

Risk assessing products that contain small, high-powered magnets

Guidance for local authorities

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Introduction

OPSS has issued a safety alert in relation to products that contain small highpowered magnets (the safety alert). Products that contain or are comprised of small high-powered magnets are often novel and differ from products that are clearly toys or have a food imitating quality. Toys and food imitating products are subject to product-specific legal frameworks and as such, the risks are well understood. The safety alert can be found here:

https://www.gov.uk/government/news/uk-safety-alert-issued-for-small-high-poweredmagnetic-products

The safety alert includes a risk summary (the risk summary) that sets out the outcomes of OPSS' product-specific risk assessments which were performed on a range of products purchased online, and can be found here:

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachm ent_data/file/987542/opss-risk-summary-magnets.pdf

This guidance document will expand on the safety alert and the risk summary and provide additional context to support your authority in carrying out risk assessments on products that contain small, high powered magnets in relation to the **ingestion hazard where two or more magnets attract each other across soft tissue**. This document should be read alongside the risk summary as well as the RAPEX guidance in relation to performing product safety risk assessments, which can be found here:

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32010D0015

When considering the harm posed by small high-powered magnets, evidence shows that internal injuries can occur when two or more magnets (or a magnet and ferromagnetic object such as a nickel disc) are ingested at slightly different times such that the two high strength magnets, although in different parts of the intestine, could attract each other, potentially resulting in severe injury such as the perforation of the intestine.

It is possible for all magnets (or a magnet and ferromagnetic object) whether weak or strong to attract each other. However, higher strength magnets are of greater concern because they will attract each other over longer distances and are more difficult to pull apart once in contact. In contrast, weaker strength magnets need to be closer to attract each other and are more easily pulled apart. Therefore, part of determining the risk requires measuring the magnetic flux density (the force that a magnet exerts over a given contact area) of a magnet, thereby providing an indication of the magnet strength or attractive force and the corresponding pressure that may be exerted by two magnets when they come into contact.

The British Standard EN 71-1:2014+A1:2018 Safety of Toys – Part 1: Mechanical and physical properties (see A.51, page 171 of the Standard) provides a definition of a sufficiently weak magnet for use in toys defined as a magnetic flux index below 50 kG²mm². It is possible to still suffer harm in relation to ingesting two or more weak magnets with a flux of less than 50 kG²mm², but the likelihood of the harm occurring is considered much lower by comparison with higher strength magnets for the reasons outlined above.

For the purposes of this guidance, OPSS defines high powered magnets as those which have a magnetic flux of greater than 50 kG²mm². However, it is important to recognise that magnet strength should be considered along a continuum and is not a binary low-high categorisation (see section Harms below).

How OPSS has applied the magnetic flux strength within the risk models is discussed in more detail below, under 'The Hazard'.

The product

The risk summary which accompanied the safety alert referenced four types of products that contain small high-powered magnets. These are:

- 1. Novelty items comprised of small high-powered accessible magnets which include desk toys or stress relievers. Typically, these products are comprised of a high number of small magnetic balls and can be used to create patterns and shapes. Also in this category are small non-food imitating novelty magnetic stationery (such as fridge/notice board magnets) that may have a play value because the design is child appealing and the product is defined as a small part when it is in its entirety (i.e. it doesn't need breaking down). We have included these types of products because there may be debate as to the applicable legal framework and accordingly, to assist OPSS' analysis, OPSS has commissioned an expert view on products that contain or are comprised of small high-powered magnets and may be child appealing due to appearance or design.
- 2. Magnetic mouth or nose jewellery. This is jewellery that imitates jewellery that would require a piercing (such as a tongue barbell) but instead uses a magnet/s to hold the jewellery in place. However, by their design, these products require the placing of at least one magnet in the mouth or nose, increasing the risk the product could be ingested.
- 3. Magnetic ear and/or body jewellery. Like magnetic mouth or nose jewellery, these products do not require a piercing. Whilst they are marketed for wear on body, there is a risk the product could be worn in the mouth or nose or temporarily placed in the mouth as part of the fitting process or for other reasons, giving rise to a risk of ingestion.
- 4. Magnetic glassware charms. These products are used to decorate glassware. The charms typically vary in design and are used to identify the user's drink from someone else's.

These four product types were identified for their increased potential to cause harm, principally because of the products' design in the context of their intended and foreseeable use. Some of these product types have been linked to harms that have already occurred.

Principally, the products subject to the Safety Alert are regulated by the General Product Safety Regulations 2005. However, a product investigation will require a case-by-case evaluation of the relevant regulatory framework. For instance, where the product could be defined as a toy, and/or have a food imitating quality.

Hazards

The risk summary that accompanied the safety alert considered the **hazard of ingestion where, as a result of the ingestion, two magnets attract each other either side of soft tissue**, however, when performing your own product safety risk assessments, consideration should be given to all hazards that might be present. For instance, if a product has a small part and the product could be used by a child under 36 months, or because of its design, may put the user at risk of inhaling the product, your risk assessment should also consider the harm in relation to potential choking/inhalation hazards. Also, magnetic jewellery may cause an external compression injury when used as intended, in addition to the ingestion hazard.

The ingestion of small, high-powered magnets is a recognised hazard referenced in the BS EN 71-1:2014+A1:2018, Safety of toys – Part 1: Mechanical and physical properties. It is this Standard that sets the limit value for the magnetic flux index of 50 kG²mm² in accessible magnets in toys that are also a small part, along with a supporting rationale and the exemption in relation to magnetic/electrical experimental sets.

Whilst the Standard sets a limit, it doesn't mean that magnets with a flux index below the stated limit are always safe. The Standard notes that, if ingested, weak magnets can apply enough pressure to cause severe harm in the event the two weak magnets end up on opposite sides of the intestinal wall where the intestinal wall is extremely thin. However, the probability of this event is regarded as very low. When considering a product that contains or comprises weak magnets, the assessment should consider the extent of any such risk and whether mitigating measures are required.

The risk assessment should consider hazard perception in relation to magnets both generally and how the design as well as any warnings or product information may affect magnet hazard perception. Here, it is useful to consider whether the hazard is an inherent feature of the product, for instance, magnetic mouth jewellery that requires the placing of two magnets in the mouth. A user may assume that if the product is designed to be worn this way, it must be safe. Likewise, if a product looks like a toy and has a play value, it is reasonable to assume a user might consider the product safe to be given to a child and supervision will be relative to the perceived hazard.

Consideration should also be given to how supporting instructions and even warnings might steer foreseeable use and engagement. For example, might the intended use and inherent risk dilute the effectiveness of warnings to such an extent they do not mitigate the risk sufficiently?

Harms

OPSS performed a rapid literature review in relation to the harms caused by magnet ingestion. The literature review should be read alongside this guidance. Amongst other findings, it provides a breakdown on the types of harms associated with magnet ingestion and the severity of harms in the cases examined. The literature review also noted that:

- when the ingestion of two or more magnets causes an injury, this injury can be very severe, particularly if there is a delay in seeking medical intervention after ingestion. Typically, this is because when two magnets come together on either side of internal soft tissue they can cause compression injuries, twists, and perforations of the bowel.
- the most severe harms caused when two or magnets attract each other either side of soft tissue can occur even when just a small number of magnets are ingested.
- clinicians are needed to intervene when a person presents having swallowed two or more magnets, for example, performing surgery to remove the magnets before harm can occur.

Time is of the essence and seeking medical attention is key to mitigating the harm following magnet ingestion; the literature reviewed showed some evidence that the greater the length of time until medical intervention can be undertaken after magnets are ingested, the greater the likelihood of harm. OPSS has recently surveyed consumers' awareness of the dangers of magnetic ingestion, because their awareness may influence how they can be expected to react when they or someone they care for swallow magnets.

It is important to note that OPSS did not find conclusive evidence to demonstrate that the stronger the magnet, the greater the risk of harm. As such, when performing risk assessments on relevant products, OPSS used the magnet strength of 50 kG²mm² as a reference point. This is because this level is set out in the Standard, which defines whether a magnet is sufficiently weak for use in a toy. However, the Standard itself acknowledges that magnet strength and the risks arising from it need to be considered along a continuum as opposed to a binary high or low strength.

As explained earlier, it is possible for all magnets (or a magnet and ferromagnetic object) whether weak or strong to attract each other but higher strength magnets will attract each other over longer distances and are more difficult to pull apart once in contact. In summary, whilst the evidence that the risk of harm increases as the magnet strength increases is not conclusive, we can say, as stated in the Standard¹, that as magnet strength increases:

"they attract each other over a longer distance with a force than can overcome obstructions presented by e.g. intestinal contents."

¹ Page 172, BS EN 71-1:2014+A1:2018, Safety of toys – Part 1: Mechanical and physical properties

As set out in the section on hazards above, a product that is comprised of small highpowered magnets may also present hazards that could lead to other harms. Other harms could result from the product obstructing or completely blocking an airway if inhaled. This risk is likely to be higher in a product that is designed to be worn in the nose or mouth (or foreseeably could be) or a product that has a food imitating quality.

The RAPEX risk assessment guidelines for consumer products provides more information on hazard identification.

Consumers most at risk

The literature review compared cases relating to paediatrics and adults presenting at Accident and Emergency departments after ingesting magnets. Most cases were in relation to the paediatric population, accounting for 102 case studies identified, compared to three case studies in the adult population. The literature review noted:

- that foreign body ingestion in adults is rare and when it does occur, in 95% of all cases (i.e. not just in relation to magnet ingestion) it is accidental.
- an increased risk for adults with psychiatric illnesses or learning difficulties, reflecting that two of the three identified adult cases concerned individuals with pre-existing learning difficulties, but the observation was caveated due to the sample size.

The harm from magnetic glassware charms which are marketed directly at adults for the purposes of personalising drinks may arise as a result of accidental ingestion. The extent of this risk will then be a function of the typical magnet strength, the design of the product and the context of use such as the effect of alcohol on the user.

There is also some evidence to suggest that the risk to children is not just in relation to very young children who have a greater propensity to mouth objects. This may relate to the types of products that contain small, high-powered magnets, such as the magnetic mouth or nose jewellery. A study in relation to UK hospital admissions concerning paediatric patients (children aged 16 years or under) following the ingestion of magnetic balls between 1 January 2020 to 31 December 2020, and collected data on 53 admissions, noted a uniform distribution between age ranges, with a median age of 7 years².

² Price J, Malakounides G, Stibbards S, et alBall magnet ingestion in children: a stronger and more dangerous attraction? Emergency Medicine Journal Published Online First: 20 September 2021. doi: 10.1136/emermed-2021-211767

Developing injury scenarios

It is feasible that the risk assessment of a product with accessible small highpowered magnets will identify the same hazard, for example the accessible small high-powered magnet, but differing resulting harms, which in turn may have varying likelihoods of occurring. For example, a certain sized magnet will have the potential to cause an obstruction to an airway and separately, give rise to ingestion hazard if two or more are swallowed. These hazards are independent and should be assessed individually.

Below, are suggested injury scenarios in relation to the <u>ingestion</u> hazard, with some commentary on arriving at suitable probabilities per step. These injury scenarios can be used as a baseline for a product risk assessment that is then adapted to the specifics of the product identified by your authority and informed by way of additional information, such as test reports.

You may also find it useful to consult the Product Safety Database (PSD). OPSS can provide MSAs with a list of products reported to the PSD that have been assessed by OPSS and include a risk assessment. You may find it useful to consider these risk assessments when developing your own assessments.

For all the scenarios, we have considered the RAPEX level four injury severity as plausible on the basis that whilst the ingestion will rarely result in a fatality, because the injury is to the digestive system, there is a probable outcome of life changing injuries if medical intervention is delayed. It is possible that as consumers become more aware of the harms resulting from magnet ingestion, a level three injury outcome will involve the highest risk.

Small magnetic ball sets

Injury step	Factors informing the probability	Suggested likelihood ranges
Desk toy is left unattended and is accessible to a young child.	Inadequate/confusing or contradictory warnings may be a key factor here as to whether the child is more likely than not to be left unsupervised with the product. Also consider supervising adult's awareness of harm from magnets. If the product is relatively inexpensive it may not be so carefully guarded.	0.05 to 0.4
The child investigates the desk toy, including mouthing some or all the magnetic balls.	Is the product intriguing and/or eye catching? Does it have food imitating qualities? Would it appeal to a young child as something to play with?	0.1 to 0.4
Some or all the magnetic balls that have been mouthed are swallowed.	Product size and shape is one of the key factors in informing the likelihood of this step occurring in relation to more than one magnet.	0.05 to 0.1
As the magnets pass through the body, they are drawn to each other either side of soft tissue.	Evidence suggests this should be a relatively conservative assumption and it remains an area of uncertainty.	0.01
The user becomes seriously unwell and medical intervention is required to remove the magnets, but the user suffers life-changing injuries, or death occurs before medical intervention can occur.	 Fatalities relating to magnet ingestion appear to be exceptionally rare but have occurred overseas. Note also, the kinds of medical intervention required to remove ingested magnets usually constitute invasive surgery, which can carry risks of its own – this harm maybe less severe so when considering this outcome make sure it is reflected in the injury level selected. The literature review also notes 'What is unavailable from the evidence collected is information on the potential long-term effects on a patient's physical and mental health several years post-surgery/ingestion event'. 	0.1

Magnetic jewellery worn in the mouth

Note, this will relate to jewellery that is designed to be worn in the mouth, or where it is foreseeable the product could be used this way.

Injury step	Factors informing the probability	Suggested likelihood ranges
Jewellery is positioned so that both magnets are worn inside the mouth, for example, either side of the tongue.	Consider wording of any warnings and instructions for use as well as marketing material, supporting images and foreseeable use.	0.5 to 0.9
The magnets come apart unintentionally.	This could occur during the fitting of the magnetic jewellery, during activities such as eating, drinking, sleeping, participation in physical activities etc.	0.05 to 0.2
The magnets are swallowed.	Product size and shape is one of the key factors in informing the likelihood of this step occurring in relation to more than one of the magnetic components. Because the product is designed to be worn inside the mouth and to imitate jewellery fixed by way of a piercing, it is assumed the individual components will not be large.	0.05 to 0.1
As the magnets pass through the body, they are drawn to each other either side of soft tissue causing injury.	Evidence suggests this should be a relatively conservative assumption and it still remains an area of uncertainty.	0.01
The user becomes seriously unwell and medical intervention is required to remove the magnets, but this is unsuccessful, or death occurs before medical intervention can occur.	 Fatalities relating to magnet ingestion appear to be exceptionally rare but have occurred overseas. Note also, the kinds of medical intervention required to remove ingested magnets usually constitute invasive surgery, which can carry risks of its own – this harm maybe less severe so when considering this outcome make sure it is reflected in the injury level selected. The literature review also notes 'What is unavailable from the evidence collected is information on the potential long-term effects on a patient's physical and mental health several years post-surgery/ingestion event'. 	0.1

To adapt the above scenario for magnetic jewellery marketed to be worn on the body (such as the ear), adjust the first step to reflect the likelihood they would be worn in the mouth. The assumption is as this is not how the product is marketed and warnings may advise against wearing in the mouth, accordingly this likelihood will be lower.

Magnetic glass charms

Injury step	Certainty/rationale	Suggested likelihood ranges
A magnetic glass charm is positioned on the user's glass.	This could be highly probable depending on how the product is marketed for use and whether it is foreseeable the product could be placed on the glass where it would be less likely to lead to accidental ingestion, such as on the base or on the stem of the glass.	0.5 to 0.8
The magnets come apart, at least one magnet falls into the user's drink.	This probability would reflect the overall positioning of the product and potentially the thickness of the glass.	0.01 to 0.02
The user takes a drink from the glass and swallows the magnet.	There will be several unknowns here such as the lighting conditions and other factors that may distract the user from realising the charm has fallen into the drink. Consideration could be given to whether the user is taking a large gulp vs smaller sips for example, is the product designed for use on beer glasses or smaller/shorter drinks? Consideration should also be given to the likelihood the action of drinking from the glass results in the mouthing of the magnet – does the supporting product information show the charms positioned high up on the glass? Is there any supporting information/imagery on the positioning of the charms?	0.01 to 0.02
A second glass charm is placed on the glass which also falls in the user's drink and is swallowed.	Consideration should be given to whether this probability should be no greater than probability of the first three steps occurring. After ingesting one charm already, some users will be less inclined to risk using a new charm on their glass. Other matters to include how likely is it that the user will have additional charms with them or access to them? And is there a possibility of multiple charms being placed on the rim of the glass and both being swallowed simultaneously?	This will be less than, equal to but no greater than the first three steps combined.
As the magnets pass through the body, they are drawn to each other in the bowels causing injury.	A <i>relatively</i> conservative assumption on this basis but this is an area of uncertainty.	0.01

The user becomes seriously unwell and medical intervention is required to remove the magnets, but this is unsuccessful, or death occurs before medical intervention can occur.	 Fatalities relating to magnet ingestion appear to be exceptionally rare but have occurred overseas. Note also, the kinds of medical intervention required to remove ingested magnets usually constitute invasive surgery, which can carry risks of its own – this harm maybe less severe so when considering this outcome make sure it is reflected in the injury level selected. The literature review also notes 'What is unavailable from the evidence collected is information on the potential leng term effects on a potient's physical and mental. 	0.1
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Once all possible hazards with the product have been identified and assessed, the highest risk identified is regarded as 'the risk' of the product, i.e. if you identify a medium risk ingestion hazard and a high risk choking hazard, the product risk is high. The above scenarios only reflect the hazard of from the magnetic component of the product if they are ingested and your risk assessment may have identified other hazards, such as a choking hazard, which may then be subject to risk modelling.

Risk evaluation and deciding next steps

The risk in relation to the ingestion of two or magnets that then attract each other either side of soft tissue **may not result in the highest risk in relation to the product's other hazards**. This is because there is a more complex pathway to injury (injury scenario) for the harm to occur.

Nonetheless, when evaluating the risk outcomes, including the risk in relation to the ingestion hazard, in order to determine whether risk management action is required, it is useful to record a narrative that addresses the following as well as any other relevant risk evaluation factors appropriate to the product:

- The vulnerability of the potential users
- Balancing an unlikely harm occurring with a high severity of harm if it did occur
- The number of individual hazards and risks identified with the product
- The inherent nature of the hazard/s
- Confusing or contradictory warnings that may increase the potential risk
- Any concerns expressed locally or nationally about the safety of the product or type of product.

Finally, once the risk has been evaluated, the estimated total number of consumers exposed to the product risk and the expected future demand for the product are at least two matters to consider as part of the need for and nature of risk management action.

The Product Safety Database

OPSS encourages all identified non-compliant products to be added to the PSD, along with the supporting information generated, such as photos, test reports etc, and the risk assessment. This is vital in helping build a national picture of product safety issues, including the types of products on the market and the typical interventions. It also enables best practice and a comprehensive catalogue of supporting information to be built that will potentially support future case work. OPSS is also interested to hear from authorities who have commissioned experts, are aware of emerging trends in relation to magnet hazards or have any other information that they would specifically like to flag.

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