Office for Product Safety & Standards

PRISM: Risk Assessment (With Supplementary Rationale) – Non-Compliant Car Seat

1. THE PRODUCT

The product in question is a child's rear facing car seat, used to reduce the risk of injury to an infant when travelling by automobile, particularly in the event of a collision. The seat is designed for infants 0-18kg in weight.

Note: As this is a worked example further product details are not provided here, but would typically 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 and identify the product.

2. HAZARD/S

The product was subject to testing by a competent laboratory, and the subsequent test report includes the following:

In case of a frontal crash, the child car seat (CRS) may not give the protection against head displacement as required. As a consequence the child could be injured, their neck being particularly at risk. Furthermore, the mass group in the manual does not correspond to one indicated in the label and for which the product is intended.

The product does not comply with Regulation UN/ECE N. 44-04

The product hazard in this scenario is not one where the product itself causes injury, rather it is a reduction in the protection offered by the product and specifically to the occupant of the car seat when the vehicle is involved in a particular type of collision (a frontal crash).

Further, there is some risk of confusion over the mass of the child that the seat is suitable for, and therefore there is potential for a child who is too large being placed in the seat which could compromise the protection it is designed to provide. However, consideration of foreseeable human behaviour would suggest that parents would most likely use a car seat until their child starts to grow out of it, rather than the actual mass of the child being the primary consideration. Therefore any inconsistency

between instructions and the product itself is unlikely to change behaviour or use. The primary point of reference will be the marking on the product itself, and if this is correct then the parent will most likely follow the usual progression in product use.

In summary, testing of this product has indicated a deficiency in its design, which can increase the probability of serious injury in the event of a collision. A full risk assessment is required, the hazard being the lack of protection offered in the event of a frontal crash.

3. WHO WILL BE HARMED?

The child occupying the seat when the vehicle is involved in a collision will be the only person who can be harmed by this hazard.

This seat falls within car seat group 0+/1 which means that it can only be used in the rear facing position, is permanently attached to the vehicle, and can be used for infants and children up to four years old.

4. HARM SCENARIOS

There are two ways of constructing the pathway to harm. The first considers the probability of a frontal impact occurring; the second assumes this has already happened and considers only the step where the protective mechanism becomes important. The first harm scenario, having three steps, will provide for a lower level of risk, but no less uncertainty. The approach taken in the second harm scenario is referenced under Part 2(6) “Relative risk” of the PRISM guidance. Both scenarios will need to be considered at the risk evaluation stage of the risk process.

Harm scenario 1

There is a relatively direct route to injury for this product hazard. It can be assumed that if the product is in use then it contains a child of the appropriate age/size, and therefore if involved in a collision it will be expected to offer the relevant protective qualities for the occupant. The second step considers the probability of a frontal collision, which is a combination of the probability of the car being involved in a collision and the probability that the collision is a frontal one.

Step 1: The car seat is occupied by an infant while the vehicle is in use.

Step 2: The vehicle containing the seat/child is involved in a frontal collision of sufficient magnitude that the protection offered by the seat is necessary.

Step 3: The occupant of the seat suffers injury as a result of the collision and the lack of expected protection offered.

Consideration was given to framing the third step in terms of the probability of either injury or increased injury as a result of the ineffective protection offered by the seat, but this was discounted due to the difficulty in estimating this differential. Therefore just fact of injury was used, with the underlying assumption being that if the seat offered the appropriate protection then injury would not be sustained.

Harm scenario 2

Here, the harm scenario is reduced to the following:

Step 1: A frontal collision has taken place and the occupant of the seat suffers injury as a result of the collision and the lack of expected protection offered.

5. SEVERITY OF HARM

The severity of harm is dependent upon a number of factors, in particular:

- The severity of the collision and the forces to which both the seat and the child are subjected;
- The type of injury likely to result from the particular defect in the product; and
- The age, developmental stage, and way in which the child is holding itself at the time, for example being asleep, awake or agitated.

There is no data available on exclusively paediatric neck injuries, and even if there were it would be in the context of compliant car seats. Thus, while the above factors are essentially unknowns, inferences can be drawn from the data in relation to the forces present in vehicle collisions. While the level of injury possible in these circumstances could be anywhere between level 1 and level 4, a plausible worst-case level of injury can be demonstrated to be cervical bone fractures (i.e. neck region) or spinal cord injury which is amplified in children and can be life altering. A level 4 injury will therefore be considered for the purposes of this assessment.

6. PROBABILITY OF HARM

Harm scenario 1

For harm scenario 1, the following probabilities can be estimated using the available data and knowledge of human behaviour:

Step 1: The car seat is occupied by an infant while the vehicle is in use.

For this step the proportion of time the child is in the car seat while the car is in use must be considered. This is impossible to do with any degree of confidence as different children spend more or less time in the car when it is being driven. A reasonable estimate is considered to be 25% of the time, which accounts for regular travelling and also significant mileage by one or more drivers when the child isn't present.

Probability: 0.25

Step 2: The vehicle containing the seat/child is involved in a frontal collision of sufficient magnitude that the protection offered by the seat is necessary.

This is a difficult step to estimate. There is some data which estimates the average probability of collision at a rate of 0.12 collisions per vehicle[1] and another study estimates that 8% of multi-vehicular collisions are head on[2]. Whilst the second figure relating to head on collisions is from the U.S, it provides an estimation of the probability of a head on collision of 0.0096. However, this doesn't account for the fact that this is a vehicle lifetime estimate, and the seat in question is unlikely to be in use for the entirety of the vehicle's life. If a vehicle's average life is estimated to be 12 years[3] and the car seat is likely to be in use for approximately 3 years (if it is assumed a baby carrier seat is used for the first year, and the seat is used until the child is four years old) this provides a further probability factor of 0.25, reducing the

1 Accident Frequency Rates – Driving for Better Business
2 Predicting crash frequency for multi-vehicle collision types using multivariate Poisson-lognormal spatial model: A comparative analysis – ScienceDirect
3 What is the Average Life of a Car? (Vehicle Lifespan) | Cascade Collision

probability of a frontal collision with the seat in the car to 0.0096 multiplied by 0.25 giving a figure of 0.0024.

Probability: 0.0024

Step 3: The occupant of the seat suffers a serious injury as a result of the collision.

This is also difficult to estimate. The dependent factors are the magnitude of the forces involved in the accident (that arise as a result of the speed of the vehicle the seat is in and either the strength or speed of what is collided with) and the specific protective failure identified in the seat. Vehicles moving in the opposite direction will exert a different force to immobile objects such as trees or walls, and some objects will absorb force, for example crash barriers. In addition, the type and features of the car – the design of its safety cage etc. – will have an effect on these forces.

One method of making an estimation is to consider the incidence of serious neck injury in frontal collisions in adults, thereby providing an analogue for the likelihood that this will occur for a child who is in a seat with insufficient or ineffective protection.

Data addressing the specifics of this step is difficult to find. US data for 2019 indicates that out of a total of 6.76 million vehicular accidents, there were 17 810 spinal cord injuries[4]. Whilst these may not all be at level 4; they offer a basis for estimation. Therefore, we can estimate there is a probability of 0.0026 for this step (17,810 / 6,760,000).

Probability: 0.0026

This provides a compound probability of 0.000 00156 or approximately 1.6 incidences in a million, equating to **Low Risk.**

Harm scenario 2

If the scenario 1 probabilities are applied to scenario 2 (where it is assumed that the frontal collision has already happened), then the probability is 0.0026 or 2.6 cases per 10,000, which equates to **Serious Risk.**

7. LEVEL OF RISK

The two injury scenarios discussed above give significantly different outcomes. The first three-step scenario represents the actual (absolute) level of risk associated with the product (i.e. low risk), and the second scenario represents the relative risk (i.e. serious risk).

This product is subject to formal type approval and production control by virtue of Regulation ECE 44[5], and therefore can be assumed to be homogenous.

8. UNCERTAINTY

There are significant uncertainties in these probabilities, and some of the sources are derived from commercial organisations rather than statistical publications or academic journals. That said, they are likely to be the best open-source information available to the risk assessor for the harm scenario under consideration. The data

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4 How Often Do Car Accidents Result in Spinal Cord Injuries? – Solomon Law Group (solomonlawsc.com)

5 Regulation No 44 of the Economic Commission for Europe of the United Nations (UN/ECE) – Uniform provisions concerning the approval of restraining devices for child occupants of power-driven vehicles (‘Child Restraint Systems’).

sources used are for modelling purposes rather than as a predictive tool; they provide a sense of what is the most likely outcome and are stronger than mere estimation alone. The data used is at population level and is therefore more reliable than anecdotal or small sample sizes (this principle is explained further in Part 2(3) of the PRISM guidance, “Use of data”).

The uncertainty level for this risk assessment within PRISM is medium, as the risk is well understood, but the statistical data is not directly relevant to the scenario under consideration.

Sensitivity Analysis

Sensitivity analysis can be undertaken in a variety of ways for this product. There is little benefit in carrying out such an analysis for scenario 1 given its low risk outcome. Even if parameters are significantly adjusted, the risk outcome is not sensitive to change.

Sensitivity analysis should therefore focus on the scenario 2 outcome. Although the probability used is subject to significant uncertainties, it is suggested that the estimate may in fact be on the low side (2.6 instances of level 4 injury per 10 000 frontal accidents could potentially be significantly higher because the relevant data includes all accidents rather than frontal accidents only). However, any upward adjustment of this figure to reflect uncertainties in the probability estimation and the limitations of the data will not change the serious risk outcome.

RISK EVALUATION

The two harm scenarios discussed above give significantly different outcomes. When applying the relative risk approach within scenario 2, this product presents a serious risk. Standard risk assessment methodologies using the actual harm event probability are generally unsuitable for protective devices, due to the low probability of their protective qualities being needed. Relative risk provides a clearer indication of societal tolerability of risk, the general expectation being that protective devices or products should and will provide the specified level of protection. Moreover, in this particular case the particular people at risk is also relevant to tolerability, there being a generally low tolerability of risks presented by products intended for use by young children.

Serious risks are normally considered intolerable. While this assessment has some uncertainty in the probabilities, the risk outcome is as would be expected and may be used to justify the need for risk management action to be undertaken.

In summary, although the absolute risk is low, the relative risk is serious. Overall, the risk cannot be considered tolerable.

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