Boron in Viscous Masses Such As Toy Slime and Bouncing Putty - Health Impairments for Children Are Not Considered Likely

Viscous masses such as toy slime, bouncing and intelligent putty are particularly popular with children because of their consistency. To create the slimy form, toy manufacturers might use the chemical element boron in the form of boric acid or sodium borate during the production process. Boric acid can enter the human body through oral ingestion or contact with the skin during play. The German Federal Institute for Risk Assessment (BfR), therefore, performed a health risk assessment for children due to contact with boron from viscous masses.

Assessment Outcome:
The probability that accidental swallowing of a larger amount of a viscous mass will result in an acute health impairment is very low. The probability of adverse health effects increases only when the amount of boron migration (i.e., the amount of boron released from the material) is elevated to almost 40 times the limit value of 300 mg/kg for liquid/sticky toy material given in the European Toy Safety Directive (TSD). However, the BfR is of the opinion that it is unlikely that children will inadvertently swallow large amounts of viscous mass that show such a high level of boron migration. According to the labelling, most of these toys are not suitable for children under the age of three years. The BfR has calculated that children aged three to six years (15.7 kg bodyweight) can swallow up to 58 milligrams (mg) of boron with a low probability of acute adverse health effects (poisoning). In the event that higher amounts are ingested, gastrointestinal effects such as nausea with vomiting, diarrhoea or abdominal pain can occur as initial symptoms of acute poisoning.

When considering the continuous intake of boron arising from an assumed daily intake via swallowing of 400 mg of viscous mass and from intensive skin contact, the BfR bases its approach on the ADI value derived by the European Food Safety Authority (EFSA). The ADI value indicates the acceptable daily intake that can be taken throughout life without the likelihood of adverse health effects. Thus, the amount of boron that can be released from the material is ≤2,950 mg per kilogram (mg/kg) of viscous mass. The absorption of boron through the skin, for example due to intensive contact with the palms of the hands during play, accounts for only a fraction of the total intake from viscous masses. Model calculations by the BfR estimate this proportion at around six percent. Study data from the 2017 Federal Monitoring Plan (BÜp) show that around 80% of the viscous masses tested complied with the legal limit value of 300 mg/kg for boron migration of liquid/sticky toy material.

Manufacturers are obliged to comply with the legal limit values for boron migration. Parents are advised to follow the manufacturer's recommendations concerning the minimum age at which a child should start playing with viscous masses. Viscous masses are mainly sold with a label stating that they are not suitable for children under the age of 36 months. Parents should also make sure that the child does not put the viscous mass in its mouth in order to ensure minimal contact to boric acid.

BfR	BfR risk profile: [Swallowing or skin contact with boric acid released from a viscous mass (e.g. toy slime, bouncing putty)] (Opinion number 013/2022)				
A Affected persons	**Children**				
B Probability of a health impairment via swallowing or skin contact with boric acid released from viscous mass	**Very low**	Low	Middle	High	Very high
C Severity of health impairment from swallowing or skin contact with boric acid released from viscous mass [1]	No impairment	**Mild impairment [reversible]**	Moderate impairment [reversible/irreversible]		Severe impairment [reversible/irreversible]
D Validity of available data	**High: The most important data are available and are internally consistent**	Medium: Some important data are missing or inconsistent		Low: A large volume of important data is missing or inconsistent	
E Controllability by the consumer [2]	Controls not needed	**Controllable with precautionary measures**	**Controllable through avoidance**	Not controllable	

Explanations

The risk profile is intended to visualise the risk outlined in the BfR Opinion. The profile is not intended to be used to compare risks. The risk profile should only be read in conjunction with the corresponding Opinion.

Row C - Severity of health impairment from swallowing or skin contact with boric acid released from viscous mass
[1] – The information in the risk profile refers to the assessment of potential acute exposure: In the event of a single, accidental swallowing of a large amount of viscous mass (5 g) with a boron migration of more than 11,600 mg/kg, the probability of the occurrence of acute, negative health effects such as nausea with vomiting, diarrhoea or abdominal pain increases; these effects are reversible. In contrast, the negative health effects of chronic exposure on which the assessment is based separately are partially irreversible. However, the probability of occurrence of such effects due to the use of viscous masses containing boron is considered to be very low, taking into account the very conservative assumptions on which the exposure assessment is based.

Row E - Controllability by consumers
[2] – Manufacturers are obliged to comply with the legal limit values for boron migration. Parents are advised to follow the manufacturer's recommendations concerning the minimum age at which a child should start playing with viscous masses. Viscous masses are mainly sold with a label that states that they are not suitable for children under the age of 36 months. Parents should also make sure that the child does not put the viscous mass in its mouth in order to ensure minimal contact to boric acid.

Details given in the row 'Controllability by the consumer' are merely descriptive and not to be understood as a recommendation by the BfR. The BfR has given recommendations for action in its opinion.

1   Subject of the Assessment

The BfR has assessed the health risk for children posed by boron contained in viscous masses. The regional authorities of the German federal states ("Laender") have provided data on the boron migrations measured in toy slime (see Table 1). Based on this, the BfR considered (oral) intake via swallowing of a viscous mass and potential (dermal) uptake via skin contact.

Boron in the form of boric acid or sodium borate (borax) can be used in viscous masses such as toy slime and bouncing putty to cross-link macromolecules and thus to give these products a certain consistency. According to the labelling, most of these toys are not suitable for use by children under the age of three years.

Boric acid (CAS No. 10043-35-3 and 11113-50-1) and various borates have a harmonised classification according to Table 3.1 Annex VI of Regulation (EC) No. 1272/2008 (CLP Regulation) as being toxic to reproduction category 1B (Repr. 1B) and are labelled with the H360FD hazard statement ("May damage fertility. May harm the unborn child.").

The Toy Safety Directive 2009/48/EC (TSD) sets migration limits for elemental boron from toys or toy components, e.g. 300 mg boron/kg of liquid and/or sticky and 1,200 mg boron/kg of dry, brittle, powder-like or pliable toy materials. Viscous masses are assigned to one of these toy material categories depending on the specific nature of the product. The BfR assessment relates to those products that may be assigned to the liquid/sticky material category. The term "boron migration" refers to the amount of boron that can be released from a viscous mass under certain conditions.

2   Results

The BfR has come to the conclusion that the probability of acute health effects arising from a single (accidental) ingestion of a larger quantity (5 g) of viscous mass is very low, provided that the release of boron from the product is less than 11,600 mg per kg toy material. The migration data provided by the state authorities were below this value. The probability of the occurrence of chronic health effects from oral and dermal intake of boron arising from long-term, daily use of viscous masses such as toy slimes, which are categorised as liquid/sticky materials, is very low, provided that the boron migration is less than 2,950 mg/kg. The migration data submitted by the state authorities exceeded this value in the case of two toy products. In addition to the intake from viscous masses, consideration is also given to the background exposure, i.e. the intake of boron via, for instance, food.

Based on the reported values for the migration of boron from viscous masses in gastric acid simulant, exposure and resulting risk assessments for boron intake were performed for children aged 3 to 6 years with a bodyweight of 15.7 kg. Here, it was assumed that the products in focus can be assigned to the category of liquid and/or sticky toy material. During the assessment, consideration was given to the probability that acute and chronic adverse health effects could occur. In case of acute exposure, boron intake was estimated based on a single (accidental) ingestion of a large amount of viscous mass, while in case of continuous intake, consideration was given to total exposure from both oral and dermal uptake pathways, including background exposure from other sources.

The migration data for boron from viscous masses sent to the BfR and determined in accordance with the European standard EN 71-3 (DIN 2019) were in the range of 580 - 6,384 mg/kg. The study conditions simulate how much boron migrates from a viscous mass into gastric acid during passage through the stomach. To estimate oral exposure, it is assumed that the boron released is completely absorbed systemically. Furthermore, these migration data were also used for the estimation of dermal intake, since analysis data with sweat simulation are not available.

The first symptoms of acute poisoning after swallowing of boron can be gastrointestinal effects such as nausea with vomiting, diarrhoea and abdominal pain. The dose up to which no symptoms were reported in adults is reported by the EU Scientific Committee on Consumer Safety (SCCS) as being 3.7 mg boron/kg bodyweight (bw) and is used here as reference value to rule out acute effects. Due to the lack of data, it is also assumed that this dose does not lead to symptoms in children either. Hence, for a child weighing 15.7 kg, the amount up to which no acute health effects are likely is 58 mg boron.

For the product exhibiting the highest reported boron migration of 6,384 mg/kg, an intake of up to 9.1 g of viscous mass would lead to a very low probability that acute negative health effects will occur. The BfR considers it unlikely that a child could accidentally swallow such a large amount of viscous mass while playing. If it is assumed that the maximum amount of viscous mass that can be accidentally swallowed in a single event is 5 g, a reverse assessment approach would require a boron migration of at least 11,600 mg/kg for an acute risk of

negative health effects to transpire. The migration data transmitted by the state authorities to the BfR were below this value. RAPEX notifications published in the EU Safety Gate for the years 2015-2021 also did not report on a ready-to-use viscous mass which exceeded this value.

To assess chronic effects, the value derived by the European Food Safety Authority (EFSA) for the acceptable daily intake (ADI) of 0.16 mg boron/kg bodyweight (bw) per day was used as reference value based on a developmental toxicity study in rats.

In order to estimate the continuous boron intake through daily use of viscous masses, the BfR assumes that a small amount of toy material (400 mg) is swallowed daily, while intensive skin contact with the palms of the hands is taken into account to estimate dermal intake. The product with the highest reported boron migration of 6,384 mg/kg slightly exceeded the ADI by 9% when estimating total exposure from oral and dermal intake; the addition of the background exposure led to an exceedance of the ADI by 58%. Dermal absorption only accounts for around 6% of the estimated total intake from viscous masses. A reverse assessment approach showed that up to a migration level of 2,950 mg/kg, no chronic health risk arises, since it does not lead to exceedance of the ADI even under conservative assumptions and accounting for background exposure. Exceeding the ADI when neglecting background exposure requires a boron migration of at least 5,900 mg/kg.

Since the ADI is regarded as a dose that can be ingested over a lifetime without the likelihood of incurring health effects, exceeding the value in the short-term is undesirable from a risk assessment point of view. However, the resulting risk of chronic effects is still classified as being low.

Data from the 2017 Federal Control Plan (Bundesweiter Überwachungsplan, BÜp) have shown that compliance with the migration limit values for boron from viscous masses is possible in practice and can, therefore, be implemented by the manufacturer.

3   Rationale

3.1   Risk assessment

3.1.1   Hazard identification

Boric acid, its salts (borates) and esters have an influence on consistency and possess flame-retardant, antiseptic and preservative properties. They are used, for instance, in glass production, as flame retardants, as biocidal wood preservatives and in fungicides, insecticides and herbicides, both for agricultural and non-agricultural applications. In medicines such as eye and ear drops, boric acid and borates are used as excipients, e.g. as antimicrobial preservatives, and to adjust pH and tonicity (EMA, 2017). As a food additive, boric acid (E 284) and sodium tetraborate (borax; E 285) are only permitted in the EU for the preservation of caviar (EU, 2008b). In food contact materials, boric acid and borax are permitted as monomers and additives for plastic materials and articles according to Regulation (EU) No. 10/2011.

In viscous masses such as toy slime and bouncing putty, boric acid and borax can be used to cross-link macromolecules (e.g. polyvinyl alcohol, polysiloxanes), thereby giving these products their consistency (Lembens und Abels, 2016). Crosslinking is based on a condensation reaction with the formation of oxygen bridges. There is no clear conceptual distinction between the various products of viscous masses. According to Lembens and Abels, toy

slime mainly consists of polyvinyl alcohol, while (bouncing) putty consists of polydime-thylsiloxane molecules. In this opinion, these are collectively referred to as viscous masses for the sake of simplicity.

Boron does not occur in its elemental form in the environment, but primarily in combination with oxygen in compounds such as boric acid, its salts (borates) and esters. Boric acid is a very weak acid (pK_s = 9.25). In low-concentration aqueous solutions below pH 7, boric acid is mainly present in undissociated form as orthoboric acid $B(OH)_3$; above pH 10 the tetrahy-droxoborate ion $B(OH)_4^-$ dominates. The toxicological properties of the various boron compounds are considered to be similar when present as aqueous solutions at comparable pH and boron content (WHO, 2009).

Due to its natural occurrence in groundwater, boron forms part of the diet, especially that of plant origin. Hence, food is a major source of exposure for the general public; in a US Total Diet Study from the early 1990s, the average dietary boron intake for adults was estimated at 0.9–1.2 mg/day (Anderson, Cunningham et al., 1994). However, the increased consumption of individual, boron-rich foods such as avocados, and of drinking and mineral water enriched with boron, leads to a significant increase in dietary boron intake (RIVM, 2008; EFSA, 2013). In addition, dietary supplements and additives, food contact materials and other consumer products provide other possible sources of boron intake. It is estimated that an average of 0.1 mg boron/day is ingested via consumer products (EFSA, 2013).

In 2004, EFSA derived an acceptable daily intake level (ADI) of 0.16 mg boron/kg body-weight (see 3.1.3.5) (EFSA, 2004). The Dutch National Institute for Public Health and the En-vironment (RIVM) assumes the background exposure for children to be 0.08 mg boron/kg bodyweight per day (RIVM, 2008). Data from an international survey from the late 1990s also revealed an average boron intake for 4-8 year old children in Germany of 1.17 ± 0.47 mg bo-ron per day (Rainey und Nyquist, 1998), which for a child weighing 15.7 kg (3–6 years) corre-sponds to a dose of 0.075 ± 0.03 mg/kg bodyweight per day.

In its assessment, the BfR therefore considers a background exposure for children aged three to six years of 0.08 mg boron/kg bodyweight per day.

3.1.2 Regulation of boron in toys

According to the CLP Regulation (EU, 2008a), boric acid and its borates have a harmonised classification as being toxic to reproduction category 1B (Repr. 1B). According to Annex II Section III of the Toy Safety Directive 2009/48/EC (EU, 2009), the use of carcinogenic, muta-genic and reprotoxic (so-called CMR) substances in toys is prohibited unless, amongst oth-ers, these substances are contained in individual concentrations that are below the relevant classification concentrations of the CLP Regulation. Here, specific concentration limits (SCLs) are currently set for boric acid and its borates; in case of boric acid, the SCL is ≥ 5.5%, which corresponds to a boron content of 1%. However, in November 2018, Sweden submitted a proposal for the harmonised classification and labelling (CLH proposal) with the aim of replacing the SCLs for boric acid and its borates by the general concentration limit of ≥ 0.3% for substances toxic to reproduction category 1A or 1B (ECHA, 2018). The Risk As-sessment Committee (RAC) and the European Commission supported this proposal. With the 17th Amendment to Technical and Scientific Progress (ATP), which came into force on June 16, 2021, the SCLs from Annex VI for boric acid and six other borates were conse-quently deleted (EU, 2021). Thus, the generic concentration limit of ≥ 0.3% will apply to these substances from December 17, 2022.

In addition to the concentration limit, the Toy Safety Directive also sets migration limits for boron for the various toy material categories, which are currently set at 1,200 mg/kg for dry/brittle/powder-like/pliable, 300 mg/kg for liquid/sticky and 15,000 mg/kg for scraped-off

toy material. Depending on the specific nature of the product, viscous masses are either assigned to the dry/brittle/powder-like/pliable or liquid/sticky toy material category.

3.1.3 Hazard characterisation

3.1.3.1 Oral and Dermal Absorption

Soluble boron compounds are almost completely systemically available after oral intake (WHO, 2009). The dermal absorption rate, however, is low. It is often given as 0.5% in the literature. This dermal absorption value was derived from an *in-vivo* study on eight volunteers receiving a 5% aqueous solution of isotopically-labelled boric acid that was applied non-occlusively to a 30 cm × 30 cm area (2 µL solution per cm^2) on their backs (Wester, Hui et al., 1998). 24 hours after application, the exposed skin area was washed thoroughly to remove any unabsorbed residues. Urinary excretion of boron was determined over a period of six days following dermal exposure. During this period, 0.23 ± 0.13% (mean ± standard deviation) of the dermal dose was excreted via urine. A permeability coefficient (K_p) of 1.9×10^{-7} cm/h was obtained for the selected concentration (5% boric acid solution) and the applied volume per area of 2 µL/cm^2 (finite dose). The SCCS derived a value of 0.5% for dermal absorption from the *in-vivo* study (Wester, Hui et al., 1998) to calculate exposure via cosmetic products, based on the mean plus twice the standard deviation (0.23 + 2 × 0.13%) (SCCS, 2010).

The dermal absorption of boric acid was also measured *in vitro* on human skin samples using a flow-through diffusion cell over 24 hours. The skin samples were trimmed with a dermatome to a thickness of 500 µm (Wester, Hartway et al. 1998, Wester, Hui et al., 1998). The application of 2 µL/cm^2 (finite dose) of a 5% aqueous boric acid solution resulted in a dermal absorption of 1.75% and a K_p value of 1.4×10^{-6} cm/h. In contrast, the application of 1,000 µL/cm^2 (infinite dose) of various diluted boric acid solutions (0.05%, 0.5%, 5%) resulted in dermal absorption values of 0.28–1.20% and K_p values of $1.2–5.0 \times 10^{-4}$ cm/h (average: 3×10^{-4} cm/h).

The permeability coefficient (K_p) normalises dermal absorption by dividing the dermal flux rate under steady-state conditions by the concentration of the test substance. The mean K_p value of 3×10^{-4} cm/h is considered to be the best representative value for dermal absorption of boric acid under infinite dose conditions (Wester, Hartway et al. 1998, Wester, Hui et al., 1998). Under these conditions, a chemical is available in unlimited quantities for dermal uptake throughout the exposure phase. A corresponding exposure scenario would be, for example, to immerse a hand in a bath containing boric acid for a long time. In the absence of product-specific data, the dermal absorption of boron from a viscous mass is estimated to correspond to an aqueous boron solution under *infinite dose* conditions.

3.1.3.2 Toxicokinetics

The oral administration of boric acid or borates in animal experiments leads to the uptake of boric acid into the blood compartment, where under physiological pH conditions (due to its high pK_s value of 9.25) it is largely present as orthoboric acid $B(OH)_3$. From the blood compartment, undissociated boric acid gets evenly distributed throughout the various soft tissues, with the exception of lower levels in adipose tissue. The low tendency of boric acid to partition from blood plasma into adipose tissue is consistent with the negative *n*-octanol-water partition coefficient (log K_{OW}) of -1.09 at 20 °C and pH 7.5 (ECHA, 2011). Distribution into bone tissue leads to an accumulation of boron in bone. For example, after seven days of oral administration of boric acid (corresponding to 93–96 mg boron/kg bodyweight per day) in rats, a value of 47.4 µg boron per gram bone tissue was measured which was two to three times higher than measured in plasma (Moore, 1997). Even after a 32-week follow-up period,

during which no further boric acid was administered to the rats, the boron concentration in bone tissue was still 3 times higher than that of the control animals (Chapin, Ku et al., 1997).

The ability of boric acid to form esters with OH groups of other molecules may be related to the accumulation of boron in bone. There is experimental evidence that boron can stimulate bone growth through a variety of mechanisms (Gaffney-Stomberg, 2019). These include increased intestinal resorption of bone-forming minerals, an interaction with the metabolism of vitamin D, and the stimulation of the proliferation of mesenchymal stem cells as the precursor cells of osteoblasts.

Data on boron distribution in the human body are limited. Boron compounds cross the human placenta (FSA, 2003) and are excreted in breast milk (Hunt, Butte et al., 2005).

Animal and human experimental studies on the elimination and excretion of boric acid and borates are available. These show that most of the orally ingested boron is excreted unchanged in the urine within a relatively short period of time (FSA, 2002). Human studies with intravenous injection and oral administration of boric acid revealed a mean biological half-life of 21 h (Jansen, Andersen et al., 1984, Schou, Jansen et al., 1984).

3.1.3.3 Acute Toxicity

The acute toxicity of boric acid and borax in rats and mice can be described as moderate with LD_{50} values of 400–700 mg boron/kg bodyweight (Weir and Fisher, 1972). The LD_{50} value depicts the dose at which 50% of the test animals died after oral intake of the substance. In humans, potentially lethal oral intakes of boric acid are generally given as 3–6 g for small children (corresponds to approx. 0.5–1 g boron) and 15–20 g for adults (Litovitz, Klein-Schwartz et al., 1988, EFSA, 2013).

An analysis of data from US poison centres from the 1980s revealed 784 cases of oral exposure to boric acid (Litovitz, Klein-Schwartz et al., 1988). With the exception of two cases, these were acute ingestions. The median age was two years (age range: two weeks to 98 years); children under the age of six accounted for 80.2% of cases. Most cases (692) were asymptomatic. The most frequently reported symptoms were diarrhoea, nausea, vomiting and abdominal pain; (mild) effects on the central nervous system in the form of dizziness, headache and lethargy were observed more rarely. The amount of boric acid swallowed by children under the age of six ranged from 10 to 22,200 mg (mean: 500 mg). This corresponds to 2 – 3,900 mg (mean value: 87 mg) of boron. In the overall group of patients with clinical symptoms (all age groups), ingested amounts were between 100 and 55,500 mg boric acid (mean value: 3,200 mg). This corresponds to 17 – 9,700 mg (average: 560 mg) of boron. These data display high inter-individual variation. For patients with a boron dose of up to 200 mg/kg bodyweight who weigh less than 30 kg, their observation rather than therapeutic intervention is recommended. For a 15.7 kg child, this corresponds to a dose of up to 3,140 mg of boron.

The SCCS reported acute oral intake levels of 1.4–70 mg boron/kg bodyweight (SCCS, 2010) for adults, with cases of oral intake of less than 3.7 mg boron/kg bodyweight being asymptomatic.

Conclusion: The BfR considers a dose of 3.7 mg boron/kg bodyweight as a suitable reference value to assess the risk of acute effects after accidentally swallowing a large amount of viscous mass. It is assumed that this dose is also asymptomatic in children. Below this dose, the probability of occurrence of undesirable, acute health effects is very low.

3.1.3.4 Repeated Dose Toxicity

Available animal studies do not provide any indication of mutagenic, genotoxic or carcinogenic effects of inorganic boron compounds (FSA, 2003). However, boric acid and borates are toxic to reproduction and development (EU, 2008a).

In a study on chronic health effects in rats with oral administration of boric acid via food, the highest boron dose of 58.8 mg/kg bodyweight per day led to reproductive toxic effects in male and female animals (sterility, absence of spermatozoa, testicular atrophy, decreased ovulation) (Weir and Fisher, 1972). The NOAEL ("*No Observed Adverse Effect Level*") was determined to be 17.5 mg boron/kg bodyweight per day. The NOAEL is the highest tested dose at which no adverse effects are observed.

In a study on prenatal developmental toxicity in rats with oral administration of boric acid via the diet, an increased incidence of shortened ribs and reduced foetal weights were observed in the offspring of dams that were treated during pregnancy (Price, Strong et al., 1996). These effects occurred at boron doses from 13.3 mg/kg bodyweight per day. The NOAEL was at 9.6 mg boron/kg bodyweight per day. There was no evidence that these developmental toxicity effects were secondary to other toxic effects.

3.1.3.5 Derivation of Acceptable Daily Intake (ADI)

Based on the NOAEL of 9.6 mg boron/kg bodyweight per day, EFSA established an ADI of 0.16 mg boron/kg bodyweight per day (EFSA, 2004; EFSA, 2013). When deriving the ADI, a safety factor of 60 was taken into account instead of the usual 100. This value resulted from the standard uncertainty factor of 10 for interspecies variability and a reduced uncertainty factor of 6 for intraspecies variability, which in turn is obtained by multiplying the value of 1.8 for the intraspecies variability in toxicokinetics with the standard value of 3.2 for the intraspecies variability in toxicodynamics (1.8 × 3.2 = 5.7, rounded 6) (WHO, 1998). The intraspecies toxicokinetic variability was set to a lower value (1.8 instead of the default value of 3.2) since it can primarily be assigned to variations in renal clearance (glomerular filtration rate) in the subpopulation of pregnant women.

3.1.3.6 Relevance for Assessing the Risk of Toys

The rat study used to derive the ADI showed prenatal effects in the offspring of females being treated during pregnancy. However, the shortening of the ribs observed in this context is a prenatal effect that is probably not relevant to (exclusively) postnatal exposure of children to boron in viscous masses. Alternatively, using the NOAEL of 17.5 mg/kg bodyweight per day from the rat study on chronic health effects and using the standard safety or uncertainty factor of 100 results in an acceptable daily intake of 0.175 mg/kg bodyweight per day. Since the two values (0.175 and 0.16 mg/kg bodyweight per day) are very close together, the BfR considers the ADI of 0.16 mg/kg bodyweight per day to be a suitable, and more conservative, reference value.

Conclusion: To assess the health risk of chronic effects, the BfR considers the ADI of 0.16 mg/kg bodyweight per day to be a suitable reference value.

3.1.4 Exposure

Viscous masses can contribute to the uptake of boron in children. Another relevant and above all, continuous, source of exposure to boron compounds is intake via food and drinking water as well as via consumer products. The average boron exposure from these sources, given as 1.3 mg/day (food: 1.2 mg/day, consumer products: 0.1 mg/day (EFSA, 2013)), translates into a background exposure of about 0.08 mg/kg bodyweight per day for a

3-6 year old child weighing 15.7 kg. This value is in accordance with the background exposure assumed by RIVM for children under 36 months (RIVM, 2008) and implies a utilization of the ADI of 50%.

Viscous masses are predominantly labelled as toys that are not intended for children under the age of three years. Therefore, exposure estimation for these toy materials is performed for 3-6 year old children with a bodyweight of 15.7 kg (RIVM, 2014). This bodyweight value is close to the US EPA value of 15.8 kg (25th percentile) for 3-6 year old children (US EPA, 2011a).

When playing with viscous mass, it can accidentally be swallowed or ingested through hand-to-mouth contact. A distinction must be made here between a single, unintentional intake of a larger quantity of toy material (see 3.1.4.2) and the repeated, long-term intake of smaller quantities (see 3.1.4.3 - oral). In addition, the toys considered here are materials with intensive skin contact, implying an additional dermal uptake (see 3.1.4.3 - dermal).

3.1.4.1 Migration Values provided by the State Investigation Offices

From analyses according to EN 71-3, data on boron migration from viscous masses in gastric acid simulant were reported to the BfR (see Table 1). The analysed boron migrations for the examined products were between 580 and 6,384 mg/kg.

Table 1: Migration values for some samples of viscous mass provided by State Investigation Offices .

Sample (no.)	Migration [mg boron/kg]
1 (Different colours)	5,884 5,930 6,023 6,036 6,103 6,177 6,384
2	1,396
3	976 1,070 1,870
4 (4 subsamples)	3,817 ± 763
sample size unknown	580–886

The European standard EN 71-3 lists methods for simulating the migration of certain elements from ingested toy material in the stomach, which are also used to simulate the release of boric acid from viscous mass after swallowing. However, as far as the BfR is aware of, an experimental approach for simulating the release of substances from toy material into the intestinal lumen is still lacking. The BfR, therefore, does not have any knowledge or data on simulating the migration of boron or boric acid from toys under alkaline conditions (as present in the intestinal lumen).

It should be noted that, from a scientific standpoint, it is not necessarily possible to obtain reliable information on exposure from toys from the available migration data. The methods for measuring migration rather represent a convention, since the release taking place under *in vivo* conditions and the associated relevant parameters are not known in detail. Further research is needed.

3.1.4.2 Single Accidental Swallowing of a Large Amount of Viscous Mass

In order to assess the health risk of acute effects, information on the maximum amount of viscous mass that can be swallowed is required. However, for the toy materials under consideration, these data are currently not available to the BfR. According to the European standard EN 71-1 (DIN 2008), all parts that fit into a test cylinder with a diameter of 3.17 cm are considered potentially swallowable, but the BfR considers the likelihood of an event in which a child accidentally swallows such a large amount of viscous mass as being low. According to the BfR estimates, a scenario seems just about possible whereby a quantity of up to approx. 5 g (corresponding to a sphere of an exemplary sample of viscous mass with the approximate diameter of a 2-euro coin) is accidentally swallowed (see Figure 1). The risk of suffocation is not within the scope of this assessment.

The reported migration values are used for the oral exposure scenarios, since the release of substances into gastric acid simulant was measured with the analysis method according to EN 71-3 (DIN 2019). It is assumed that after swallowing the viscous mass, 100% of the released boric acid is absorbed in the gastrointestinal tract and, thus, becomes systemically available.

In the following, the BfR has estimated the level of boron migration, up to which the probability of acute health effects occurring after accidental swallowing of 5 g of viscous mass can be classified as very low. To assess the risk of occurrence of acute health effects, the dose of 3.7 mg boron/kg bodyweight is used as a reference value (see 3.1.3.3). For a 3-6 year old child with a bodyweight of 15.7 kg, this would correspond to an intake of 58 mg boron.
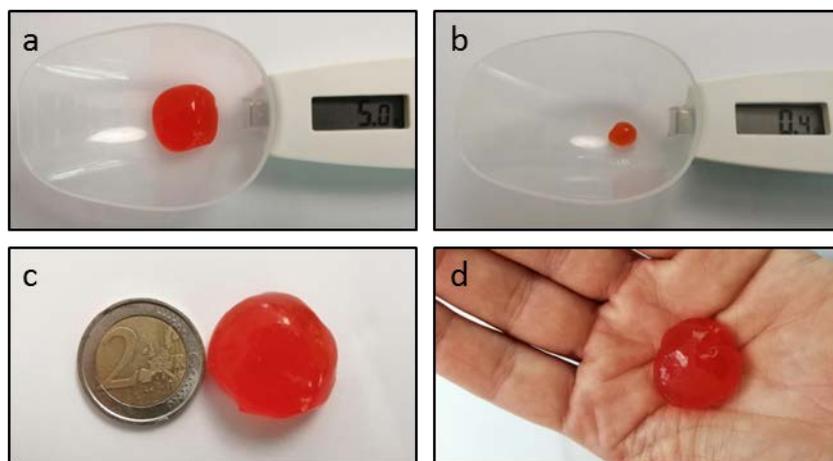

Figure 1: Size of a 5 g (a) and 400 mg (b) spheric of viscous mass, and comparison of the 5 g sphere with a 2 euro coin (c) and in relation to the palm of an adult (d). The photos shown here are for illustrative purposes only. The BfR does not intend to implicitly assign the viscous mass shown to one of the three toy material categories.

Table 2: Estimate of the toy material quantities to be swallowed and the critical boron migration up to which the probability of acute adverse health effects occurring after swallowing 5 g of viscous mass is very low.

	Boron migration	Acute health reference value	(Critical) toy quantity swallowed
	[mg/kg]	[mg boron/person]	[g]
Highest reported boron migration	6,384	58	9.1
Critical boron migration	11,600	58	5

The result shows that subject to a boron migration of up to 11,600 mg/kg, the probability of acute health effects occurring as a result of swallowing 5 g viscous mass can be assessed as being very low (see Table 2). Conversely, if one assumes the highest reported boron migration of 6384 mg/kg (see Table 1), a child would have to swallow almost twice the amount of viscous mass (9.1 g) in order to take up the critical amount of 58 mg boron.

3.1.4.3 Boron Intake Through Daily Playing with Viscous Mass

Oral

In addition to the probability of acute health effects occurring as a result of a single unintentional or accidental swallowing of a large amount of viscous mass, the same estimation procedure was also conducted for chronic effects resulting from the daily ingestion of small amounts of toy material. In the following, a viscous mass assigned to the liquid/sticky toy material category (Category II) is considered. Accordingly, the standard assumption is made that a child swallows 400 mg (4×10^{-4} kg) of liquid/sticky toy material (see Figure 1b) per day, even though the assumption of daily swallowing of such an amount is considered to be very conservative (SCHER, 2016).

Using the provided migration values (see Table 1), the daily oral exposure doses given in Table 3 apply to a child aged 3 to 6 years with a bodyweight of 15.7 kg. This results in a systemic exposure dose (SED) of 0.163 mg boron/kg bodyweight per day (6,384 mg/kg $\times$ (4×10^{-4} kg)/15.7 kg bw) for the viscous mass with the highest reported boron migration of 6,384 mg/kg.

Dermal

Due to intensive skin contact with the viscous mass, potential dermal exposure is taken into account in addition to oral exposure. In the absence of product-specific data, it is assumed that the viscous mass corresponds to an aqueous boron solution under infinite dose conditions. Furthermore, it is assumed that only the boron content of the viscous mass that migrates into sweat is available for dermal absorption. Since the boron migration in sweat (simulant) is unknown, boron migration in gastric acid simulant (in µg boron released per gram of viscous mass) is used as a surrogate. It is thereby assumed that the migration of boron compounds from viscous masses into sweat is no greater than that into gastric acid simulant.

The following approach is used to calculate dermal absorption: The flux rate (µg cm^{-2} h^{-1}) is estimated by multiplying the permeability coefficient (K_p) of 3×10^{-4} cm/h (see 3.1.3.1) by the boron migration. Furthermore, a density of 1 g/cm³ is assumed for viscous masses.

$$Flux\ rate\ \left[\frac{\mu g}{cm^2\ x\ h}\right] = K_p\ \left[\frac{cm}{h}\right] \times Boron\ migration\ \left[\frac{\mu g}{g}\right] x\ Density\ \left[\frac{g}{cm^3}\right]$$

For the maximum boron migration of 6,384 mg/kg (or µg/g), for example, this results in an estimated boron flux rate of 1.92 µg per cm² and hour (3×10^{-4} cm/h $\times$ 6,384 µg/g $\times$ 1 g /cm^3). To calculate the systemic exposure dose (SED$_{derm}$), the flux rate is multiplied by exposed skin area and exposure duration and divided by bodyweight (see below).

Furthermore, it is assumed that a child aged 3 to 6 years with a bodyweight of 15.7 kg plays with viscous mass for one hour a day. According to the US EPA (2011b), the 95th percentile of hand surface area (inside and outside) of children aged 3 to 6 years is 460 cm², while the mean is given as 370 cm². Since the calculation of the SED is performed with the 25th percentile of bodyweight, the use of the 95th percentile for the hand surface area appears too

conservative, hence the mean value is used in this assessment. This value is consistent with the 25th percentile of hand surface area of Dutch children aged 3 to 6 years, which, according to the General Fact Sheet (RIVM, 2014), is given as 320 cm^2. Furthermore, the palms, which make up about half of inner hand surface (or a quarter of the inner and outer surface area of the hands), are regarded as the relevant contact area. This results in a total contact area of 90 cm² (~25% of 370 cm², see Figure 2) for both palms (Rhodes, Clay et al., 2013).

Figure 2: Inner hand surface area of a child aged almost four years. The red circle (7.57 cm diameter) represents an area of 45 cm^2 and is slightly larger than the child's palm.

For the product with the maximum boron migration of 6,384 mg/kg, the systemic exposure dose (SED_{derm}) can, therefore, be calculated as follows:

$$\mathrm{SED_{derm}} = \frac{1{,}92 \, \frac{\mu g}{cm^2 * h} * 90 \, cm^2 * 1h/day}{15{,}7 \, kg \, bw} = 11 \text{ µg/kg bodyweight per day} = 0.011 \text{ mg/kg bw per day}$$

For the lowest measured boron migration of 580 mg/kg, this approach results in an SED_{derm} of 0.001 mg/kg bodyweight per day at a flux rate of 0.174 µg/cm² and hour.

Conclusion: Depending on the measured boron migration, the estimated dermal uptake is between 0.001 and 0.011 mg/kg bodyweight per day. Hence, demal uptake from these products accounts for only about 6% of the total exposure, while the dominant portion is taken up orally.

In the absence of experimental data, the estimation approach is based on some assumptions that are subject to uncertainties. However, the BfR considers the dermal exposure estimation to be conservative. Reasons for this include the exposure time of one hour, which is not long enough to reach the steady-state conditions and thus the maximum dermal flux rate, and the thick horny skin layer on the palms of the hands compared to other parts of the body, which makes it more difficult for substances to be absorbed through these skin areas.

Table 3: Exposure assessment and calculation of ADI utilisation for aggregated boron uptake via daily swallowing of small amounts of viscous mass and via skin contact, based on the reported boron migration data and calculation of the critical boron migration that leads to full ADI utilisation, with and without inclusion of background exposure.

Boron migration	SED (Product only) Oral	SED (Product only) Dermal	SED (Product only) total	ADI utilisation (Product only) Oral + dermal	SED (+ Background)	ADI utilisation (+ Background)
(mg/kg)		(mg/kg bw/day)		(%)	(mg/kg bw/day)	(%)
Min: 580	0.015	0.001	0.016	10	0.096	60
Max: 6,384	0.163	0.011	0.174	109	0.254	158
2,950	0.075	0.005	0.080	50	0.160	**100**
5,900	0.150	0.010	0.160	**100**	0.240	150

A viscous mass with the maximum measured migration of 6,384 mg boron/kg leads to systemic exposure of 0.174 mg/kg bodyweight per day, which slightly exceeds the ADI of 0.16 mg boron/kg bodyweight per day, based on an estimate of oral plus dermal uptake (see Table 3). In case of a boron migration above 2,950 mg/kg, the ADI is fully exhausted if the background exposure is taken into account, and above 5,900 mg/kg, respectively, when only the uptake via the toy is considered.

If, in case of very liquid viscous masses, one assumes that the entire inner surface of the hands are in contact with the product (i.e. 180 cm^2 instead of 90 cm^2 contact area), the dermal uptake amount doubles for the same playing time, but the share of the total uptake is still comparatively low (approx. 13%). In addition, it can be assumed that the playing time and the service life of the product is shorter for very liquid viscous masses than for more solid products, so that the above estimate may also cover these toys within the range of uncertainties.

3.1.5   Risk characterisation

3.1.5.1 Risk Characterisation for Acute Exposure

A single accidental swallowing of a larger amount of viscous mass (5 g) does not lead to an acute health risk for children aged 3 to 6 years if the boron migration is less than 11,600 mg/kg. At least 9.1 g of toy material from the product with the highest reported migration (6,384 mg/kg) would need to be swallowed in order to incur a risk of acute, adverse health effects for the child. These estimates are based on a comparison with reported cases of acute boron ingestion of up to 3.7 mg/kg bodyweight which (in adults) were asymptomatic (see 3.1.3.2). However, the BfR considers swallowing approximately 10 g of viscous mass to be an unlikely scenario. In addition, the values available to the BfR for boron migration in ready-to-use products from various data sources (monitoring, BÜp, EU Safety Gate; see below) were all below 10,000 mg/kg.

3.1.5.2 Risk Characterisation for Long-term Exposure

In order to assess possible health risks from long-term (chronic) exposure, the BfR considered the question of whether substance intake should be considered solely as resulting from the product under consideration or as total exposure from all sources.

The BfR is of the opinion that, from a scientific point of view, the health risk assessment of viscous masses should take into account overall exposure. Therefore, taking into account the background exposure of 0.08 mg per kg bodyweight per day via food and consumer products for children with a bodyweight of 15.7 kg (3 to 6 years), the viscous mass with the highest reported migration would result in an ADI utilisation of 158%. Exceeding the ADI regularly over

longer periods of time leads to a medium probability of the occurrence of adverse health effects. However, since children probably do not play with viscous masses on a daily basis in which case the boron migration would at least be 2,950 mg/kg, the BfR considers it unlikely that the ADI will be exceeded continuously. This becomes even less likely considering the limited service life of these products.

Although it is not known what proportion of all products on the market have a migration >2,950 mg/kg, data from the 2017 Federal Control Plan have shown that of the 65 viscous masses tested, almost 80% complied with the migration limit of 300 mg/kg liquid/viscous toy material; the 90th percentile was given as 1,076 mg/kg (BVL, 2018). Therefore, there is a low probability that a child will play with a viscous mass that has a migration rate greater than 2,950 mg/kg on a daily basis. It, therefore, seems unlikely that the ADI will be exceeded over the long-term.

3.2   Other Aspects

3.2.1   Additional toy products

Various viscous products are available in the market (play slime, fart slime, bouncy putty, etc.), which differ in properties such as consistency or density. This leads to additional variability in the exposure parameters (e.g. maximum amount that can be accidentally swallowed, contact area with the skin, playing time, product lifetime and thus contributes to the uncertainty in the exposure assessment.

The assessment of the chronic effects carried out by the BfR applies to viscous masses that can be assigned to the toy material category II (liquid/sticky). For products that can be assigned to category I (dry/brittle/powder-like/pliable), critical boron migration is higher than the value calculated for viscous masses assigned to the toy material category II, partly because it is assumed that the quantity that gets swallowed daily is lower (100 mg instead of 400 mg).

3.2.2   RAPEX Notifications in the EU Safety Gate

An evaluation of the notifications in the EU Safety Gate from 2015 to 2021 resulted in 141 entries for toys in the "viscous mass" category. The maximum reported migration during this period was 9,807 mg/kg for a slime toy and 6,968 mg/kg for a modelling clay. According to this, none of the ready-to-use products, for which non-compliance with the TSD was notified, featured a boron migration >10,000 mg/kg. However, a boron migration of 26,850 mg/kg was determined for the final product made with a slime kit with which children make the viscous mass themselves using components provided with the kit (RAPEX, 2015). The BfR has currently no information on other toy sets for the making of viscous masses.

The BfR advises against the domestic production of boron-containing viscous mass from individual components using other consumer mixtures such as contact lens cleaners; boron migration from home-made viscous mass could well exceed the levels measured in commercial finished products.

Approximately ~83% of the products (117 out of 141), which had been notified to the Safety Gate during the last six years, had a boron migration below the critical value of 2,950 mg/kg, which was derived for viscous masses in toy material category II. Based on the conservative exposure assessment, which involved the consideration of background exposure, these products would not be associated with an exceedance of the ADI. From the standpoint of the BfR, there is therefore a very low probability of occurrence of chronic negative health effects.

3.3 Risk management options / measures

The limit values for the boron migration of toy materials as specified in the Toy Safety Directive were derived using the ADI and an allocation factor of 10%, and take into account the oral ingestion of toy material by a child aged 6 to 9 months with a bodyweight of 7.5 kg. They are therefore risk-based limit values. The migration limits are 1,200 mg/kg for dry/brittle/powder-like/pliable (category I), 300 mg/kg for liquid/sticky (category II) and 15,000 mg/kg for scrapable toy material (category III). According to the current state of knowledge, if those limits are met, the probability of the occurrence of health impairments in children is regarded as being very low.

Viscous masses are mainly sold with a label that states that they are not suitable for children under the age of 36 months. For children aged three to six years (assumed bodyweight: 15.7 kg) the ADI is only exceeded at a boron migration above 2,950 mg/kg together with the estimated background intake of 0.08 mg/kg bodyweight per day, taking into account the oral and dermal uptake of boron through daily handling during play with a category II viscous mass for one hour. Exceedance of the ADI is undesirable from a toxicological standpoint. However, if the ADI is only occasionally and slightly exceeded, the BfR regards the probability of occurrence of adverse health effects to be low. Similarly, the probability may be described as very low in case of a boron migration below 2,950 mg/kg and, when neglecting background exposure, below a boron migration of 5,900 mg/kg.

Investigations within the framework of the 2017 Federal Control Plan showed that around 80% of the viscous masses tested complied with legal limit values for boron migration. This shows that compliance with the limit values is possible in practice.

More Product Safety Information on the BfR Website

Health assessment of toys: https://www.bfr.bund.de/en/health_assessment_of_toys-54510.html

BfR "Opinions app"

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About the BfR

The German Federal Institute for Risk Assessment (BfR) is a scientifically independent institution within the portfolio of the Federal Ministry of Food and Agriculture (BMEL) in Germany. The BfR advises the Federal Government and the States ('Laender') on questions of food, chemicals and product safety. The BfR conducts independent research on topics that are closely linked to its assessment tasks.

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