Office for Product Safety & Standards

PRISM: Risk Assessment (With Supplementary Rationale) – Non-Compliant Remote Control for Lighting Chain

1. THE PRODUCT

The product is a lighting chain operated by a remote control that allows users to change colour settings and lighting mode. The remote control is powered by a coin cell battery. The battery compartment does not appear to have any features to mitigate access to the coin cell battery.

The product is deemed to be electrical equipment within the scope of the Electrical Equipment (Safety) Regulations 2016. The product was submitted for formal testing to assess compliance with the principal elements of the safety objectives stated in the Regulations. In relation to the coin cell battery, the safety objectives were determined by reference to PAS 7055:2021 Button and coin batteries – Safety requirements – Specification (PAS 7055:2021), and the test house findings were that the product did not meet the safety objectives due to the accessible coin cell battery.

The total number of items of this product estimated to be in use across the UK is 2500.

Note: As this is a worked example further product details are not provided here, but would normally include:

- Manufacturer/brand
- Model
- Batch numbers and any other coding
- Quantities supplied and over what time period
- How the matter came to the attention of the market surveillance authority (e.g. complaint, intelligence or ports and borders work).
- Details of any reported incidents or injuries
- Photographs of the product and packaging that, where possible capture the hazard as well as acting as a means of enabling identification of the product.

2. THE HAZARD

The hazard under assessment is the coin cell battery which due to its size and shape has the potential to be inhaled or ingested by persons who are unaware of or unable to appreciate the injuries this might cause, or who might confuse the battery with something edible.

Whilst there is a choking hazard associated with the battery, there is an additional type of injury that can result from the ingestion of coin cell batteries because once swallowed, internal tissue burns can result from electrolysis as the battery reacts to bodily fluids. This can occur relatively quickly after ingestion, often within a few hours, but without any immediate symptoms. Because of the time lag between swallowing and symptoms, correct diagnosis of the problem once symptoms do appear can be problematic.

3. WHO COULD BE HARMED?

The people most at risk of harm are those with the highest likelihood of swallowing the coin cell battery and then being unable to identify and articulate this as the cause of any subsequent symptoms.

Children under 36 months who engage with their environment through mouthing objects would be one such group. Further, the lights could be attractive to them and may consequently be used to decorate their bedroom, thereby increasing the likelihood of the remote control also being in the child's bedroom. If able to access the remote, a young child may be inclined to play with it given that it is attractive with bright colours and has buttons that change the lighting chain's appearance which can potentially be operated by a child. Some of this may arise from mimicking the behaviour of an older child or adult. During such interactions with the remote there is potential for the coin cell battery to be accidentally or deliberately released.

Older children and some adults (particularly those with poor eyesight) may be at risk of swallowing the coin cell battery after becoming detached from the remote, which is most likely to occur when the battery is confused for something edible. Certain pets may be similarly at risk.

4. HARM SCENARIO

This scenario involves a young child gaining access to the battery and swallowing it, causing injury. For this harm scenario to apply, there is an assumption that the remote control is in a dwelling that is visited or occupied by children under 36 months.

Step 1: The remote control is left in a location accessible to a child.

Step 2: The child handles the remote and, in the process, the coin battery is released.

Step 3: The child picks the battery up and mouths it.

Step 4: The battery is swallowed.

Step 5: Injury occurs.

5. SEVERITY OF HARM

It is considered that the most severe type of harm that is plausible is at level four. This is on the basis of injuries known to have been caused by ingested button batteries, which include fatalities. As noted above there is often a significant time gap between ingestion and symptoms, which can occur even where a supervising adult is aware that ingestion has taken place, if that adult is unaware of the need to take immediate action.

Early intervention can potentially prevent death or very serious injury, and it is also possible for the battery to pass through the body without causing harm. However, for the reasons discussed above, a level four injury is plausible and therefore is the most appropriate severity level to apply to the initial harm scenario.

6. PROBABILITY OF HARM

The following probabilities can be estimated using the available data and knowledge of human behaviour:

Step 1**:** The remote control is left in a location accessible to a child.

Remote controls are typically kept within easy reach of users for convenience and could foreseeably be left on coffee tables or low surfaces near seating arrangements. They are only likely to be deliberately placed out of reach of young children if there is some awareness of the hazard, however it is reasonable to assume that the hazards presented by coin cell button batteries are not as well understood as other, more familiar and traditional hazards to small children. Even where the there is some appreciation of the hazard, users may not recognise the risk arising from the insecure battery compartment. Based on best judgement, a probability of 0.1 is given to the likelihood of the controller being left in a location accessible to a child.

Probability: 0.1

Step 2**:** The child handles the remote and, in the process, the coin battery is released.

The remote control has brightly coloured buttons and is potentially highly appealing to a child, particularly if they have seen it in use. Once handled, the likelihood of the battery then being released is primarily a function of the ease of release, how the child interacts with the remote and for how long. The view of the test house who performed the compliance assessment is that the battery is easily accessed after only limited engagement. Accordingly, a probability of 0.05 is given.

Probability: 0.05

Step 3**:** The child picks the battery up and mouths it.

Oral sensory seeking behaviour (or mouthing items) is a normal behaviour of babies and young children[1]. In 2002 The Department of Trade and Industry conducted a study which considered the frequency at which mouthing behaviour was performed[2]. The mouthing time was moderated by age group and per item, and ranged between 50 minutes to 10 hours (per day). Taking into account the high propensity towards mouthing behaviour by young children, and the frequency with which it occurs, the probability the battery will be mouthed is estimated to be 0.5.

Probability: 0.5

Step 4**:** The battery is swallowed.

It is not uncommon for children to swallow foreign bodies (non-food items). Swallowing may be accidental or deliberate following the child sucking or gagging on the battery. The child might have the battery in their mouth and accidentally swallow

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1 Tulve, N. S., Suggs, J. C., Mccurdy, T., Cohen Hubal, E. A., & Moya, J. (2002). Frequency of mouthing behavior in young children. Journal of Exposure Science &Amp; Environmental Epidemiology, 12(4), 259–264. https://doi.org/10.1038/sj.jea.7500225

2 https://www.humanics-es.com/mouthsum.pdf

it when running or falling. However, mouthing will not automatically lead to swallowing, and in the case of a coin battery the metallic feel and taste may result in it being spat out. In the absence of any empirical evidence relating to the factors that influence the likelihood of swallowing, judgement must be applied and in this case the probability of swallowing is estimated to be 0.1

Probability: 0.1

Step 5: A level 4 Injury occurs.

The probability of a level 4 injury occurring is primarily a function of:

1. The site of injury; and
2. The time taken for effective treatment to be given.

As regards (1), if the battery becomes lodged in the oesophagus, it can react with saliva producing caustic soda. This can burn a hole in the tissue and lead to internal bleeding. The battery's spherical shape may increase the likelihood of it becoming lodged. If the battery passes into the digestive system, injury is still possible and the child may remain asymptomatic for a period[3]. The battery may, however, pass through the body without causing harm.

As regards (2), this will be dependent upon either the caregiver knowing the child has ingested a button battery and seeking medical assistance, or seeking such assistance on the basis of symptoms observed. In the latter case, there may be delay in the application of the appropriate treatment depending upon the speed with which the correct diagnosis of the problem is made.

Again, judgement must be applied in determining the probability of a level 4 injury occurring, taking into account the above.

Probability: 0.05

7. LEVEL OF RISK

The steps to harm are summarised in the table below.

Step 1: The remote control is left in a location accessible to a child	0.1
Step 2: The child handles the remote and, in the process, the coin battery is released	0.05
Step 3: The child picks the battery up and mouths it	0.5
Step 4: The battery is swallowed	0.1
Step 5: A level 4 injury occurs	0.05

[3] Lee, J. H., Lee, J. H., Shim, J. O., Lee, J. H., Eun, B. L., & Yoo, K. H. (2016). Foreign Body Ingestion in Children: Should Button Batteries in the Stomach Be Urgently Removed? Pediatric gastroenterology, hepatology & nutrition, 19(1), 20–28. https://doi.org/10.5223/pghn.2016.19.1.20

The compound probability is the sum of the probabilities at each step, which equates to 0.0000125 (or 1 in 80,000). For a level 4 injury, this is a **high-risk** outcome (see PRISM guidance Table 3 in Part 1, section 2.2(vii).

Because the risk outcome is less than serious, consideration needs to be given to whether there are any alternative harm scenarios that could produce a higher level of risk (in this case, there are not).

When the risk presented by all items of the product estimated to be in use across the UK (estimated to be 2500[4]) is taken into account, the risk level remains at high (see PRISM guidance Table 4 in Part 1, section 2.2(vii)).

8. UNCERTAINTY

There is a medium level of uncertainty in relation to this assessment which is attributable to the fact that supporting evidence is limited. The harm scenario is largely based on predicting the behaviour of young children and of adult caregivers, both of which come with uncertainty. It is considered that button battery risks are not as widely appreciated as many other risks to young children, but the degree to which this is the case is difficult to estimate and can be expected to change over time as knowledge of such risks grows.

Sensitivity analysis

The probabilities associated with steps four and five are two areas of significant uncertainty. There is currently little empirical data and the utility of injury data from hospitals is limited. However the outcome of the risk assessment is not particularly sensitive to changes in these probabilities, which would need to change significantly to move the risk level outcome from high to serious.

RISK EVALUATION

The people primarily at risk in this scenario are children under 36 months of age. The public is assumed to have a low tolerability of non-compliant products that can cause avoidable injury to children, particularly very young children and particularly where the injury is potentially serious. The highly distressing nature of the potential injury and the circumstances in which it can arise are such that there is potential for psychological impact on the caregiver, the child's family, and anyone involved in dealing with the incident.

In addition, the nature of the risk in this case is low probability and high severity, and such risks tend towards low tolerability. Finally, the product performs a decorative purpose with no practical utility. The particular risk is not part of the essential functioning of the product and can be readily designed out by, for example, securing the battery compartment with a suitable small screw.

This high-level risk is therefore considered intolerable and action will be required to reduce the risk to a tolerable level.

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[4] In reality, because not all of the product items would be in dwellings frequented by young children, a downward adjustment to the "all items" estimate would need to be made to take account of this.