

SUFFOCATION ASSESSMENT AND DESIGN REVIEW OF HOODINI SWADDLE BLKANKET

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**GENERAL
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PRODUCT NAME
Hoodini Swaddle Blanket

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TABLE OF CONTENTS

Executive Summary.....	4
1. Introduction	5
2. Suffocation HazardAssessment.....	6
2.1. Background	6
2.2. Method	7
2.3. Results.....	8
3. Design Review	10
3.1. Foreseeable Use.....	10
3.2. Essential Safety Identification.....	11
4. Discussion.....	15



EXECUTIVE SUMMARY

KnitIT requested for Intertek to conduct a suffocation assessment and design review on the Hoodini Swaddle Blanket. Two samples have been submitted by the customer, and were assumed to perform identically, therefore, only one product was considered for the suffocation screening. The sample was assessed in two ways- folded and unfolded, with a child mannequin placed in the thickest part of the product – ribbed chest section. Upon completion of the suffocation assessment, it was found that in the worst-case scenario with the child face down on the folded product, the product is considered low potential for suffocation hazard as all readings were less than 15 cm-H₂O with the highest of those readings being 3.61 cm-H₂O.

In addition to that, Intertek has also conducted a design review on two samples of the Hoodini Swaddle Blanket. Included in the review is the foreseeable use assessment to identify intended and unintended use of the product and a human factors analysis to identify any potential hazards associated with the design.

Improper orientation and uninstructed uses create potentially hazardous conditions for infants. Removing the foot flap may allow for similar functionality, while reducing or mitigating hazards associated to entrapment, falling, and strangulation. Ligature strangulation due to extension of knitting is also identified as a potential hazard related to this product. Suffocation/ CO₂ rebreathing, overheating and diaphragm/constriction of infant breathing are other hazards described in this report and mitigation recommendations are provided.



1. INTRODUCTION

Intertek has been contacted by KnitIT to conduct a suffocation hazard screening assessment and a design review of a Hoodini Swaddle Blanket shown below in Figure 1. As two samples were received, they were assumed to have identical material composition regardless of size, therefore only one sample was assessed for suffocation.

Using the information gathered and through document review, Intertek safety engineers also conducted a design review of the product to identify potential essential safety concerns. Intertek convened an internal panel of experts consisting of Human Factors, Foreseeable Use, and Safety Engineering team members in order to identify foreseeable use behaviors and potential essential safety concerns in regard to the Hoodini Swaddle Blanket. Intertek also conducted high level research to understand the various types of hazards associated with the product, and mitigation recommendations. The two samples received were of different sizes, one intended to be used on children 0-3 months of age that are 16-23 inches in height and a larger sample that is to be used on children 0-6 months of age that are 23-28 inches in height.



Figure 1 Hoodini Swaddle Blanket



2. SUFFOCATION HAZARDASSESSMENT

2.1. Background

Asphyxia is a lack of oxygen supply to body tissues which can have negative effects on the organs, including the brain. Lack of oxygen, depending on how severe it is and how long it lasts, can lead to serious injury to the brain and the rest of the body, as well as death. There are many circumstances that can induce asphyxia, all of which are characterized by an inability of an individual to acquire sufficient oxygen through breathing for a n extended period of time.

Suffocation takes place when an object is placed externally over the mouth and nose, blocking the passage of air. When respiration is interrupted, carbon dioxide (CO₂) levels in the blood increase. In adults, raised CO₂ levels incite increasingly strenuous respiration attempts. However, for infants, if initial attempts at respiration fail, there is no increase in respiration effort.

Suffocation injuries and fatalities are most common in children less than 2 years of age. The types of objects most commonly involved in suffocation incidents are plastic films or bags, but may be any product that makes a seal against the face of a child, obstructing airflow to the mouth or nose including bedding and toys. The face of a child in this age group has greater amounts of fat and undeveloped prominent bony structures and is consequently more likely to provide an effective seal.

If the mechanical blockage is complete and the agent of suffocation is not removed, the incident will be fatal after 2-3 min. Partial blockage may be survived for longer periods of time, depending on the level of resistance and the strength of the child.



2.2. Method

Intertek worked closely with Dr. William W. Fox, Division of Neonatology, Children's Hospital of Philadelphia as well as Dr. Thomas H. Shaffer, Director of Respiratory Physiology, Professor of Physiology and Pediatrics, Alfred I DuPont Institute. Both physicians helped to design and develop a test methodology and acceptance criteria to quantitatively assess the potential suffocation hazards posed by various types of materials and consumer products.

A mannequin representative of a child in the at-risk age group was used to evaluate the product's potential to mechanically obstruct the passage of air into the nasal and oral airways. A mechanical lung system, representing an average 4-6 month old child, was utilized to simulate the human breathing mechanism with a 60 ml tidal volume and 26 bpm breathing frequency. The suffocation hazard assessment instrumentation showing the mannequin and mechanical lung system is shown below in Figure 2.



Figure 2 - Suffocation Hazard Assessment Instrumentation

Potential airflow blockage occurs when an item is placed near or next to the face of the mannequin and the peak pressure inside of the mechanical lung is measured to determine if breathing can be sustained. The mannequin is placed face-down on the sample and moved to different areas on the product in order to assess a worst-case scenario.

Based on the recommendations from Dr. William W. Fox and Dr. Thomas H. Shaffer, a limit of 15 cm-H₂O or less for each applicable testing technique is required for a product to be classified as having low potential for fatal outcome by airway obstruction. Products will be assigned a low, moderate, or high hazard level based on their proximity to the limit. It should be noted that normal breathing for the mannequin is around 2-3 cm-H₂O.

- A low hazard level will be assigned to products that have pressure values well below the limit of 15 cm-H₂O. Examples of materials that typically display a low hazard level are items you can easily breathe through, such as mesh. When items fall into the low hazard level category, there is no major concern for a fatal suffocation event to occur.



- A moderate hazard level will be assigned to products with pressure values at or around the limit of 15 cm-H₂O. When items fall into the moderate hazard level category, there is a potential for a fatal suffocation event to occur under certain circumstances.
- A high hazard level will be assigned to products with pressure values above the limit of 15 cmH₂O. The higher the value goes above 15 cm-H₂O, the amount of time a child could sustain breathing goes down. Examples of material that typically display a high hazard level are plastic films and dry cleaning bags, as well as water proof materials. When items fall into the high hazard level category, they are typically not breathable and therefore likely to pose a potentially fatal suffocation event.

2.3. Results



The Hoodini Swaddle Blanket was assessed for suffocation as shown below in Figure 3 along with the results in Table 1. The blanket was assessed in both folded and unfolded conditions, and a worst-case scenario was identified to be Orientation 1 - Folded Sample, as shown in Figure 3 . Upon completion of the 5 readings, it was found that both Orientation 1 - Folded Sample and Orientation 2 – Unfolded Sample have a low potential for suffocation as all readings were below 15 cm-H₂O (as shown in Table 1 below).



Figure 3 Worst Case – Folded Hoodini Swaddle Blanket



Table 1 Suffocation Assessment Sample Readings (cm/H₂O)

Position	Assessment Readings (cmH₂O)	
	ORIENTATION 1 – FOLDED	
	Trial 1	3.43
	Trial 2	3.47
	Trial 3	3.46
	Trial 4	3.61
	Trial 5	3.55
	ORIENTATION 2 – UNFOLDED	
	Trial 1	3.29
	Trial 2	3.21
	Trial 3	3.34
	Trial 4	3.47
	Trial 5	3.31

Green = Pass (below 15 cm-H₂O)

Yellow = Close to Failing (very close to 15 cm-H₂O)

Red = Failure (above 15 cm-H₂O)



3. DESIGN REVIEW

3.1. Foreseeable Use

It is important to take into consideration the ways in which consumers will use and interact with the product, as certain foreseeable uses can help to identify potential hazards associated with the item. For this product in particular, it is especially important to understand the behaviors of adults since they are the ones placing the item on the child. It is also critical to understand the developmental skills and abilities of the children that will be interacting with the item as constant supervision may be limited since it is intended to be used for sleep.

With respect to adults, they may not thoroughly read through the instructions regarding how to properly use the Hoodini swaddle. As such, they may attempt to put the product on the child upside down which could result in additional fabric being close to the child's face. Even when used in the correct orientation, they may try to pull the opening up as high up as possible, which could also result in fabric being close to the child's face. When used in the correct orientation, caregivers may either intentionally or unintentionally not use the arm holes and instead place the child's arms next to their body inside the main compartment. It is also foreseeable that caregivers may use an incorrect size such as using the 0-3 month size for a baby that is larger than 16-23 inches or the 0-6 month size for a baby smaller than 23-28 inches. If the child sleeps well with this product, some parents may continue to use it for children greater than 6 months of age. Other foreseeable uses include: dressing a child in multiple layers prior to placing them in the swaddle, using the product on a mobile infant that is capable of rolling or greater, and not following proper washing instructions. Some caregivers may also use it as a blanket by placing it over the child or leaving it in a child's sleep environment such as in a crib or bassinet. It should also be noted that while a majority of caregivers would know not to place a child to sleep on their stomach while wearing this, some may still do this if they feel their child sleeps best while in this position.

As previously noted, it is important to take into consideration the skills and abilities of children that will be wearing the product to understand how they will interact with the item. During the 0-6 month age range, children make significant advances in brain and motor development. Over the course of this age range they will learn how to hold their head up and roll from side to side. Therefore, it is foreseeable that they may exhibit these skills while wearing the product. A baby may roll from back to stomach when placed in the swaddle but then be unable to roll back. Some caregivers may continue to use the swaddle for children older than 6 months of age and possess greater motor skills, such as sitting, crawling, and pulling up to stand. Infants of all age ranges will likely explore the product with their hands, especially while they are contained within the product. They may work to remove their hands from the product, especially so they can bring them to their mouth to self soothe. Finally, since mouthing objects is how infants explore their environment, it is anticipated that they will place any accessible portions of the product into their mouth.




3.2. Essential Safety Identification

Through panel document review comprised of Intertek’s Safety Engineers and Human Factors specialists, the following hazards were identified in Table 2 and further recommendations are given to mitigate safety concerns observed with the Hoodini Swaddle Blanket.



The hazards below are labelled as follows:

- **High Hazard** is defined as having a potentially fatal outcome or resulting in longer term hospitalization
- **Medium hazard** is likely to result in a trip to the hospital and may require an overnight stay
- **Low hazard** is either a perceived hazard or an injury requiring minor first aid treatment at home

Table 2 Hazard Identification

HAZARD TYPE	FORESEEABLE USE	MITIGATION	PHOTO OF COMPONENT
Ligature Strangulation	Knitting can expand with use, potentially allowing the admission of fingers between the fibers.	Ensure expansion of knitting is not capable of producing openings greater than 4.0mm in diameter. This dimension represents the smallest cross section of a 5 th percentile new-born’s little finger. Should this finger not be able to admit, larger fingers from larger users should not be able to admit their fingers as well. Should the hazard present during periods of sleep, long term durations of decrease perfusion may exist.	




HAZARD TYPE	FORESEEABLE USE	MITIGATION	PHOTO OF COMPONENT
<p>Suffocation/CO₂ Rebreathing</p>	<p>The intended use of this item is to be used during sleep. Should the item become loose or positioned in a way not intended, users may end up with the item covering their nose and mouth.</p>	<p>The item shall allow for the diffusion of gas into and out of the lungs with minimal interference. This attribute has been demonstrated in the included suffocation hazard assessment. It is important to note that interstitial voids between the knitted material may accumulate carbon dioxide. As such, minimizing thickness and multiple layers, and ensuring a proper fit and instruction for caregivers will help reduce the potential for carbon dioxide rebreathing.</p>	
<p>Strangulation</p>	<p>Should the foot opening be placed over the head, an open loop can form over the submental location of the neck.</p>	<p>Minimizing the size of the opening to ensure that when stretched by a ~25lb load does not exceed 13.94" in perimeter length. This will effectively eliminate the potential for the smallest head size to be inserted into the opening, coupled with the heaviest ~12-month-old from admitting their head into the opening. Consider removing the foot flap to allow for an open pass through.</p>	



HAZARD TYPE	FORESEEABLE USE	MITIGATION	PHOTO OF COMPONENT
Overheating	Product may be used with other swaddles/accessories.	Instruct caregivers to use the product only as intended, in an environment of approximately 70°F, and only by itself. Unless used in a cold environment, do not encourage the use of caps unless infant occupant is <8lbs, (AAP). Material provides insulation value, however, allows for the transference of heat and air.	
Entrapment	The product may be used without supervision leading to improper restraint/positioning of the occupant.	Hand and foot openings allow for the admittance and removal of hands with minimal force applied. During use, the product may reposition causing difficulty to remove appendages.	
Diaphragm/Constriction of infant breathing	Elastic nature of material circumferentially constricts about occupants.	Infant breathing originates from their belly (diaphragmatic breathing) and not from their chests. Ensure the constriction of the material does not overcome the bodies ability to expand while inhaling. For example, creating an internal perimeter of ~50cm+ accounts for a 95% percentile 12 month old at the largest dimension of the chest.	



HAZARD TYPE	FORESEEABLE USE	MITIGATION	PHOTO OF COMPONENT
Fall Hazard	Should older users continue to use the product while mobile, the lack of feet access, or the potential for incumbered feet motion may cause a fall hazard.	Encasing the feet with material may be difficult for mobile infants to remove in order to walk safely. As the product may not be removed as infants walk, consider removing the additional foot flap and allowing for an open pass through.	



4. DISCUSSION

Upon request from KnitIT, Intertek conducted a suffocation assessment and design review on the Hoodini Swaddle Blanket. The blanket has been assessed for suffocation in two ways – folded and unfolded with a mannequin’s face on the thickest portion of the product to mimic the worst-case scenario.

Suffocation values indicate that both Orientation 1 - Folded and Orientation 2 – Unfolded showed readings below the failure criteria of 15.0 cm H₂O, and as such the product material may pose a low potential for suffocation hazard. Note that changes to the product material should be assessed for suffocation as these results only apply to the assessed material.

In addition to that, Intertek has also reviewed the two sizes of the Hoodini Swaddle Blanket and conducted a design review based on the two received samples. Included in the review is the foreseeable use assessment to identify intended and unintended use of the product and a human factors analysis to identify any potential hazards associated with the design.

The Hoodini Swaddle Blanket is intended to be used during sleep on children 0-6 months of age. Some of the foreseeable uses of the blanket include putting the product on in the wrong orientation, not using the arm compartments, using incorrect size, using the product as a blanket, or leaving it in the crib accessible to children. Some of these intended and unintended uses may lead to potential hazards associated with this product.

As mentioned above, improper orientation and uninstructed uses create potentially hazardous conditions for infants. Removing the foot flap may allow for similar functionality, while reducing or mitigating hazards associated to entrapment, falling, and strangulation. It is recommended that hazards are investigated to determine potential risk.