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Safety of toys —

Part 3: Migration of certain elements

AMENDMENT 1: Limits for boron and other elements in slime, and barium in modelling clay

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Foreword

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This document was prepared by Technical Committee ISO/TC 181, *Safety of toys*.

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Safety of toys —

Part 3:
Migration of certain elements

AMENDMENT 1: Limits for boron and other elements in slime, and barium in modelling clay

Introduction

Add the following content below "— 25,0 µg for barium;".

— 30,0 µg for boron;

Clause 3

Add the following terminological entries.

3.13
slime
water-based gel or gel like material, clear or coloured, which is viscous, slippery, and often non-Newtonian fluids, intended for play by hand manipulation, kneading and stretching

Note 1 to entry: A material behaving in a non-Newtonian manner will have a change in viscosity, i.e. become more or less viscous, when subjected to shear forces such as manipulation, with such a change being reversible when the shear forces cease to be applied.

3.14
modelling clay and putty
flexible solid or semi-solid mixtures that retain their shape and form when moulded into a shape, intended to create representations of objects by hand manipulation or to be extruded into profiles by the toy

4.2

Replace Table 1 with the following table.

Table 1 — Maximum acceptable element migration from toy materials

Values in milligrams per kilogram of toy material

Toy material	Element								
	Sb	As	Ba	Cd	Cr	Pb	Hg	Se	B
Any toy material given in Clause 1, except modelling clay and putty, finger paint, and slime	60	25	1 000	75	60	90	60	500	-
Modelling clay and putty	60	25	350	50	25	90	25	500	3 750
Finger paint	10	10	350	15	25	25	10	50	-
Slime	10	10	350	15	25	25	10	50	1 250

Replace Table 2 with the following table.

Table 2 — Analytical correction

Element	Sb	As	Ba	Cd	Cr	Pb	Hg	Se	B
Analytical correction (%)	60	60	30	30	30	30	50	60	60

9.8.1

Add the following paragraph after the second paragraph.

Slime is not to be dewaxed.

D.3

Add the following text after the list item.

The maximum acceptable level of soluble barium in modelling clays has been raised from 250 mg/kg to 350 mg/kg for the following reasons:

— Previous versions of this document have had an anomaly whereby the maximum acceptable element migration for barium in modelling clays was lower than for finger paints.

— The exposure from modelling clay is likely to be lower than from finger paints due to the nature of the material and the age at which children start playing with clay.

— The increase to 350 mg/kg of toy material is a pragmatic solution to resolve the anomaly and based on the accepted maximum intake of barium from toy sources, the adjusted limit still provides an acceptable margin of safety determined by bioavailability and risk models.

The maximum acceptable level of boron has been added in modelling clay, putties and slime for the following reasons:

— Boron may be present in certain types of toy material in the form of boric acid or borates and is used to facilitate cross-linking of polymers as seen in certain putties and slime toys.

— The critical adverse effect of boron is reproductive and developmental toxicity, and it is therefore appropriate to provide safe limits for the exposure of children to boron in toys.

— The tolerable daily intake (TDI) of boron has been determined by the World Health Organisation to be 160 µg/kg of bodyweight per day [9].

— Adult exposure to boron from the diet and drinking water has been estimated as 1 200 µg per day. Child exposure from these sources is estimated to be 600 µg per day. As a principle, exposure to boron from toys should not exceed 10 % of the daily intake however, this may be modified depending on exposure from other sources and toxicity.

— Children are unlikely to be exposed to boron from sources other than the diet and drinking water. Based on a 10 % contribution from toys total exposure is predicted to be lower than the TDI for boron so no modification is required for concurrent exposure.

— However, due to the reproductive and developmental toxicity of boron and taking early life stage susceptibility into account, an additional safety factor is justified. The limit for contribution from toys has been set at 5 % of daily exposure or 30 µg per day to account for this susceptibility.

— For determining a limit value, only oral exposure is relevant since boron is poorly absorbed through the skin. Combining the daily exposure with the average daily intake of the various toy materials of 8 mg/d, a limit of 3 750 mg/kg of toy material can be calculated.