannot be applied directly to a pigment-specific matrix.

Given the nature of pigments and irrespective of the fact that manufacturing processes are meticulous, ubiquitous trace impurities – which per se can be above some of the maximum limits – are impossible to avoid. For example, the value for selenium is 9.4 / 37 or 460 ppm, depending on the toy material. In such conditions, a pigment might still comply with the value of toy category III (in this case: 460 ppm) but not with the values of the other two categories.

In particular with the very low limits of categories I and II, testing of the pigment does not necessarily enable the conclusion that the migration values can be complied with in the testing of the finished product too. Migration values can be influenced during processing in toy production – both by matrix-related effects and ion effects (solubility product).

Chromium (VI) is a special case. As described in Annex I to EN 71-3:2013, for chromium (VI) the detection limit is higher than the migration limit for toy materials of categories I and II. For organic pigments see *ETAD Recommendation for "Total" Element Limits for Organic Pigments Products Sold Into Toys.*

This means that the formerly common practice, where the raw material manufacturer generally confirms compliance with all values to the processor, will be no longer workable in this form.

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