



July 1, 2024

TRANSMITTED VIA EMAIL

Michelle Barry & Tara Williams
Subcommittee Co-Chairs for ASTM F15.19
100 Barr Harbor Dr.
West Conshohocken, PA 19428-2959

Dear Ms. Barry & Ms. Williams:

Attached you will find updated incident data on wearable infant blankets prepared for the ASTM F15.19 subcommittee.¹ We are providing the updated data to support the subcommittee's focus on potential hazards associated with these products. The time span for these 167 incidents (160 CPSRMS, 7 NEISS)² covers January 1, 2011 to April 10, 2024.³ You will find an additional 4 redacted in-depth investigations (IDIs) from 2020 to 2024 to provide additional context for those incidents.

To provide the most comprehensive data possible, CPSC staff has included more product codes than in prior shared datasets on this topic. Some of the additional product codes searched were children's nightwear, durable nursery products intended for infant sleep (cribs, bassinets), juvenile products not intended for infant sleep (motorized swings, strollers, etc.), and adult sleep products such as adult-sized nonelectric blankets found in co-sleeping settings. Additionally, staff searched a wider range of keywords including "swaddle," "sleep sack," "wrap," and "weight." Staff also used a list of brands, product names, and model names to identify responsive incidents. Staff then reviewed the resulting dataset to remove incidents that do not identify a wearable infant blanket product. The resulting preliminary dataset included many incidents that were responsive to ASTM's data request.

To determine whether an incident likely involved a wearable product that was in scope, CPSC's Office of Hazard Reduction and Identification (EXHR) reviewed the incident data. Staff examined the narrative content and non-public information, DIs, and any available source documents. Staff kept only those incidents with evidence of wearable product features like zippers, hook-and-loop fasteners, snaps, dedicated swaddle bands, or other wearable features. Incidents involving wearable swaddle products were the most challenging to identify as there is often insufficient detail and overlapping terms are used to refer to wearable and non-wearable

¹ Disclaimer: The views expressed in this letter are those of CPSC staff. The attached spreadsheet was prepared by the CPSC staff. They have not been reviewed or approved by, and may not reflect the views of, the Commission. CPSC staff does not guarantee the accuracy, completeness, or adequacy of these data particularly with respect to information submitted by people outside of CPSC. Pursuant to 17 U.S.C. § 105, there is no copyright in works of the U.S. government. Therefore, this material is in the public domain and may be freely copied or reprinted.

² CPSRMS: Consumer Product Safety Risk Management System, NEISS: National Electronic Injury Surveillance System

³Based on reports entered into CPSC's CPSRMS database no later than May 17, 2024. The data primarily concern infants and children younger than 2 years old, although data indicating older victim ages were also searched.



United States
Consumer Product Safety Commission

products. To facilitate the subcommittee's work of identifying addressable hazard patterns, staff categorized each in-scope incident by product type (wearable blanket / "sleep sack", swaddle, etc.) and whether such products were weighted (yes, no, unknown); whenever possible, staff used the definitions from the April 2024 balloted standard.⁴ Staff is including product type and weighted category columns in the incident data.

Staff worked to ensure all incidents involving wearable infant sleep products from the prior data set (delivered to the subcommittee on April 21, 2023) were retained. However, staff did not include any incidents from the previous dataset where wearable features could not be identified, and considered them out of scope.

Some limitations to this dataset include:

- No single product code applies uniquely to infant sleep sacks and swaddles (although most were found under 4008 nonelectric blankets);
- The current CDC SUID-I form focuses on arms in or out and rolling position but does not specify products (wearable swaddle vs. loose blanket swaddle);⁵
- Incidents typically involve multiple products and complex factors, adding to the complexity of identifying relevant incidents; and
- Incidents may not have been captured due to miscoded product codes, unanticipated misspellings or typographical errors, as well as any unanticipated age mis-categorizations (7-years-old instead of 7-months-old).

Staff appreciates the continued efforts of the subcommittee towards improving the safety of wearable infant blanket products.

Feel free to contact me with any questions.

Sincerely,

A handwritten signature in black ink, appearing to read "Khalisa Phillips".

Khalisa Phillips, Ph.D., Psychologist,
Division of Human Factors (301) 987-2592, or kphillips@cpsc.gov

CC: Molly Lynyak, ASTM F15 Staff Manager
Donald Mays, ASTM F15 Chair
Jailynn McGhee, JPMA Government Affairs Standards and Certification Associate
Jacqueline Campbell, CPSC Voluntary Standards Coordinator

⁴ See worksheet labeled "Key" for the modifications to the product categories and definitions from the April 2024 balloted versions used by CPSC staff

⁵ <https://www.cdc.gov/sids/SUIDRF.htm>

Wearable Infant Blanket Related Incidents
1/1/2011 to 4/10/2024*
CPSRMS Database

*Based on reports entered into CPSC's CPSRMS database no later than 5/17/2024.

This data primarily concerns infants and children younger than 2 years old, although data indicating older victim ages was also searched.

Fatalities shown in bold font.

Disclaimer: CPSC does not guarantee the accuracy, completeness, or adequacy of these data particularly with respect to information submitted by people outside of CPSC. This spreadsheet was prepared by the CPSC staff. It has not been reviewed or approved by, and may not represent the views of, the Commission.

Incident #	Document #	Date	Age/ Sex	State	Narrative	Wearable Infant Sleep Products	Weighted / NonWeighted / Unknown
1	I11A0390A	2011- Oct	4 MOM	VA	I placed my 4 week old son in his [SWADDLE] blanket, sides securely fastened, only to find him 45 minutes later having gotten out and the entire product bunched up around his throat and his struggling to breathe!	TransitionSwaddle	NonWeighted
2	I11B0257A	2011- Nov	7 MOF	VA	My daughter went to sleep in a [SLEEP SACK] on [REDACTED] 2011. When I went in to wake her up on [REDACTED], the slider body and pull tab of the zipper were no longer attached. The slider body piece was in her right ear and the pull tab was near her left hand. One piece could have easily gotten lodged in her ear. She could have choked on both. I have contacted the company via email but have not gotten a response from them.	WearableBlanket	NonWeighted
3	I1410197A	2011- Dec	9 MOF	Unk	My daughter was in a [SLEEP SACK]. When she woke up the zipper was detached. The zipper and its parts were in the crib near her ear. It very easily could have been stuck in her ear or swallowed by my daughter.	WearableBlanket	NonWeighted
4	I1220588A	2012- Feb	8 MOF	NJ	<p>I want to make you aware of a very serious safety concern involving [SLEEP SACKS] for infants that recently occurred with my 8 month old daughter. The [SLEEP SACK] is a wearable blanket designed for babies to wear in their cribs to prevent SIDS (Sudden Infant Death Syndrome). The [SLEEP SACK] has a tag that is attached to the back. My daughter managed to pull it off while she was in her crib for her nap and then put it in her mouth. By the time I got up to her room, the entire tag was lodged in her throat. Thank god she made some noise and I went up to check on her and saw that she was gagging. The tag was in the back of her throat, halfway down her airway. I pulled it out and she was alright, but I shutter to think what might have happened if the tag had gotten into her mouth earlier in her nap and I had not gone upstairs to check on her. She could have choked to death.</p> <p>When you are dealing with products that are designed for infants to sleep in, knowing they will be unattended while in their cribs, anything that could be a potential safety hazard should be removed. I have three kids and have used the [SLEEP SACK] with all three, and nothing like this ever occurred before, so I never even thought twice about cutting off the tags. However, I would highly recommend that [REDACTED] go "tagless" and instead simply print a label on the back of the [SLEEP SACK] itself. I would hate to hear of any baby suffocating or choking on a tag they managed to dislodge while in their crib when their parents believe they are sleeping.</p> <p>Thank you for your attention</p>	WearableBlanket	NonWeighted
5	121128CCC3170 I12B0437A	2012- Nov	22 MOM	WA	A 22 MONTH-OLD BOY WAS PUT TO BED IN HIS CRIB DRESSED IN PAJAMAS AND A WEARABLE BLANKET [SLEEP SACK]. DURING THE NIGHT THE BOY WAS ABLE TO UNZIP THE WEARABLE BLANKET AND CRAWL OUT OF THE PRODUCT. HE THEN CRAWLED BACK INTO THE WEARABLE BLANKET, HEAD FIRST. HE WAS DISCOVERED BY HIS MOTHER EARLY THE NEXT MORNING, FACE-DOWN, TIGHTLY WRAPPED IN THE WEARABLE BLANKET. HIS FEET WERE STICKING OUT OF THE PRODUCT'S ARM HOLES. HE WAS ASLEEP. HE WAS UNINJURED.	WearableBlanket	NonWeighted
6	X1660012B	2013- Apr	2 MOF	MI	2 MOF died in bouncy seat inside [PLAY YARD] to nap, wearing [SLEEP SACK] at an in-home daycare. She was put to sleep in a bouncy seat inside a [PLAY YARD], but she couldn't secure the infant to the seat because she was wearing a [SLEEP SACK]. The provider checked on the infant 2 hours later and found her completely turned around with her face and chest up against the bouncy seat.	WearableBlanket	NonWeighted
7	I13A0144A	2013- Jun	4 MOF	PA	My baby was born in feb. all my friends where using [SLEEP SACKS], and told me i had to get one, so i went online and ordered one, i am currently unsure because i cant remember where i ordered it from but it was online- Since it was my first girl out of two boys, i picked a pretty frilly one with a [REDACTED], she wore it a couple times before- she was 4 months old i woke up from the noise on the monitor i knew we was wake and kicking legs or rolling in crib, i walk over and she had the [REDACTED] off in one hand sucking on it! I WAS SCARED! She was fine!!!! BUT since she didn't wake up crying she woke up HAPPY, what would of happened if she did that in the middle of the night and chocked???? I WAS SOOOOOOOO UPSET! I called to ask friends if anything was attached to theres they told me no they got theres free from the hospital at [REDACTED] and it was just plain. I just kept thinking about this! And decided well maybe it just came off??? What if she pulled it off??? So i threw it away!!!!!! Now!!!!!! 5:30 in the morning i was just randomly checking recalls bc of the [REDACTED] (childrens medicine recall) and saw this AND THIS HAS HAPPENED TO US!!!!!!!!!!!! I felt the need to share! Other mama's need to know! And it wasn't very well avertized! Recalls are scary to parents with small children! I was also looking at the food recalls- some things have been recalled for failure of might have nuts or peanut butter cookies in wrong choc.chip bag- MY SON STOPS BREATHING FROM NUTS! And he's 4! We thank god haven't had problems with that BUT RECALLS NEED A BETTER WAY TO BE SHARED BC THE AVERAGE MOTHER OF 2-3 CHILDREN DONT HAVE ALOT OF TIME TO SURF THE WEB TO CHECK TO MAKE SURE EACH DAY THE PRODUCTS THAT HAVE GOTTEN FOR THERE CHILDREN ARE GOING TO KEEP THEM ALIVE THE NEXT DAY! - this mama is upset!	WearableBlanket	NonWeighted
8	I1360229A	2013- Jun	11 MOF	OR	I use wearable blankets for my 11 month old daughter. I purchased 2 [REDACTED] Wearable Blankets by [REDACTED] on [REDACTED]. When I zipped up the sack for her nap this morning the pull tab of the zipper came off. It is small enough to be a choking hazard. I'm going to take both of them back to [REDACTED]. I'm very concerned that these blankets are unsafe.	WearableBlanket	NonWeighted
9	I1360384A	2013- Jun	10 MOF	MN	We swaddled our baby using the [SWADDLE] wrap and heard a choking sound coming from her room. Her arms had broke through the bottom of the arm wraps and she had lifted her arms over her head causing the upper fabric to become tightly wrapped around her neck. No obvious injury occurred as we quickly unwrapped her and discontinued use of the swaddle following this incident.	WearableBlanket	NonWeighted

5 USC 552(a)(2)(D)(ii) Posting

Incident #	Document #	Date	Age/ Sex	State	Narrative	Wearable Infant Sleep Products	Weighted / NonWeighted / Unknown
10	I1380002A	2013-Aug	7 MOM	PA	My son was wearing a fleece [SLEEP SACK] and the zipper pull came off the end. He likes to pull his legs up and chew/suck/teethe on the material of his [SLEEP SACK], so while he was sitting on my lap, I noticed the zipper was askew and when I attempted to pull it to unzip the [SLEEP SACK], the pull came off in my hand. This could have VERY EASILY ended up in my baby's mouth and choked him. I am thankful that I was nearby, as he sleeps for 12 hours in these [SLEEP SACKS] at night!	WearableBlanket	NonWeighted
11	I1410332A	2013-Oct	4 MOF	DC	<p>Using a gift card at [REDACTED] I purchased a 3-6 month old baby [SLEEP SACK] called [REDACTED]. This was purchased when I was still pregnant. I washed and dried the product according to the care instructions which are to machine wash and tumble dry on low. I put the product away until further use.</p> <p>When my daughter was about three months old I started using the [SLEEP SACK] for her nighttime sleep. I didn't notice anything wrong with the product until after about two weeks I washed and dried the product again, according the instructions. After this I noticed that the product was pilling slightly. The material is incredibly soft and shaggy, like short fur. I didn't think much of the pilling and put my daughter to bed as normal. The next morning however her fitted sheet was covered in the fuzzy pilling. I could run my hand over the sheet and feel them everywhere. This became a scary choking hazard nightmare because my baby would suck on her hand, get it wet with saliva, run her hand on her bed, which would create a large fuzz ball, then put her hand back in her mouth. When I found her that morning, she was safe and fine, but she did have a fuzz ball in her mouth about the size of pea. I hate to think what could have happened if she had choked on this.</p> <p>I contacted [REDACTED], who got me in touch with the owner, [REDACTED] of the local company, [REDACTED]. After photographing the product, I gave the [SLEEP SACK] over to him to investigate. After analyzing the product [REDACTED] was adamant that the product itself was not pilling, but had picked up the pilling from another article in the laundry. I found this hard to believe since nothing else was shedding any sort of fuzz. However, [REDACTED] was certain, stating that the fuzz was not the same material as the [REDACTED]. I disagreed, to the naked eye and just by touching, they did seem to be the same. I was swayed however to try the product again, as he told me he had never received any criticism for this product. [REDACTED] gave me the next size up, 6 - 12 month, in the same [REDACTED] pattern as a replacement for the original.</p> <p>Since receiving the new product I have washed the garment 3 times. The first two times I only put it in the washing machine, then let it air dry. The third time I put it in the drier. I didn't notice it shedding until that evening when I gave my daughter her nighttime bottle. I was wearing black [REDACTED] pants, while my daughter was sitting in my lap wearing the white [SLEEP SACK]. When I picked her up to carry her to her crib, my lap was covered in fuzz balls. I immediately removed her from the [SLEEP SACK]. This was a few days ago. I have not contacted [REDACTED] since this last incident because I don't trust his judgment. A child could die from choking on the pilling of this product. My daughter is 7 months old now and would most likely just swallow a fuzz ball and be fine, but that is not a risk I'm willing to take. And furthermore, this product is meant to be used for much smaller babies, who would probably not be able to easily swallow something like that.</p> <p>I still have the photographs that were taken of the first [REDACTED], the email correspondence between [REDACTED] and myself, and the second [SLEEP SACK] is still in my possession.</p> <p>Please help me in investigating this. This product is unsafe for little ones.</p> <p>Thank you for your help.</p>	WearableBlanket	NonWeighted
12	I13C0452A	2013-Dec	5 MOM	NJ	Our 5 month old/ 16 pound baby pulled the [SLEEP SACK] over his nose. It covered his mouth and nose. Luckily we have a camera so we could see and we took him out. However if we were asleep he could have suffocated. The point of these [SLEEP SACKS] is for safety and warmth. It was used correctly.	WearableBlanket	NonWeighted
13	H1420139A	2014-Feb	1 MOM	NJ	<p>Caller stated that the infant [SWADDLE] failed to keep her 7 weeks old child safe because the arms that went across the chest moved up to his neck posing a strangulation hazard. She feels that if she had not gotten to her child on time the product could have strangled her child.</p> <p>The manufacturer was not contacted as yet.</p> <p>Caller is concerned that this product is unsafe and should be investigated.</p>	Swaddle	NonWeighted
14	140930CCC2909 X1490974A	2014-Jul	1 MOM	MN	THE VICTIM, A 15 WEEK OLD MALE, WAS PLACED IN A PLAYPEN WHILE WRAPPED IN A SWADDLER. AFTER BEING IN THE PLAYPEN FOR AN UNKNOWN PERIOD OF TIME THE VICTIM WAS FOUND IN A FACE DOWN POSITION AND WAS UNRESPONSIVE AND COULD NOT BE RESUSCITATED. THE MEDICAL EXAMINER'S REPORT DISCLOSES THE VICTIM'S DEATH WAS CAUSED BY POSITIONAL ASPHYXIA WHICH RESULTED IN AN ANOXIC BRAIN INJURY DUE TO OR AS A CONSEQUENCE OF A COMPROMISED SLEEPING ENVIRONMENT.	Swaddle	NonWeighted
15	141030CNE0002 I14A0393A	2014-Oct	1 MOF	IL	A 4 WEEK OLD GIRL'S FACE WAS COVERED BY AN INFANT SWADDLING SLEEPER SACK. MOTHER STATED THAT THE MATERIAL OF THE SWADDLE PORTION OF THE PRODUCT HAD MIGRATED UPWARD AND WAS OBSCURING BOTH HER BABYÆS MOUTH AND NOSE. THE CHILD WAS NOT INJURED DURING THIS INCIDENT.	TransitionSwaddle	NonWeighted
16	141031CCC1072 I14A0372A	2014-Oct	9 MOF	MA	WHEN A PARENT CHECKED ON THE WELL BEING OF A 9-MONTH-OLD BABY THAT WAS PUT DOWN TO SLEEP WHILE WEARING A WEARABLE BLANKET SACK, SHE FOUND THAT THE TOP END OF THE ZIPPER HAD DETACHED ALLOWING THE CHILD TO REMOVE HER LEGS AND LOWER TORSO FROM THE [SLEEP SACK]. THIS SAME SCENARIO OCCURRED ON ONE OTHER OCCASION WITH THE SAME WEARABLE BLANKET.	TransitionSwaddle	NonWeighted
17	I14A0514A	2014-Oct	3 MOF	IN	<p>My daughter, who is 3.5 months old, was swaddled in the [REDACTED] swaddler. She is approximately 25 inches long, and the swaddler was on its largest setting, appropriate (according to the product instructions) for a 25 inch infant.</p> <p>When I checked on her in the middle of the night because I heard her rustling, she had worked her way out of the swaddler and somehow some of the fabric from the swaddler was over her face.</p> <p>I lifted her up and removed the swaddle and she was not injured. Obviously, though, fabric covering the face of an infant is quite dangerous and the outcome could have been different if I had not heard her and checked on her promptly.</p>	Swaddle	NonWeighted
18	I1520038A	2015-Feb	Unk	IA	Consumer reported that the sleeper sack has a hand sewn snap. Consumer assumes that it is a serious choking hazard as the snap is located at the top of the [SLEEP SACK], and would be easy for the child to remove.	WearableBlanket	Unknown
19	I1520333A	2015-Feb	3 MOM	AL	12 week old baby in [SWADDLE] [SLEEP SACK] by [REDACTED]. He was asleep and the [HOOK-AND-LOOP FASTENER] edge scratched his chin and made it bleed when he was being restless.	Swaddle	NonWeighted

Incident #	Document #	Date	Age/ Sex	State	Narrative	Wearable Infant Sleep Products	Weighted / NonWeighted / Unknown
20	I1560058A (Terminated IDI)	2015-Feb	2 MOF	NY	When I had my daughter, the hospital provided me with a [SWADDLE] or [SLEEP SACK]. I used the [SLEEP SACK] for quite some time, until one day my daughter squirmed her way out of the two wings that come across her chest and fastens to create a swaddle. The wing was up near her face. I was curious since the tag seemed rather thick, so I put the tag up to my face and was shocked to find that I could not breathe through the tag. I have not used that [SLEEP SACK] since.	TransitionSwaddle	NonWeighted
21	220509CAA1555 Mfr/Retailer Report	2015-Mar	3 MOM	SC	THE 3-MONTH-OLD MALE VICTIM WAS SLEEPING IN A PORTABLE BASSINET WITH A FITTED SHEET AND MATTRESS. THE VICTIM WAS POSITIONED ON HIS BACK IN A SWADDLE WITH BOTH ARMS RESTRICTED. THE VICTIM WENT TO SLEEP WITH A PACIFIER IN HIS MOUTH. THE VICTIM'S MOTHER CHECKED A VIDEO BABY MONITOR AND NOTICED SEVERAL HOURS LATER THAT THE VICTIM WAS LYING FACE-DOWN IN THE BASSINET. THE VICTIM WAS DISCOVERED NOT BREATHING AND UNRESPONSIVE. THE VICTIM'S MOTHER AND EMERGENCY MEDICAL PERSONNEL ATTEMPTED TO RESUSCITATE THE VICTIM BUT WERE UNSUCCESSFUL, AND THE VICTIM WAS DECLARED DECEASED ON SCENE. THE VICTIM'S CAUSE OF DEATH WAS DETERMINED TO BE POSITIONAL ASPHYXIATION.	TransitionSwaddle	NonWeighted
22	I1550298A	2015-May	2 MOF	Unk	Product: [REDACTED] Baby size small/medium. The swaddle pajamas were being used as intended with the correct size and age of a baby, and followed the directions of how to [fastener] them snugly on the baby. After using the swaddle for 4 weeks, our baby would get her hands and then arms out of the swaddle due to the material becoming stretched out from normal use. The hazard was due to when she would wiggle, the stretched out material/swaddle would wiggle up towards her head, giving her hands access to the opening of where the vertical leg sack material and the horizontal material parts meet. She would stick both of her hands out, then would pull her arms up towards her face in her sleep. I would find her like this asleep, and the horizontal material would be all pushed and squished up around her neck and partially or completely covering her mouth (still able to breathe out of her nose luckily). Thinking I was not swaddling her tight enough, I would continue to try using the product, but this same scenario happened 6 times in 1 month (even though I would [fastener] the swaddle so tight that there was no space between the swaddle and her skin, and she was unable to move when I first swaddled her until wiggling and stretching it out over a few hours and the material stretched and then moved). I stopped using the swaddle when one time I came in to check on my baby and the same scenario had happened again, but this time the material was pushed up over her mouth AND nose (still breathing when found her). The swaddle would never come undone and still was together, but would become stretched out and move as she slept, which allowed her hands to poke out of the opening (see photo) of where the corners of the material meet, causing a dangerous suffocation hazard.	Swaddle	NonWeighted
23	150828CCC3903 I1580338A	2015-Aug	8 MOM	CA	AN EIGHT MONTH OLD MALE WAS FOUND STANDING IN HIS CRIB, WITH HIS [SLEEP SACK] UNSNAPPED AND AT HIS WAIST. THE COMPLAINANT FELT THE SNAPS WERE NOT SUFFICIENTLY SECURE TO PREVENT A SUFFOCATION HAZARD. THERE WERE NO INJURIES.	WearableBlanket	NonWeighted
24	I15B0148A	2015-Nov	Unk	Unk	The consumer reported that several Chinese companies selling baby [SLEEP SACKS] online are not complying with many US safety and compliance standards. They sell sleepwear that is made of cotton which is not snug fitted and is not flame resistant. Their labels are in Chinese only	WearableBlanket	Unknown
25	X1680902A	2016-Jul	Unk	NY	The [SLEEP SACKS] was taken out of the package and the zipper broke in 4 places. This is a potential choking hazard. It was identified that this had occurred prior with 2 other [SLEEP SACKS].	WearableBlanket	NonWeighted
26	I16A0005A	2016-Oct	2 MOF	DC	Less than one month after purchasing the [SLEEP SACK], its metal zipper pull broke into multiple, sharp pieces in my hand while I was zipping it onto my two month old daughter. The part of the zipper remaining on the [SLEEP SACK] had a sharp metal edge that could easily injure an infant. The broken metal pieces from the zipper would have posed a serious choking hazard had they come off in the crib while she was asleep. The sharp broken pieces could also easily become lodged in an infant's skin or eye. The [SLEEP SACK] was subjected to normal nightly use by a two month old (8-12 hours a day) and was washed and dried in a home washer/dryer once or twice a week.	WearableBlanket	NonWeighted
27	I16A0222A	2016-Oct	2 MOF	CO	My baby was wearing an original [SWADDLE] made by [REDACTED] the other night. When I got up to feed her, it was bunched up around her neck and partially covering her face. I believe that if I wouldn't have gotten up when I did, it could have covered her nose and suffocated her.	Swaddle	NonWeighted
28	I16B0188A (Terminated IDI)	2016-Nov	3 MOF	MO	We have been using the [REDACTED] wearable blanket swaddle for our 11 lb daughter (size Newborn listed as 6-12lbs) since we brought her home from the hospital in August. This item is a zip up "sack" that has fabric that attaches in the back via fastener patches that you swaddle around the baby. The purpose of having the removable fabric is to be able to use the [SLEEP SACK] from the newborn swaddling stage and then transitioning into just the [SLEEP SACK]. This morning I woke up horrified when I opened my eyes and saw my baby in the bassinet beside the bed with the removable piece of fabric around her neck and over her mouth and nose. She had wiggled enough to get her hands out and the [HOOK AND LOOP FASTENER] in the back apparently came loose and allowed the fabric to cover slip up around her neck and over her face. I immediately yanked the fabric off her face and was so relieved to see that she was safe. Once I knew she was safe, I took a quick picture of the fabric around her neck (but I had removed from her face) before picking her up because I knew immediately that I had to share this information to hopefully prevent what could be a fatal accident for another family. We are extremely cautious when it comes to our infant's sleeping specifics. She sleeps in a bassinet next to our bed. There is NEVER anything else in the bassinet and she is always zipped into a [SLEEP SACK]. She is always swaddled in this [SLEEP SACK] or the fleece version if it's colder. We always swaddle snugly as recommended and make sure she is using the correct item for her age/size. We have done everything right. We took every step possible to make sure she has a safe sleeping environment and this is something that should not EVER happen. It's apparent that we swaddled the sack correctly, because the front [HOOK AND LOOP FASTENER] never broke open. If it would have been a looser swaddle, then the [HOOK AND LOOP FASTENER] would have become detached and not wrapped around her neck and covered her face. This item needs to be pulled from the market and replaced with a [SLEEP SACK] that does NOT have a removable swaddle piece. I know the company is trying to market the item as "versatile" and appealing to the consumer by saying that it will transition with your baby. But it's not safe.	TransitionSwaddle	NonWeighted

Incident #	Document #	Date	Age/ Sex	State	Narrative	Wearable Infant Sleep Products	Weighted / NonWeighted / Unknown
29	170327CCC3656 I1730448A 1641031191	2016-Nov	1 MOM	OR	A SEVEN AND A HALF WEEK OLD MALE TWIN DIED AS A RESULT OF POSITIONAL ASPHYXIA. THE VICTIM WAS PUT DOWN TO SLEEP ON HIS BACK ALONG WITH HIS TWIN BROTHER. BOTH BOYS WERE SWADDLED IN [SLEEP SACKS] AND PUT INSIDE AN INFANT PORTABLE BED/ BASSINET WHICH WAS ON TOP OF QUEEN SIZE MATTRESS COVERED BY A QUEEN SIZE COMFORTER. THE VICTIM'S MOTHER WAS LYING ALONGSIDE THE INFANT PORTABLE BED/ BASSINET WITH HER ARM CURLED AROUND THE TOP OF IT. WHEN THE VICTIM'S MOTHER AWOKE SHE DISCOVERED THE VICTIM WITH HIS FACE MOUTH AND NOSE PUSHED UP AGAINST THE UPPER SIDE WALL OF THE PORTABLE BED/BASSINET AND HE WAS UNRESPONSIVE. SHE ATTEMPTED CPR BUT COULD NOT REVIVE HIM. THE VICTIM WAS TRANSPORTED TO THE HOSPITAL WHERE HE WAS PRONOUNCED DECEASED.	TransitionSwaddle	NonWeighted
30	X1721369A	2017-Feb	6 MOM	CA	6 MOM decedent was found prone and unresponsive in a travel crib. Was placed in a swaddling [SLEEP SACK] with arms swaddled. Originally placed supine with animal pacifier. COD: sudden unexpected infant death.	TransitionSwaddle	Unknown
31	H1740050A	2017-Apr	Unk	NC	The submitter believes this sleep suit weighs down the infants arms and legs which restricts their natural movement and inhibits their startle reflects. She indicated that the startle reflects is protective and reduces the risk of sudden infant death.	SleepSuit	NonWeighted
32	170620CBB3011 Mfr/Retailer Report	2017-Apr	2 MOM	TX	A 2-MONTH OLD MALE WAS FOUND UNRESPONSIVE AND NOT BREATHING IN A BABY LOUNGER/MATTRESS TYPE ITEM IN HIS BEDROOM AT HIS RESIDENCE. THE BABY LOUNGER/MATTRESS WAS PLACED INSIDE A STANDARD-SIZE CRIB ATOP A STANDARD-SIZE CRIB MATTRESS. FOUR PILLOWS AND A CRIB BUMPER APPEARED TO BE INSIDE THE CRIB; HOWEVER, THESE ITEMS WERE NOT INSIDE THE BABY LOUNGER/MATTRESS. THE AUTOPSY IS NOT YET COMPLETE AND THE CAUSE OF DEATH IS PENDING.	Swaddle	NonWeighted
33	H1750012A	2017-May	Unk UnkF	MA	Consumer was taking [SLEEP SACK] off of her child & saw something wrong with its zipper. She noticed that metal pull tab of zipper was missing & found small pieces of the part that attaches zipper to zipper teeth had disintegrated. There were also sharp metal pieces in crib.	WearableBlanket	NonWeighted
34	I1770355A	2017-Jul	Unk	Unk	Consumer reported that baby blanket has very strong chemical smell. It was washed several times but smell persists. Consumer thought that blanket was from bad batch & ordered three more hoping at least one of them will be chemical odor free - they all smelled.	WearableBlanket	NonWeighted
35	I1770486A	2017-Jul	Unk	CA	Nothing "happened" that consumer is aware of but consumer is concerned that infant sleeping bag is not safe for infants to sleep based on the description, photos and AAPs current guide to safe baby sleeping.	SleepBag	NonWeighted
36	H1780076A	2017-Aug	4 MOF	NJ	[REDACTED] The consumer's baby was in the crib in the [SLEEP SACK]. The consumer was downstairs . She went upstairs to check on the baby. The consumer found her baby facedown in her crib. The baby was twitching back and forth with her head trying to turnover. There were welts on the baby's face. There was also a bluish ting around the baby's lips. The consumer took the baby out of the crib and took a photo of the baby's face. The consumer is taking the baby to the pediatrician today [REDACTED]. [REDACTED]The consumer contacted the firm and was advised that someone would contact her.	WearableBlanket	NonWeighted
37	I1840096A	2018-Apr	5 MOM	PA	I swaddled my son using the [SWADDLE]. My husband heard my son moving furiously in his bassinet and checked on him. He found our son with the arm flaps up around his neck, still secured by the [HOOK AND LOOP FASTENER], strangling him. Fortunately, he was able to get him out in time to prevent injury. Had he not been in a bassinet at our bedside with my husband in the room, my baby would have been severely injured or killed. This product needs to be recalled.	TransitionSwaddle	NonWeighted
38	200917CCC2881 1847029558	2018-May	2 MOM	TN	[In the morning], A 25-YEAR-OLD MOTHER WOKE TO FIND HER 2-MONTH-OLD SON IN HIS CRIB, FACE DOWN AND COLD TO THE TOUCH. THE SON WAS LAST SEEN ALIVE SWADDLED IN A [SLEEP SACK] GARMENT AND PLACED ON HIS SIDE IN A U-SHAPED NURSERY PILLOW. THE PILLOW WAS PLACED WITHIN A CRIB. DURING THE NIGHT, THE VICTIM COMPLETELY ROLLED OVER ONTO HIS STOMACH WHILE STILL BEING SWADDLED. HIS FACE WAS COVERED WITH THE TOP OF THE U-SHAPED NURSERY PILLOW. THE CAUSE OF DEATH WAS LISTED AS POSITIONAL ASPHYXIA.	TransitionSwaddle	NonWeighted
39	211007CBB1038 Mfr/Retailer Report	2018-May	2 MOM	IN	IN THE 1-2 WEEKS PRIOR TO [REDACTED], THE CONSUMER USED THE INCIDENT SWADDLE WITH HER 2-MONTH-OLD SON WHILE HE SLEPT IN A BASSINET. DURING NEARLY EVERY USE, HER SON'S ARM WOULD END UP POKING OUT OF THE BOTTOM OF THE SWADDLED AND THE SWADDLE WOULD BE SCRUNCHED UP AROUND HIS HEAD AND NECK. AFTER POSTING THESE ISSUES IN A REVIEW ON THE MANUFACTURER'S WEBSITE, THE FIRM PROVIDED A REPLACEMENT PRODUCT IN EXCHANGE FOR THE RETURN OF THE INCIDENT SWADDLE.	TransitionSwaddle	NonWeighted
40	200611CFE0004 X2060749A	2018-Jun	6 MOM	CA	AT [Night-time], A 6 MONTH OLD MALE WEARING A CHILDRENÆS JUMPSUIT WAS SWADDLED AND PLACED INSIDE OF A BASSINET TO SLEEP. THE VICTIM'S HEAD WAS RESTING ON A PILLOW, AND HIS FEET WAS COVERED BY A BLANKET. [About 8 and a half hours later], THE VICTIM WAS FOUND UNRESPONSIVE IN THE SAME POSITION, AND WAS TRANSPORTED TO A HOSPITAL WHERE HE WAS LATER PRONOUNCED DECEASED. THE VICTIM'S OFFICIAL CAUSE OF DEATH WAS SUDDEN UNEXPECTED DEATH IN INFANCY.	TransitionSwaddle	NonWeighted
41	201102HCC1123 1823513552 X1930552A	2018-Dec	5 MOM	ME	A FIVE-MONTH OLD MALE SWADDLED IN A SWADDLE [SLEEP SACK] WAS FOUND DECEASED IN A PORTABLE PLAY YARD AFTER BEING PLACED TO SLEEP IN THE PLAY YARD APPROXIMATELY SIX HOURS PRIOR TO THE INCIDENT. THE ME REPORTED THE CAUSE OF DEATH AS ASPHYXIA DUE TO POSITION AND ENTRAPMENT AND THE MANNER OF DEATH AS ACCIDENTAL.	TransitionSwaddle	NonWeighted
42	211007CBB3021 Mfr/Retailer Report	2019-Jan	1 MOM	NE	A 1-MONTH-OLD MALE WAS WRAPPED IN AN INFANT SLEEP SWADDLER. AFTER A SHORT TIME, THE SWADDLER MATERIAL CREPT UP AROUND THE INFANT'S NOSE AND MOUTH. THE MOTHER IMMEDIATELY REMOVED THE INFANT FROM THE PRODUCT. NO INJURIES WERE REPORTED.	TransitionSwaddle	NonWeighted

Incident #	Document #	Date	Age/ Sex	State	Narrative	Wearable Infant Sleep Products	Weighted / NonWeighted / Unknown
43	I19A0261A	2019-Feb	1 MOM	WA	<p>The decedent was a 2 week old male with no medical history. The decedent was last known to be alive on [REDACTED], just after midnight. At [REDACTED], the decedent's mother woke and found the decedent unresponsive. She woke her husband, who began CPR per 911 operator instructions. EMS transported the decedent with CPR in progress to a local hospital, where he was pronounced shortly after arrival.</p> <p>The decedent had been sleeping on the same bed with the entire family (parents and two siblings). The decedent was wrapped in a [REDACTED] type pajama and was again swaddled in a [REDACTED].</p>	TransitionSwaddle	Unknown
44	I1920396A	2019-Feb	2 MOM	Unk	On [REDACTED] my son was using the [REDACTED] swaddler off of [REDACTED]. I woke up to the whole swaddler being around my son's neck. He was 9 weeks old at the time. I took a picture before I took it off. This is a choking hazard. The next day I contacted the company they gave me a refund and said they would do something about it and they would have quality control contact me. They have not contacted me and are ignoring my messages. It is clear the company does not care that the [REDACTED] swaddler could have killed my son from choking him. I can attach a picture and you can call me.	Swaddle	NonWeighted
45	X1930265A	2019-Feb	3 MOM	TX	3 MOM decedent was found unresponsive in a crib. Mattress was firm. He was wrapped in a swaddling blanket, but not tightly and he could get his hands out. He was found breathing, bit limp. He was taken to a hospital and was pronounced.	TransitionSwaddle	Unknown
46	I1920342A	2019-Feb	8 MOM	WA	<p>This concerns an infant [SLEEP SACK] made by [REDACTED]. Our 8 month child was able to chew off the plastic 'tape' securing the top of the zipper to the cloth. He subsequently gagged on this, throwing up several times.</p> <p>This seems like an obvious product flaw that is easily mitigated by using non-tape style zipper.</p>	WearableBlanket	NonWeighted
47	I1930082A	2019-Mar	Unk	IL	The Submitter expressed extreme concern over what appears to be a swaddler that's very blanket like. The pictures feature babies sleeping in it, but it's got big fluffy sides at the top. Some moms are letting their babies sleep in it. Very dangerous due to suffocation or SIDS	SleepBag	NonWeighted
48	I1940373A	2019-Mar	9 MOM	Unk	I purchased a sleeping bag from [REDACTED] in size 6 - 18 months, [REDACTED] print, made of [REDACTED] in March 2019. I attempted to use this sleeping bag (also called a "[REDACTED]") on my 9 month old baby as a safer alternative to blankets. Unfortunately, the neckline is not reinforced and the [REDACTED] material is very stretchy. After placing it on my child, he was able to pull the [REDACTED] over his entire face including his nose and mouth. This presents a risk for SIDS because even a thin blanket placed over the nose/mouth risks causing hypercarbia. These sleeping bags come in a smaller size for even younger babies, which is especially dangeroud.	WearableBlanket	NonWeighted
49	I1930380A	2019-Mar	Unk	NY	Consumer reports that child was using a [SLEEP SACK] blanket at home and the zipper fell off in the night. It was found laying in the crib next to the baby. The product was still zipped.	WearableBlanket	NonWeighted
50	I1960226A (Terminated IDI)	2019-Apr	1 MOF	CT	I used a [SLEEP SACK] [REDACTED] to swaddle my newborn baby. Despite using the correct size and following the manufacturer's instructions, my baby was able to wriggle in her swaddle resulting in it covering her face while she was sleeping. It did not matter how tightly I wrapped her, she still wound up with the swaddle covering her mouth. I discontinued use of the product. I have read several reviews online of this happening to other babies.	TransitionSwaddle	NonWeighted
51	210526HCC1079 1936028659	2019-Apr	2 MOM	NY	A TWO MONTH OLD BOY WAS FOUND UNRESPONSIVE, FACE DOWN IN A SWADDLING BLANKET INSIDE HIS BASSINET LOCATED IN THE PARENT'S BEDROOM. THE DEATH CERTIFICATE LISTS THE CAUSE OF DEATH AS POSITIONAL ASPHYXIA.	Swaddle	NonWeighted
52	I1950278A I1960052A (Terminated IDI)	2019-May	7 MOF	Unk	The baby was being placed into the [SWADDLE]. The parent tried to fold the baby's left arm back into the arm area that is located on the side and behind the head. The baby was resisting, but the parent fit her arm in. When the parent zipped up the [SLEEP SACK] the baby began to cry and could not move her left arm. The parents brought her to the hospital, where she was found to have a left midshaft humerus fracture.	TransitionSwaddle	NonWeighted
53	200930CCC3920 I19A0095A	2019-Jun	3 MOM	CO	A WOMAN PLACED HER THREE MONTH OLD SON INTO A SWADDLING [SLEEP SACK] FOR THE NIGHT WITHIN A BASSINET. THE MOTHER AWOKE IN THE NIGHT FOLLOWING A DISCOMFORT SOUND FROM HER SON. SHE CHECKED ON HIM AND SAW THAT THE ARM BANDS WHICH WERE INITIALLY PLACED OVER OR NEAR THE BABY'S HANDS WERE NOW MOVING UP TO THE BASE OF HIS NECK. HE WAS NOT INJURED.	TransitionSwaddle	NonWeighted
54	211007CBB1043 Mfr/Retailer Report	2019-Jun	3 MOF	PA	A MOTHER DISCOVERED HER 3-MONTH-OLD INFANT WITH A SWADDLE BLANKET COVERING BOTH HER NOSE AND MOUTH. THE INFANT WAS TAKING A NAP IN HER CRIB WHEN THE INCIDENT OCCURRED. THE MOTHER REMOVED THE INFANT FROM THE SWADDLE BLANKET AND NO INJURIES OCCURRED.	TransitionSwaddle	NonWeighted
55	H1970014A	2019-Jun	5 MOF	MN	The consumer stated that her 5-months-old daughter was able to get out of the sleepwear and it was over her face when she went to get her. The consumer believes this product is a suffocation hazard.	SleepSuit	NonWeighted
56	210111HCC3347 1908027926	2019-Sep	1 MOF	CO	A 24-DAY-OLD FEMALE WAS FOUND UNRESPONSIVE WITH HER FACE PARTIALLY PRESSED AGAINST THE SIDE OF HER BASSINET AND BLANKET. HER 29-YEAR-OLD MOTHER HAD MODIFIED THE BOTTOM OF THE BASSINET WITH A BABY MAT. THE VICTIM WAS PRONOUNCED DECEASED AT THE HOSPITAL. THE CAUSE OF DEATH WAS PROBABLE POSITIONAL ASPHYXIA.	TransitionSwaddle (sleep sack mode)	NonWeighted
57	210622CBB1259 I19A0202A	2019-Oct	3 MOF	NY	THE FACE, NOSE AND MOUTH OF A 3-MONTH-OLD FEMALE WAS OBSERVED BY HER MOTHER TO BE COVERED BY THE TOP PORTION OF A [SLEEP SACK] THE VICTIM HAD BEEN PLACED TO SLEEP IN THE EVENING PRIOR.	TransitionSwaddle	NonWeighted
58	201106HCC1142 1923514799 X2020193A	2019-Dec	5 MOM	ME	A 5 MONTH OLD INFANT WAS FED, SWADDLED, AND PLACED ON HIS BACK TO SLEEP IN THE LATE EVENING. THE INFANT'S PARENTS SLEPT ON EITHER SIDE OF THE INFANT AND A LARGE DOG SLEPT NEAR THE FOOT OF THE ADULT-SIZE BED. APPROXIMATELY NINE HOURS LATER, THE VICTIM'S FATHER WOKE TO GET A GLASS OF WATER AT WHICH TIME HE NOTICED THAT THE INFANT, STILL SWADDLED AND LYING ON HIS BACK, APPEARED PALE IN COLOR AND WAS NOT BREATHING. EMERGENCY PERSONNEL WERE CALLED AND RESUSCITATIVE MEASURES WERE ATTEMPTED. THE INFANT WAS PRONOUNCED DEAD AS A RESULT OF ASPHYXIATION DUE TO CO-SLEEPING IN AN ADULT SIZED BED.	Swaddle	NonWeighted

Incident #	Document #	Date	Age/ Sex	State	Narrative	Wearable Infant Sleep Products	Weighted / NonWeighted / Unknown
59	210224HCC2349 X2120178A 2039009807	2020-Jan	3 MOF	OH	A 31 YEAR OLD MOTHER FOUND HER 3-MONTH-OLD DAUGHTER UNRESPONSIVE AFTER BEING SWADDLED AND PLACED ON HER BACK IN HER BASSINET. THERE WAS A BLANKET BENEATH HER HEAD THAT WAS USED AS A CUSHION WHILE SHE SLEPT. THE CAUSE OF DEATH WAS RULED AS ASPHYXIA DUE TO OBSTRUCTION OF MOUTH AND NOSE BY BEDDING. THE MANNER OF DEATH WAS RULED AN ACCIDENT.	TransitionSwaddle	Unknown
60	I20B0146A	2020-Feb	UnkF	CA	Consumer reports that their 1 YOF woke up with the sleep slack ripped down the backside of it. The child could have gotten an arm or anything caught in that area. This poses a potential choking or strangulation hazard. This product is unsafe.	WearableBlanket	NonWeighted
61	230518HCC1469 2019008391	2020-Mar	6 MOM	IA	A 6-MONTH-OLD MALE WAS FOUND UNRESPONSIVE LYING FACE DOWN IN A PLAY YARD. THE VICTIM WAS SWADDLED IN A [SLEEP SACK]. THE VICTIM WAS TRANSPORTED TO THE HOSPITAL AND SUFFERED FROM SEVERE NEUROLOGIC DAMAGE RESULTING FROM COMPLICATIONS OF PROLONGED RESUSCITATION. THE VICTIM DIED FROM HIS INJURIES. THE CAUSE OF DEATH WAS DETERMINED TO BE DUE TO COMPLICATIONS OF RESUSCITATED ASPHYXIA.	TransitionSwaddle	NonWeighted
62	200520HFE0001 I2050203A	2020-Apr	1 MOM	MI	A 4 DAY OLD INFANT WAS FOUND UNRESPONSIVE IN THE BASSINET PORTION OF A PLAYPEN. HE WAS SLEEPING ON HIS BACK ON TOP OF ONE FITTED SHEET. HE WAS WEARING AN INFANT SLEEPING SACK. HE WAS FOUND UNRESPONSIVE IN THE SAME POSITION, ON HIS BACK. TOXICOLOGY WAS UNREMARKABLE. THE PRELIMINARY CAUSE OF DEATH IS LISTED AS SUDDEN, UNEXPLAINED INFANT DEATH.	WearableBlanket	NonWeighted
63	211203CBB1467 Mfr/Retailer Report	2020-Apr	UnkM	NY	A MOTHER AT HOME SWADDLED HER BABY BOY IN AN INFANT BLANKET AND PLACED HIM FACE UP IN A CRIB TO SLEEP. LATER SHE FOUND THAT THE SWADDLE BLANKET HAD MOVED UP AND WAS PARTIALLY COVERING HER BABY'S FACE. SHE REMOVED THE BLANKET AND NO INJURY OCCURRED.	Swaddle	NonWeighted
64	230518HCC3728 I2050068A	2020-Apr	1 MOF	WA	3 week old infant was brought to the hospital for petechiae and purpura (small spots of bruising) on her abdomen as well as a linear bruise on her right upper arm that were ultimately thought to be related to being wrapped tightly in the [WEIGHTED] Swaddle which has 3 pockets of hard beads that end up pressed firmly against the baby in the areas where she was bruising/injured. In addition to the bruises themselves, the marks resulted in a full workup for abuse (head CT, x-rays of entire body, labwork, and a short hospital stay).	Swaddle	Weighted
65	220103CBB3349 Mfr/Retailer Report	2020-May	2 MOF	TX	THE PULL TAB OF A ZIPPER SEPARATED FROM THE ZIPPER CLOSING MECHANISM OF AN INFANT [SLEEP SACK] SWADDLE WHILE THE SWADDLE WAS DRYING IN AN ELECTRIC CLOTHES DRYER AT HOME. THE INFANT [sleeping sack] WAS USED BY THE 2 MONTH-OLD FEMALE. NO INJURY OCCURRED WITH THIS INCIDENT.	TransitionSwaddle	NonWeighted
66	220103CBB1655 Mfr/Retailer Report	2020-Jun	Unk	OH	THE 35-YEAR-OLD FEMALE CONSUMER WASHED HER [SLEEP SACK] SWADDLE FOR THE FIRST TIME AND THE PULL TAB FROM THE ZIPPER FELL OFF. THE SWADDLE WAS NEVER USED ON HER BABY. NO INJURIES WERE REPORTED.	TransitionSwaddle	NonWeighted
67	I2070012A	2020-Jun	3 MOM	Unk	[REDACTED] sells a product called the [REDACTED], which is an infant [SWADDLE]. The fabric on the [SLEEP SACK] bunches up around my infant's face over the mouth, obstructing his breathing. [REDACTED] company censor the reviews on their website (only 4 and 5 star reviews are shown) but if you look on [REDACTED] and parent forums you'll see similar photos of the [SLEEP SACK] covering the child's mouth.	TransitionSwaddle	NonWeighted
68	210714HCC3287 X2161145A	2020-Jul	2 MOM	TX	A 2-MONTH OLD MALE WAS FOUND UNRESPONSIVE IN HIS BED TOP PORTABLE BASSINET AT HIS RESIDENCE. THE CHILD WAS SWADDLED IN AN INFANT SWADDLE BLANKET AND PLACED SUPINE IN THE BASSINET WHICH SAT UPON A KING-SIZE ADULT BED. THE FATHER FOUND THE CHILD IN THE SAME POSITION AS HE WAS PLACED AND THE CHILD'S FACE WAS UNOBSTRUCTED. EMERGENCY SERVICES WERE SUMMONED AND THE FATHER INITIATED CHEST COMPRESSIONS; EMS ARRIVED AND PRONOUNCED THE CHILD DECEASED.	Swaddle	NonWeighted
69	211109HCC1320 2029310867	2020-Jul	1 MOF	MO	ON THE EVENING OF [REDACTED] A COUPLE ARRIVED HOME WITH THEIR SIX-WEEK-OLD DAUGHTER IN A CAR SEAT. THE INFANT WAS WEARING A DIAPER AND ONESIE AND WAS PLACED IN A SWADDLE SACK. THE INFANT WAS PLACED ON HER RIGHT SIDE IN A BASSINET NEXT TO THE PARENT'S BED. [The next day in the early morning], THE MOTHER REMOVED THE INFANT FROM THE BASSINET AND PLACED HER IN THE BED WITH HER AND THE FATHER. THE MOTHER FELL ASLEEP WHILE BREAST FEEDING THE INFANT. [About two and a half hours later], THE WOMAN WOKE TO FIND THE INFANT UNRESPONSIVE. CPR WAS ATTEMPTED UNTIL EMS ARRIVED WHO ALSO ATTEMPTED CPR. MUCUS/BLOOD WAS OBSERVED FROM THE INFANT'S NOSE/MOUTH AREA AND ON THE BED SHEETS. THE INFANT WAS TRANSPORTED TO A HOSPITAL WHERE SHE WAS PRONOUNCED DEAD. HER CAUSE OF DEATH WAS ACCIDENTAL PROBABLE SUFFOCATION.	TransitionSwaddle	Unknown
70	210302HCC2387 2027026142	2020-Jul	3 MOF	MN	[Early in the morning]. A 3 MONTH OLD FEMALE WAS PUT DOWN TO SLEEP IN AN INFANT CAR SEAT. WHILE IN THE CAR SEAT THE INFANT WAS SWADDLED IN A ONESIE. SHE WAS COVERED WITH A BLANKET AND A BOTTLE WAS ALSO IN THE CAR SEAT. THE CAR SEAT WITH THE INFANT IN IT WERE PLACED ON THE FLOOR WHILE THE INFANT'S MOTHER AND FIANC SLEPT IN THE SAME ROOM. EIGHT HOURS LATER AT [REDACTED], THE INFANT'S MOTHER WENT TO CHECK ON HER AND FOUND HER UNRESPONSIVE. EMERGENCY PERSONNEL WERE SUMMONED AND THE VICTIM WAS TRANSPORTED TO A NEARBY HOSPITAL WHERE SHE WAS PRONOUNCED DEAD. VICTIM DIED FROM PROBABLE ASPHYXIA ASSOCIATED WITH AN UNSAFE SLEEP ENVIRONMENT.	WearableBlanket	Unknown
71	200827CFE0004 X2080911A	2020-Jul	2 MOF	CA	A TWO-MONTH-OLD FEMALE WHO WAS WEARING A [SLEEP SACK] WAS FOUND FACE DOWN, UNRESPONSIVE, AND NOT BREATHING IN A BASSINET AT HER RESIDENCE. LIFE SAVING MEASURES WERE PROVIDED HOWEVER THE VICTIM COULD NOT BE RESUSCITATED AND WAS PRONOUNCED DECEASED AT A LOCAL MEDICAL CENTER. THE CAUSE OF DEATH WAS DETERMINED TO BE AN UNSAFE SLEEP ENVIRONMENT.	TransitionSwaddle	NonWeighted

Incident #	Document #	Date	Age/ Sex	State	Narrative	Wearable Infant Sleep Products	Weighted / NonWeighted / Unknown
72	I2090334A (Terminated IDI)	2020-Jul	6 MOM	OR	I used the [REDACTED] Infant Sleeper made by [REDACTED]/[REDACTED] for my infant from 2 months of age until 6 months of age. The [REDACTED] is supposed to help infants sleep better by keeping them swaddled and strapped in place while also providing white noise and a variable rocking motion. Due to the swaddle and straps which hold the baby in place, my infant did not have opportunity during the night to move around as an infant would normally in a regular crib. He now has some large motor delays. He has been assessed by a pediatrician and referred to physical therapy.	TransitionSwaddle	NonWeighted
73	201130HCC2105 I20B0401A	2020-Jul	2 MOM	MI	A TWO-MONTH-OLD MALE WAS FOUND UNRESPONSIVE LYING ON A PAD/INFANT POSITIONER INSIDE A PLAY PEN. THE VICTIM WAS TRANSPORTED TO THE HOSPITAL WHERE HE WAS PRONOUNCED DEAD. THE FATHER STATED HE SWADDLED THE VICTIM, PLACED HIM ON HIS BACK AND COVERED HIM WITH A BLANKET FROM THE WAIST DOWN. THE FATHER STATED THE VICTIM WAS DISCOVERED UNRESPONSIVE LYING ON HIS BACK. THE AUTOPSY REPORT STATES THE CAUSE OF DEATH WAS POSITION/COMPRESSION ASPHYXIA. PER THE AUTOPSY REPORT, PRIMARY LIVIDITY WAS PRESENT ON THE FRONT OF THE BODY.	TransitionSwaddle (swaddle mode, one arm)	NonWeighted
74	220121HCC1774 X2210507A	2020-Aug	9 MOM	FL	A 9-MONTH-OLD INFANT WAS FOUND UNRESPONSIVE, LYING FACE-DOWN, IN A PLAY YARD TYPE ENCLOSURE. CPR WAS NOT INITIATED. THE INFANT'S PARENTS DROVE HIM TO THE HOSPITAL WHERE HE WAS PRONOUNCED DEAD LATER THAT SAME DAY. THE MEDICAL EXAMINER CLASSIFIED THE DEATH AS AN ACCIDENT AND DETERMINED THE PROBABLE CAUSE OF DEATH TO BE POSITIONAL ASPHYXIA IN AN UNSAFE SLEEPING ENVIRONMENT. THE PLAY YARD THAT THE INFANT WAS FOUND IN HAD THREE BLANKETS, AN ADULT SIZE PILLOW, BOTTLE AND TOY IN IT. THE INFANT WAS WEARING A SWADDLE FOR INFANT'S 0-3 MONTHS OLD.	Swaddle	NonWeighted
75	210330HCC2543 2027031743	2020-Aug	3 MOM	MN	A 3 MONTH-OLD MALE, CLOTHED IN A [SLEEP SACK], WAS FOUND UNRESPONSIVE IN A CRIB. THE VICTIM WAS FOUND ON HIS SIDE WITH HIS FACE DOWN. ATTEMPTS TO REVIVE THE VICTIM WERE UNSUCCESSFUL. CAUSE OF DEATH WAS POSITIONAL ASPHYXIA.	Swaddle	NonWeighted
76	210308HCC2411 X2130049A	2020-Sep	6 MOM	MI	A BABY WAS BORN SIX WEEKS PREMATURE AND HAD TORTICOLLIS AND COORDINATION ISSUES. DEVELOPMENTALLY THE 6-MONTH-OLD, [REDACTED]-DAY-OLD BABY WAS SIMILAR TO A 4-MONTH-OLD BABY. HE WAS IN PHYSICAL THERAPY AND LEARNING HOW TO ROLL OVER. THE MOTHER PLACED HER BABY TO SLEEP ON HIS BACK IN A BEDSIDE BASSINET. THE BABY WAS WEARING SWADDLE-STYLE SLEEPWEAR. ABOUT 30-60 MINUTES LATER, THE MOTHER SAW HE HAD ROLLED OVER. SHE FOUND HER BABY WITH HIS FACE STRAIGHT DOWN IN THE MIDDLE OF THE BEDSIDE BASSINET, UNRESPONSIVE. EFFORTS TO REVIVE THE INFANT WERE UNSUCCESSFUL. THE MEDICAL EXAMINER RULED HIS MANNER OF DEATH WAS AN ACCIDENT. THE INFANT DIED FROM AIRWAY OBSTRUCTION.	TransitionSwaddle	NonWeighted
77	220103CBB1651 Mfr/Retailer Report	2020-Sep	1 MOF	AA	THE MOTHER OF A SIX-WEEK-OLD GIRL ATTEMPTED TO PLACE THE INFANT IN A NEW, UNUSED [SLEEP SACK]. HOWEVER, BEFORE PLACING THE CHILD IN THE SACK SHE NOTICED THAT THE METAL END OF PART OF THE ZIPPER BROKE OFF. THEREFORE, THE [SLEEP SACK] COULDNÆT BE ZIPPED, AND THE PRODUCT WAS NEVER USED. THE CHILD WAS NOT INJURED.	TransitionSwaddle	NonWeighted
78	220103CBB3348 Mfr/Retailer Report	2020-Sep	UnkM	HI	A ONE-YEAR-OLD WAS CLOTHED IN A ZIPPERED [SLEEP SACK] AND PLACED IN HIS CRIB FOR THE NIGHT. THE NEXT MORNING, HIS MOTHER FOUND THE ZIPPER OF THE [SLEEP SACK] COMPLETELY OPEN ALTHOUGH THE GARMENT WAS STILL ON THE CHILD. THIS HAPPENED THE FOLLOWING NIGHT AND ON THE MORNING AFTER THE THIRD NIGHT, THE MOTHER DISCOVERED THE INFANTÆS LOWER BODY COMPLETELY OUT OF THE [sleeping sack] AND THE EMPTY PART OF THE GARMENT WAS NEAR HIS SHOULDERS AND NECK. THAT EVENING, SHE PLACED THE CHILD IN THE [sleeping sack] AND WATCHED THE BABY MONITOR TO SEE WHAT WAS GOING ON. THE MOTHER DISCOVERED THAT WHEN THE CHILD, WHO SHE DESCRIBED AS AN δACTIVE SLEEPERδ MOVED AROUND, THE ZIPPER ON THE SLEEP SEPARATED, CAUSING THE GARMENT TO OPEN COMPLETELY. THE MOTHER DISCARDED THE [sleeping sack] AND THERE WERE NO INJURIES.	TransitionSwaddle	NonWeighted
79	201106HCC2078 I20A0306A	2020-Oct	2 MOF	AR	A 33-YEAR-OLD FEMALE WENT TO CHECK ON THE 2-MONTH-OLD FEMALE VICTIM IN THE VICTIM'S BEDROOM, AND DISCOVERED THE BLANKET THAT THE VICTIM HAD PREVIOUSLY BEEN SWADDLED WITH, WAS WRAPPED AROUND THE VICTIM'S NECK. THE VICTIM WAS FOUND AWAKE IN A CRIB, AND INCURRED RED MARKS TO HER NECK. THERE WERE NO PERMANENT INJURIES AND MEDICAL TREATMENT WAS NOT SOUGHT.	Swaddle	NonWeighted
80	221221CBB3334 Mfr/Retailer Report	2020-Nov	2 MOF	TX	THE MOTHER OF A 2MOF VICTIM PUT A SWADDLE ON THE VICTIM BEFORE PUTTING HER DOWN FOR THE EVENING IN A BASSINET IN HER RESIDENCE. APPROXIMATELY TWO HOURS AFTER PUTTING HER TO SLEEP THE MOTHER WENT TO BED. AT SOME POINT DURING THE NIGHT THE MOTHER WOKE UP TO CHECK ON THE VICTIM AND SAW HER SLEEPING WITH THE SWADDLE BUNCHED UP AROUND HER NECK. ALTHOUGH THE SWADDLE WAS ONLY AT THE CHILD'S NECK, AND NOT OVER HER MOUTH OR NOSE, AND SHE SHOWED NO SIGNS OF DISTRESS, THE MOTHER TOOK THE SWADDLE OFF OF HER. THE MOTHER STATED THAT AFTER SHE REMOVED THE SWADDLE, THE VICTIM WENT BACK TO SLEEP WITHOUT ISSUE AND WOKE UP AT HER NORMAL TIME TO EAT. NO INJURY WAS SUSTAINED.	Swaddle	Weighted
81	210224CAA2346 Mfr/Retailer Report	2020-Dec	1 MOF	MN	A NEWBORN FEMALE WHO WAS TYPICALLY CLOTHED IN A [SLEEP SACK] WOULD ON SEVERAL OCCASIONS BE FOUND TO HAVE ROLLED AGAINST THE SIDE OF A BASSINET AT HER RESIDENCE IN DECEMBER 2020 WHEN THE BASSINET'S FLOOR WOULD TILT FROM THE INFANT'S WEIGHT. USE OF THE BASSINET WAS DISCONTINUED AND NO INJURIES RESULTED FROM THESE INCIDENTS.	TransitionSwaddle	Unknown
82	220103CBB3344 Mfr/Retailer Report	2021-Jan	Unk	CO	THE CONSUMER SAID THAT THE ZIPPER GOT LOST IN THE [SLEEP SACK] SWADDLE. THE ZIPPER DID NOT DETACH AS SHE REPORTED TO THE FIRM. SHE DID NOT SEE THAT THE ZIPPER WAS UNDER A FOLD IN THE MATERIAL. SHE REPORTED THE PROBLEM WAS USER ERROR.	TransitionSwaddle	NonWeighted
83	I2210096A	2021-Jan	Unk	FN	The Consumer stated that their baby was swaddled in the [SLEEP SACK] and the fastener wrap slid up and covered the baby's face posing suffocation hazard.	TransitionSwaddle	NonWeighted

Incident #	Document #	Date	Age/ Sex	State	Narrative	Wearable Infant Sleep Products	Weighted / NonWeighted / Unknown
84	210224CAA2347 Mfr/Retailer Report	2021-Feb	6 MOF	MI	A BEDSIDE BASSINET WAS SET TO THE UPPER MATTRESS POSITION. A 6-MONTH-OLD BABY, WEIGHING 14-15 POUNDS, WAS PLACED ON HER BACK, IN THE MIDDLE OF THE BASSINET. THE BABY WAS NOT YET ROLLING OVER ON HER OWN. THE BABY WAS SWADDLED AND WEARING A [SLEEP SACK]. ABOUT 5-10 MINUTES AFTER THE BABY WAS PLACED DOWN, THE BABY SLID TO THE RIGHT SIDE OF THE BASSINET. SHE WAS FOUND ON HER LEFT SIDE, WITH HER FACE PRESSED AGAINST THE MESH SIDE OF THE BASSINET. MESH MARKINGS WERE OBSERVED ON THE BABY'S FACE. THE MESH MARKINGS DISAPPEARED IN A FEW HOURS. THE FAMILY TRIED TO USE THIS PRODUCT ABOUT 14 TIMES, AND EVERY TIME, THE BABY SLID TO THE RIGHT SIDE OF THE BASSINET. NO INJURY WAS REPORTED.	TransitionSwaddle	Unknown
85	220627CAA1868 Mfr/Retailer Report	2021-Feb	1 MOM	OH	A FOUR-DAY-OLD MALE INFANT WAS FOUND ROLLING OVER TO HIS SIDE AFTER BEING SWADDLED IN A SWADDLE/SLEEP-SACK AND PLACED ON HIS BACK INSIDE A BASSINET FOR A NAP. THE INFANT'S MOTHER NOTICED THAT THE BASSINET TILTED TO ONE SIDE, CAUSING HER SON TO ROLL. NO INJURIES WERE SUSTAINED. THE MANUFACTURER WAS NOTIFIED, BUT THE COMPLAINANT OPTED FOR FIXING THE REPORTED ISSUE HERSELF BY PLACING A SMALL WOODEN BOARD UNDERNEATH THE BASSINET'S SUPPLIED MATTRESS PAD. THIS STOPPED THE INFANT FROM ROLLING ONTO HIS SIDE. THE FAMILY CONTINUED USING THE BASSINET UNTIL THE INFANT WAS TWO-MONTHS OLD AT WHICH POINT HE TRANSFERRED TO A CRIB FOR SLEEPING.	TransitionSwaddle	NonWeighted
86	211007CBB1037 Mfr/Retailer Report	2021-Feb	4 MOF	MN	ON MULTIPLE OCCASIONS, THE ZIPPER OF A SWADDLE JACKET PARTIALLY OPENED, WITH NO INTERVENTION, WHILE ON A FOUR-MONTH-OLD FEMALE INFANT. NO INJURIES RESULTED.	TransitionSwaddle	NonWeighted
87	220103CBB1647 Mfr/Retailer Report	2021-Feb	1 MOM	TX	THE CONSUMER REMOVED THE INCIDENT INFANT SWADDLE FROM THE DRYER AND WHILE USING THE ZIPPER THE PULL TAB DETACHED FROM THE SLIDER BODY. NO PERSONS WERE INJURED DURING THE INCIDENT AND THE 1 MONTH OLD MALE VICTIM WAS NOT WEARING THE PRODUCT AT THE TIME OF THE INCIDENT.	TransitionSwaddle	NonWeighted
88	220516HCC1623 X2250587A	2021-Mar	1 MOF	VA	A 1-MONTH-OLD FEMALE WAS FOUND UNRESPONSIVE AFTER BEING PLACED ON AN INFANT LOUNGER PILLOW, ON TOP OF A MATTRESS, TO SLEEP WITH HER FATHER AT HOME. THE OFFICIAL CAUSE OF DEATH WAS DETERMINED TO BE SUDDEN UNEXPLAINED INFANT DEATH ASSOCIATED WITH CO-SLEEPING AND UNSAFE SLEEP. THE PRODUCTS INVOLVED IN THIS INCIDENT ARE A INFANT LOUNGER PILLOW, SWADDLE, AND MATTRESS.	Swaddle	Unknown
89	230213HCC3446 I2320174A I2340376A	2021-Mar	5 MOF	WA	A 5-MONTH-OLD GIRL (VICTIM) WAS FOUND UNRESPONSIVE AND NOT BREATHING IN AN INFANT LOUNGER. THE CHILD WAS REPORTEDLY SLEEPING ON THE LOUNGER NEXT TO HER FATHER IN A QUEEN-SIZED BED. THE VICTIM WAS SLEEPING IN A [SLEEP SACK] AT THE TIME OF THE INCIDENT. THE VICTIM WAS PRONOUNCED DECEASED AT THE SCENE. THE CAUSE OF DEATH WAS DETERMINED TO BE UNEXPLAINED SUDDEN DEATH. Baby was placed on her back in a [REDACTED] wearing a sleep sack next to dad. Dad woke "a few hours later" and noticed baby had rolled to the left side and was not breathing. Baby's face was pressed against the inside of the [REDACTED].	WearableBlanket	NonWeighted
90	I2140263A	2021-Apr	UnkM	NC	I purchased 2 sleep sacks from [REDACTED]. The neck opening of both of these sleep sacks (age 9-18 months) is a huge 7 inches, 3 inches wider than any other sleep sack we own. The sack slipped down our sons shoulders and he was able to take the sack off multiple times without unzipping and, more worryingly, the sack crept over my sons face while sleeping as the shoulders and neck opening are so huge. My son wore an age appropriate size and is very broad and tall for his age so him being too small for the product was not a factor. I contacted [REDACTED] regarding my concerns and they denied the issue, even after I sent photos of a measuring tape next to the neck opening highlighting the vastness and a photo of my son wearing the product and it slipping down his shoulders. They have not responded Further to my report submitted earlier regarding an unsafe [REDACTED] Sleep Sack worn by my son, I have attached additional photos The sleep sacks excessive neck width of 7 inches caused the sack to ride up over my sons face while sleeping; we witnessed this on his video monitor but could not get a picture in the dark. It continually slipped down his shoulders and he was able to take the sack off himself without unzipping it The item was laundered once, per manufacturers instructions, cold wash,, air dry, and was only worn for 3 nights (manufacturer has since responded to our complaint that we must have stretched the sack, we did not). We still have the sacks and can send them for physical inspection if required	WearableBlanket	NonWeighted
91	I2140414A	2021-Apr	8 MOM	AL	I ordered a [SLEEP SACK] from the direct seller [REDACTED], but instead received a knock off with an unsafe neck hole from [REDACTED]. The neck hole is so large it came up over his shoulders and covered his whole face. It has no label inside. This knock off is a suffocation hazard!!!	WearableBlanket	NonWeighted
92	I2150053A	2021-May	11 MOM	TX	We had an incident with my son's [REDACTED] Convertible Crib. When we went to go get him from his nap this morning, his leg was stuck between the slats past his knee. He was wearing a [SLEEP SACK], so we had to carefully remove it to try and get some lotion on his leg to slide it up and back out. It didn't seem to cut off his circulation since we caught it fairly quickly. He does have a red mark that we will monitor over the next few days. After calming down from being understandably very scared, he seems to be walking just fine. He is about to be 1.	WearableBlanket	Unknown
93	230224HCC3496 I2320318A	2021-May	1 MOM	CA	A TWO WEEK OLD INFANT WAS PLACED IN A BASSINET ON HIS SIDE AND WAS HELD IN THAT POSITION BY THE SWADDLE ATTACHMENT PROVIDED WITH THE BASSINET. THE INFANT WAS EXTREMELY FUSSY, PROMPTING THE BASSINET MOVEMENT TO INCREASE TO THE MAXIMUM SPEED AND CAUSING THE INFANT'S HEAD TO WHIP BACKWARD AND FORWARD WITH THE MOTION. A NURSE NOTICED THIS TAKING PLACE, ALERTED THE DOCTOR ON DUTY AND PULLED THE PLUG ON THE BASSINET TO STOP TO THE MOVEMENT. THE INFANT WAS NOT INJURED.	TransitionSwaddle	NonWeighted

Incident #	Document #	Date	Age/ Sex	State	Narrative	Wearable Infant Sleep Products	Weighted / NonWeighted / Unknown
94	210617HCC3153 X2160696A	2021-Jun	4 MOF	TX	A 4-MONTH-OLD FEMALE WAS FOUND UNRESPONSIVE AFTER TAKING A NAP, WHILE DRESSED IN A [SLEEP SACK]. SHE WAS LYING IN A SUPINE POSITION INSIDE A PLAYARD AT DAYCARE. THE VICTIM WAS PLACED ON TOP OF A FITTED PLAYARD SHEET, AND A SOUND MACHINE WAS PLAYING AT THE CORNER OF THE THE PLAYARD. THE DAYCARE OWNER CALLED 9-1-1, AND THE VICTIM WAS TRANSPORTED TO AN AREA HOSPITAL BY EMERGENCY OFFICIALS WITH CPR IN PROGRESS. THE VICTIM WAS PRONOUNCED DECEASED BY DOCTORS A SHORT TIME LATER.	TransitionSwaddle	NonWeighted
95	211203CBB1466 Mfr/Retailer Report	2021-Jun	1 MOF	FL	A TWO-WEEK-OLD FEMALE WAS WRAPPED IN A [REDACTED] AND PLACED IN A PRONE POSITION TO NAP IN A PLAYARD AT HER HOME. APPROXIMATELY THIRTY MINUTES LATER, THE MATERIAL OF THE [REDACTED] CREPT UP AND COVERED HER NOSE AND MOUTH. THE MOTHER IMMEDIATELY REMOVED THE [REDACTED]. ALTHOUGH THE VICTIM WAS NOT INJURED, HER GRANDMOTHER WAS CONCERNED ABOUT A POSSIBLE SUFFOCATION HAZARD AND RETURNED THE PRODUCT. NO MEDICAL TREATMENT WAS SOUGHT.	TransitionSwaddle	NonWeighted
96	231106HCC3177 2140021402	2021-Jun	5 MOM	OK	A 5-MONTH-OLD-MALE (MOM) SUCCUMBED TO ASPHYXIA AFTER SLEEPING ALONE IN A PLAY YARD SWADDLED IN A FASTENING INFANT [SLEEP SACK] IN HIS PARENTS' BEDROOM INSIDE THEIR HOME. THE VICTIM WAS PLACED SWADDLED ON HIS LEFT SIDE WITH HIS BACK AGAINST THE SIDE OF THE PLAY YARD. APPROXIMATELY 6 HOURS LATER HE WAS DISCOVERED BY HIS FATHER DECEASED IN THE PRONE POSITION FACE DOWN ON TOP OF A BLANKET. THE FATHER AND MOTHER ATTEMPTED RESUSCITATION EFFORTS AND SUMMONED EMERGENCY RESPONDERS. UPON THE ARRIVAL OF EMS, THE VICTIM WAS PRONOUNCED AT THE HOME. THE CAUSE OF DEATH WAS RULED AS ASPHYXIA. THE PLAY YARD CONSISTED OF A BLANKET, PILLOW, TWO FEEDING BOTTLES, AND A PACIFIER.	TransitionSwaddle	NonWeighted
97	220613HCC1790 X2260487A 2151040685	2021-Jun	3 MOF	VA	A THREE MONTH-OLD INFANT FEMALE WAS FOUND UNRESPONSIVE, SWADDLED AND LYING FACE-DOWN IN A BASSINET. THE INFANT HAD BEEN PUT DOWN FOR A NAP BY HER BABYSITTER AND WAS FOUND BY HER FATHER TO BE UNRESPONSIVE AFTER SHE HAD BEEN SLEEPING FOR AROUND TWO HOURS. THE INFANT LATER DIED AT THE HOSPITAL. THE OFFICIAL CAUSE OF DEATH IS LISTED AS POSITIONAL ASPHYXIA WITH BLOCKAGE OF AIRWAY.	Swaddle	NonWeighted
98	210823CBB3586 I2180388A	2021-Aug	1 MOF	WA	A ONE-MONTH-OLD SWADDLED GIRL WAS PLACED IN A BASSINET TO SLEEP. THE VICTIM WAS ON HER BACK AND ELEVATED IN THE OPENING OF A C-SHAPED PILLOW. THE VICTIM WAS DISCOVERED THE FOLLOWING DAY UNRESPONSIVE, RELATIVELY IN THE SAME POSITION, BUT SLIGHTLY TURNED TO HER LEFT AND THE SWADDLE BLANKET COVERING HER MOUTH AND NOSE. THE VICTIM'S FATHER CONTACTED EMERGENCY SERVICES AND HIS WIFE BEGAN PERFORMING CPR. THE VICTIM WAS PRONOUNCED DECEASED AT THE SCENE. THE VICTIM'S CAUSE OF DEATH WAS STAPHYLOCOCCUS AUREUS PNEUMONIA. THE MANNER OF DEATH WAS NATURAL, AND THERE WAS NO MENTION OF THE VICTIM'S CAUSE OF DEATH BEING ASSOCIATED WITH THE CONSUMER PRODUCTS IN USE IN HER CRIB AT THE TIME OF THE INCIDENT.	Swaddle	NonWeighted
99	220919HCC1491 2139083223	2021-Aug	1 MOM	OH	A 2-WEEK-OLD BOY DIED FROM ASPHYXIA DUE TO AN UNSAFE SLEEP ENVIRONMENT. THE VICTIM WAS IN A "[SLEEP SACK]," AND HE WAS LAID TO SLEEP ON HIS BACK NEXT TO HIS MOTHER IN HER ADULT BED. THE VICTIMS FATHER WAS ALSO SLEEPING IN THE BED NEXT TO THE MOTHER. THE MOTHER AWOKE TO FEED THE VICTIM, BUT HE WAS UNRESPONSIVE WITH BLOOD AROUND HIS NOSE. HE WAS PRONOUNCED DEAD AT THE HOSPITAL.	Swaddle	NonWeighted
100	210902CCC1924 I2180333A	2021-Aug	UnkF	AA	A FEMALE INFANT WAS FOUND WITH THE STRAPS OF HER [SLEEP SACK] AROUND HER NECK. THE INFANT WAS PLACED TO SLEEP ON HER BACK IN A BASSINET AND SWADDLED ACCORDING TO THE DIRECTIONS PROVIDED WITH THE [SLEEP SACK], WITH HER ARMS UNDER THE STRAPS. WHEN HER MOTHER AWOKE TO CHECK ON HER, SHE FOUND THAT THE INFANT WAS ABLE TO REMOVE HER ARMS FROM THE SWADDLE AND ABOVE HER HEAD, WHICH CAUSED THE STRAPS TO SHIFT UPWARDS AND AROUND HER NECK. THE INFANT WAS INSTANTLY REMOVED FROM THE SWADDLE AND NO INJURIES WERE SUSTAINED.	TransitionSwaddle	NonWeighted
101	210917HCC3692 I2190169A	2021-Sep	2 MOM	CA	A 2 MONTH-OLD MALE WAS SWADDLED IN A [REDACTED] DURING THE NIGHTTIME. WHEN THE COMPLAINANT VIEWED THE [REDACTED] CAM THE NEXT DAY, SHE OBSERVED THE FABRIC OF THE SWADDLE HAD RISEN UP AND COVERED THE CHILD'S ENTIRE FACE. AFTER A FEW MINUTES THE CHILD WAS ABLE TO WIGGLE THE FABRIC OFF HIS FACE. THIS OCCURRED THREE TIMES DURING THE ONE NIGHT. THE CHILD WAS IN MILD DISTRESS, BUT NEVER INJURED.	WearableBlanket	NonWeighted
102	220103CBB1645 Mfr/Retailer Report	2021-Sep	1 MOF	VA	A 2-WEEK OLD CHILD WAS SWADDLED IN A [SLEEP SACK] AND PLACED DOWN FOR A NAP. AT ONE POINT, THE MOTHER NOTED THE [SLIDE FASTENER] TEETH NEAR THE NECK WERE MISALIGNED AND ALLOWED THE FABRIC TO COVER THE CHILD'S MOUTH. THE [SLEEP SACK] WAS REMOVED FROM THE CHILD. THERE WERE NO INJURIES SUSTAINED.	TransitionSwaddle	NonWeighted
103	220822HBB1195 I2280267A	2021-Sep	1 MOM	IL	ON THE EVENING OF [REDACTED], A MOTHER AND FATHER PLACED THEIR 1-MONTH OLD SON TO SLEEP ON HIS BACK IN A BASSINET. HE WAS WEARING A SWADDLE OVER A ONESIE-TYPE GARMENT AND A DIAPER. NO PRODUCT COVERED HIS FACE OR MOUTH. EARLY ON [the next day], THE FATHER AWOKE AND OBSERVED HIS SON STILL ON HIS BACK IN THE EXACT POSITION. NO PRODUCT WAS COVERING HIS FACE OR MOUTH. HE WAS BLUE IN COLOR AND NOT BREATHING. THE INFANT WAS TRANSPORTED TO A HOSPITAL WHERE HE WAS PRONOUNCED DECEASED. THE CORONER COULD NOT DETERMINE A CAUSE OF DEATH.	TransitionSwaddle	NonWeighted
104	211203CBB3206 Mfr/Retailer Report	2021-Oct	4 MOF	UT	A FOUR-MONTH-OLD INFANT WIGGLED OUT OF A SWADDLE-TYPE BLANKET THAT WAS PURCHASED ONLINE. THE INFANT WAS NOT INJURED BUT THE INFANT'S MOTHER WAS CONCERNED BECAUSE SHE THOUGHT THAT THE MATERIAL WAS TOO THIN AND WAY TOO STRETCHY. THE INFANT'S MOTHER DID NOT USE THE PRODUCT TO SWADDLE HER BABY AGAIN. THE MANUFACTURER PROVIDED THE INFANT'S MOTHER A DIFFERENT MODEL REPLACEMENT SWADDLE-TYPE BLANKET.	WearableBlanket	NonWeighted

Incident #	Document #	Date	Age/ Sex	State	Narrative	Wearable Infant Sleep Products	Weighted / NonWeighted / Unknown
105	211015HCC1141 I21A0111A	2021- Oct	3 MOM	MN	A 3-MONTH-OLD INFANT WAS WEARING A SWADDLE/SLEEPSUIT. WHEN HIS MOTHER PLACED HIM IN A CRIB, ON HIS BACK, AND HE STARTING TO SQUIRM. THE MOTHER IMMEDIATELY NOTICED THE TOP PART OF THE GARMENT HAD BUNCHED UP AROUND THE INFANT'S MOUTH AND NECK, POSING A POTENTIAL ASPHYXIATION CONCERN. THE MOTHER REMOVED THE SWADDLE/SLEEPER FROM THE INFANT AND DID NOT USE IT AGAIN AS A SWADDLE. NO INJURIES WERE REPORTED.	sleep suit	Weighted
106	I21B0138A	2021- Nov	Unk	OH	Consumer reports that a sleeping bag like product for babies is being advertised as safe for newborns and babies on a social media website. They are concerned that this product is not safe for babies and they will suffocate in such a product.	SleepBag	Unknown
107	I2210098A	2021- Nov	1 MO	MI	was told it is unsafe if baby gets arms out of [REDACTED] swaddle. Newborn was using the product. Used as instructed. No injuries. Potential to hurt babies arms if they get stuck when trying to break out of the swaddle.	TransitionSwaddle	NonWeighted
108	220106CCC3366 I21C0227A	2021- Dec	2 MOM	UT	A NINE-WEEK-OLD INFANT STARTED CHOKING WHEN THE [SLEEP SACK] HARNESS ACCESSORY IN THE BASSINET THAT HE WAS SLEEPING IN CAME UNDONE AND TIGHTENED AROUND HIS NECK. THE INFANT'S PARENTS WERE ALERTED TO THE SITUATION WHEN THE BABY MONITOR ON THE INFANT'S FOOT IDENTIFIED AN IRREGULAR HEARTRATE PATTERN. THE BABY WAS NOT INJURED AND HE DID NOT REQUIRE ANY MEDICAL ATTENTION. THE MANUFACTURER ASKED THE INFANT'S PARENTS TO RETURN THE [SLEEP SACK] ACCESSORY SO THAT THEY CAN INSPECT IT.	TransitionSwaddle	NonWeighted
109	220401HCC1284 X2230862A	2021- Dec	1 MOM	FL	THE 5-WEEK-OLD MALE VICTIM WAS SWADDLED AND PLACED IN A BASSINET, ON HIS BACK, WITH HIS RIGHT SIDE AGAINST THE MESH WALL AND WITH A PACIFIER IN HIS MOUTH. THE BASSINET WAS THEN SET TO ROCK THE VICTIM TO SLEEP USING ONE OF THE FIVE MOTION CONTROL SETTINGS AND ONE OF THE FIVE SPEED SETTINGS EQUIPPED ON THE BASSINET. THE VICTIM WAS LATER FOUND UNRESPONSIVE, ON HIS BACK, IN THE CENTER OF THE BASSINET. THE VICTIM WAS TRANSPORTED TO THE HOSPITAL WHERE HE WAS PRONOUNCED DECEASED IN THE EMERGENCY ROOM. THE CAUSE OF DEATH WAS DETERMINED TO BE SUDDEN UNEXPLAINED INFANT DEATH WITH INTRINSIC AND EXTRINSIC FACTORS. THE EXTRINSIC FACTORS WERE LISTED AS LIVIDITY PATTERN NOT CONSISTENT WITH SCENE RECONSTRUCTION AND PACIFIER CORD USED DURING SLEEP.	TransitionSwaddle	NonWeighted
110	I2210116A	2022- Jan	UnkM	TN	The Consumer stated that her son was sleeping in the [SLEEP SACK] with fastener [wraps] and was able to wiggle his way down so that the [SWADDLE] of the sleep suit were partially covering his face.	TransitionSwaddle	NonWeighted
111	I2210128A	2022- Jan	1 MOF	FL	I purchased the [REDACTED] [SLEEP SACK] [SWADDLE] for my newborn. We did not experience issues until she was just shy of 4 weeks old. We put the swaddle on her in accordance with [REDACTED] directions and my newborn managed to move her arm in a way that escaped part of the swaddle and her arm was exposed on the bottom. The swaddle was still over both arms, but since her one arm was sticking out of the bottom of the swaddle attachment, she was able to move her arm upwards and as a result, it shifted the swaddle attachment up, toward her face. I caught it before the swaddle attachment actually covered her face. There were no injuries.	Swaddle	NonWeighted
112	220505HCC3814 I2250322A Mfr/Retailer Report Mfr/Retailer Report	2022- Mar	6 MOF	KS	ON [REDACTED] 2022, A SIX-MONTH-OLD GIRL WAS FOUND UNRESPONSIVE, BY HER FATHER, AFTER BEING SWADDLED TWICE AND PLACED SUPINE IN A LOUNGER WITH A BOTTLE. THE CHILD HAD BEEN LEFT UNATTENDED TO FEED FOR APPROXIMATELY 12 HOURS. THE PARENTS PERFORMED CPR UNTIL EMERGENCY PERSONNEL ARRIVED. THE CHILD WAS TRANSPORTED TO THE HOSPITAL WHERE SHE WAS PRONOUNCED DECEASED AT [REDACTED]. THE CAUSE OF DEATH WAS ASPHYXIATION DUE TO AN UNSAFE SLEEPING ENVIRONMENT.	WearableBlanket	Weighted
113	I2230238A	2022- Mar	19 MO	NJ	My 20 month old daughter woke up screaming from her nap. When I tried to get her out of her [SLEEP SACK], I found that the stitching of the quilted material had caught on her toes and wrapped around two, cutting off circulation and causing pain. I had to cut the thread and carefully unwrap from her toes, and massage the toes until color came back to them and she stopped crying.	WearableBlanket	NonWeighted
114	I2270036A	2022- Apr	9 MO	PA	I purchase a baby [SLEEP SACK] and stuff coming out from it and it can be choking hazard	WearableBlanket	Weighted
115	I2240124A	2022- Apr	9 MOM	CA	I would like to report the [SLEEP SACK]. I believe it is a dangerous item for babies. The zipper is flimsy and broke while our baby was wearing the sleeping bag. The zipper splits open and will not stay closed. This effectively turns the sleeping bag into a loose blanket, which can pose a suffocation hazard. I am happy to mail you the defective blanket. I reported this problem to the company. This is the link for the product on the [REDACTED] website, where you can see negative reviews re. the faulty zipper: [REDACTED] Here is the [REDACTED] page for this product, where you can see more negative reviews: [REDACTED]	WearableBlanket	NonWeighted
116	I2240186A	2022- Apr	Unk	Unk	Consumer states that loose baby swaddle can cause suffocation.	Swaddle	NonWeighted
117	I2430126A	2022- Aug	8 MOM	NJ	Consumer's 8 MOM nephew got a blue toe when a [SLEEP SACK] he was in, got entwined. Injury resolved itself and was not treated. [SLEEP SACK] was designed for his size and age.	WearableBlanket	NonWeighted

Incident #	Document #	Date	Age/ Sex	State	Narrative	Wearable Infant Sleep Products	Weighted / NonWeighted / Unknown
118	230710HCC3844 2206201702 I2390180A Mfr/Retailer Report	2022-Aug	6 MOF	CA	AT [redacted: night time], A 6-MONTH-OLD FEMALE VICTIM WAS NURSED THEN PLACED IN A MINI CRIB FOR NIGHT SLEEPING. SHE WAS WEARING A DIAPER, A ZIP UP SLEEPER AND A SLEEP SUIT. THE VICTIM WAS PLACED ON HER BACK IN THE MIDDLE OF A [REDACTED] PILLOW. THE PARENTS HEARD HER CRY BRIEFLY ON THE BABY MONITOR ABOUT 30 MINUTES LATER. AT [approximately 2 hours and placed in crib], THE VICTIM'S FATHER CHECKED ON HER AND FOUND HER FACE DOWN, WHICH WAS NOT UNCOMMON. HE SAW THAT HER FACE WAS DOWN IN A NEUTRAL POSITION BETWEEN THE PADDING OF THE [LOUNGER] AND THE SIDE RAIL OF THE CRIB. WHEN HE WENT TO FLIP OVER THE VICTIM, HE FOUND HER COOL TO THE TOUCH AND UNRESPONSIVE. 911 WAS CALLED AND HE BEGAN CPR. THE VICTIM WAS TRANSPORTED TO A HOSPITAL WHERE SHE WAS PRONOUNCED DEAD AT [about 3 hours and 20 minutes after victim placed in crib] AS A RESULT OF ASPHYXIA DUE TO WEDGING.	SleepSuit	NonWeighted
119	I22A0184A (Terminated IDI)	2022-Oct	6 MO	WA	The stitching on my infants[SLEEP SACK]/wearable blanket came undone. The thread became loose and became a choking hazard to my infant during sleep	WearableBlanket	NonWeighted
120	230213CCC3441 Mfr/Retailer Report	2022-Oct	8 MOM	WA	A 33-YEAR-OLD FEMALE ATTEMPTED TO ZIP HER 8-MONTH-OLD SON IN A WEARABLE BLANKET AND THE ZIPPER'S SLIDE BODY BROKE. THE ZIPPER WAS NO LONGER FUNCTIONAL AFTER THE INCIDENT. NO INJURIES WERE REPORTED.	WearableBlanket	NonWeighted
121	I22B0268A	2022-Nov	8 MOM	VA	Consumer has wearable blanket for their 8 MOM, while it was on their child and zipped into the blanket the zipper separated, leaving part of the wearable blanket loose. Consumer states it could cause suffocation and reported the issue to company.	WearableBlanket	NonWeighted
122	230213CCC1772 Mfr/Retailer Report	2022-Nov	6 MOM	PA	A 40-YEAR-OLD FEMALE CONSUMER PLACED HER SIX-AND-A-HALF-MONTH-OLD INFANT SON IN AN INFANT SIZED WEARABLE BLANKET. DURING THE NIGHT WHILE THE INFANT WAS SLEEPING IN HIS CRIB, A PIECE OF THE METAL ZIPPER DETACHED FROM THE PRODUCT. THE INFANT WAS FOUND BY HIS MOTHER THE FOLLOWING MORNING WITH HIS BODY OUTSIDE OF THE WEARABLE BLANKET AND THE ZIPPER OPEN. THE ZIPPER REMAINED ATTACHED AROUND THE NECK, WITH THE INFANT'S HEAD STILL INSIDE THE WEARABLE BLANKET'S NECK OPENING. THE CONSUMER SENT THE INCIDENT UNIT BACK TO THE MANUFACTURER IN EXCHANGE FOR A REPLACEMENT. NO INJURIES WERE SUSTAINED.	WearableBlanket	NonWeighted
123	230213CCC1774 Mfr/Retailer Report	2022-Nov	UnkM	GA	A CONSUMER PURCHASED A NEW WEARABLE BLANKET FROM THE FIRM'S WEBSITE FOR HER 12-MONTH-OLD SON. ONCE RECEIVED, SHE REMOVED THE PRODUCT FROM ITS PACKAGING AND MADE SURE THE ZIPPER WAS SECURE AS SHE WAS PREPARING THE PRODUCT TO GO INTO THE WASH. DURING HER MANIPULATION OF THE ZIPPER, SHE NOTICED THAT THE ZIPPER TEETH DID NOT APPEAR TO BE ON TRACK, WHICH CAUSED A LESS THAN SMOOTH OPENING AND CLOSING EXPERIENCE. THE CONSUMER'S SON WORE THE WEARABLE BLANKET NO MORE THAN THREE TIMES. THE CONSUMER WAS AT HOME MANIPULATING THE ZIPPER AND THE ZIPPER PULL TAG FELL OFF IN HER HAND. NO INJURIES WERE SUSTAINED.	WearableBlanket	NonWeighted
124	221207HCC3308 I22C0067A	2022-Dec	2 MOF	CO	A MOTHER PLACED HER TWO-MONTH-OLD FEMALE INFANT ON HER BACK IN A [SLEEP SACK] INSIDE A BASSINET. SHE CHECKED ON THE INFANT LATER THAT DAY. THE INFANT WAS STILL ON HER BACK. THE INFANT'S ARMS WERE FLEXED AND EXPOSED. THE [SLEEP SACK] CHEST STRAPS WERE BUNCHED UP AROUND THE INFANT'S SHOULDERS AND NECK. THE MOTHER SAID THAT THE INFANT DID NOT SLIDE DOWN INTO THE [SLEEP SACK]. THE STRAPS SLID UP. THERE WERE THREE ADDITIONAL INCIDENTS OF THIS NATURE. THE MOTHER STOPPED USING THE [SLEEP SACK] AFTER THE LAST INCIDENT ON [REDACTED]. THERE WERE NO INJURIES.	TransitionSwaddle	NonWeighted
125	I22C0434A	2022-Dec	19 MO	WI	Consumer's 19 MO child was swaddled with a [SLEEP SACK]. Child was found in the morning with zipper broken and sack around her neck. She was in empty crib and had pajamas under the [sleeping sack]. This is strangulation hazard. This occurred twice - two sacks from same company.	TransitionSwaddle	NonWeighted
126	230213CCC3442 Mfr/Retailer Report	2022-Dec	7 MOM	WA	A 27-YEAR-OLD WOMAN ATTEMPTED TO ZIP THE ZIPPER ON HER 7-MONTH-OLD SON'S WEARABLE BLANKET AND OBSERVED THE ZIPPER'S TOP STOP WAS MISSING. THERE ARE NO INJURIES OR PROPERTY DAMAGE ASSOCIATED WITH THIS INCIDENT.	WearableBlanket	NonWeighted
127	I2380545A	2023-Jan	8 MO	CA	The Consumer reported that the zipper on the [SLEEP SACK] came loose in the crib and their 8-months-old baby could have choked. The Consumer reported injury to the child. No first air or medical attention was sought.	WearableBlanket	NonWeighted
128	230726HCC1840 I2310137A	2023-Jan	6 MOF	NC	A MOTHER PLACED HER 6-MONTH-OLD DAUGHTER INSIDE A SLEEP BLANKET AND PLACED HER TO SLEEP. INSTANTLY, THE INFANT STARTED TO SCREAM, AND THE MOTHER ATTEMPTED UNSUCCESSFULLY TO CONSOLE HER. THE MOTHER TOOK HER OUT OF THE SLEEP BLANKET AND FOUND HER DAUGHTER'S MIDDLE TOE ON HER LEFT FOOT SEEMED TO BE ATTACHED TO THE BLANKET. SHE DISCOVERED A THREAD AROUND THE VICTIM'S TOE WHICH APPARENTLY CAUSED A LACERATION. THE MOTHER TREATED THE VICTIM'S INJURY AT HOME.	WearableBlanket	NonWeighted
129	231011HCC1076 2312010579	2023-Jan	2 MOM	FL	THE 2-MONTH-OLD MALE VICTIM WAS SWADDLED AND PLACED ON HIS BACK IN A BASSINET AFTER BEING BREASTFED. THE MOTHER LATER FOUND THE VICTIM LYING FACE DOWN ON HIS STOMACH, UNRESPONSIVE, WITH BLUE LIPS. SHE TRANSPORTED THE VICTIM TO THE LIVING ROOM AND STARTED CPR WHILE A FAMILY MEMBER CALLED 911. EMERGENCY PERSONNEL ARRIVED ON SCENE AND TRANSPORTED THE VICTIM TO A LOCAL HOSPITAL WHERE HE WAS PRONOUNCED DECEASED THE SAME DAY. THE CAUSE OF DEATH WAS DUE TO SUFFOCATION BY OCCLUSION OF THE NOSE AND MOUTH. THE MANNER OF DEATH WAS ACCIDENT.	Swaddle	Unknown
130	240401CBB1298 Mfr/Retailer Report	2023-Jan	4 MOM	IL	A WOMAN PLACED 4-MONTH-OLD MALE ON HIS BACK IN A PLAY YARD FOR AN AFTERNOON NAP. THE CHILD WAS WEARING A ONESIE-TYPE GARMENT AND SECURED IN A WEIGHTED SLEEP SWADDLE. THE WOMAN RETURNED APPROXIMATELY THIRTY MINUTES LATER. THE CHILD REMAINED SECURED IN THE SWADDLE ON HIS BACK AND TILTED SLIGHTLY TO HIS RIGHT SIDE. HE WAS UNRESPONSIVE AND NOT BREATHING. HE WAS TRANSPORTED TO A LOCAL HOSPITAL WHERE HE WAS PRONOUNCED DECEASED. ALTHOUGH THE CORONER DETERMINED THE INFANT DIED FROM COMPLICATIONS DUE TO COVID-19, A SUBSEQUENT HOSPITAL AND MEDICAL SCHOOL PROGRAM REVIEW DETERMINED THAT THE CHILD BECAME DECEASED DUE TO SIDS.	TransitionSwaddle	Weighted

5 USC 552(a)(2)(D)(ii) Posting

Incident #	Document #	Date	Age/ Sex	State	Narrative	Wearable Infant Sleep Products	Weighted / NonWeighted / Unknown
131	I2320050A	2023-Jan	3 MO	KS	We bought [REDACTED] Wearable Blanket with [REDACTED] Zipper [REDACTED] for 0-3 Months/3-6 Months/6-9 Months" from [REDACTED]. We received then washed. We put our 3 month old in it and realized immediately that the neck hole was huge. As this could be a suffocation issue when used, we did not. We returned immediately.	WearableBlanket	NonWeighted
132	230213CCC1773 Mfr/Retailer Report	2023-Feb	8 MOM	IL	THE COMPLAINANT WASHED HER 8-MONTH-OLD SON'S WEARABLE BLANKET IN THE WASHING MACHINE. AFTER IT FINISHED WASHING, THE ZIPPER DETACHED. THERE WAS NO INJURY.	WearableBlanket	NonWeighted
133	I2320131A	2023-Feb	4 MOF	NV	The consumer stated that 4 MOF baby had deep scratches on her face from the zipper of the [SLEEP SACK], which has a sharp end. The consumer reported that baby received 1st aid by non-medical professional.	WearableBlanket	NonWeighted
134	I2320423A	2023-Feb	3 MOM	CA	Consumer's 3 MOM grandson slept in a [SLEEP SACK]. Middle portion of the sleepsack's material was covering bottom portion of his face. It was completely covering his nose. The material then slipped down and bunched under his nose. This is not an isolated incident. No injuries.	Swaddle	NonWeighted
135	230313HCC1925 I2330131A	2023-Mar	1 MOM	NC	A MOTHER WAS AWAKENED IN THE EARLY MORNING HOURS BY HER THREE-WEEK-OLD SON'S CRYING. SHE SAT UP TO DISCOVER THE SWADDLED CHILD IN DISTRESS WITH HIS FACE AND BODY PRESSED AGAINST THE MESH WALL OF HIS PORTABLE FREE-STANDING BASSINET. SHE PICKED THE CHILD UP OUT OF THE BASSINET AND FOUND HIM TO BE UNINJURED. THE INFANT HAD BEEN PLACED TO SLEEP ON HIS BACK AND HAD NOT YET DEMONSTRATED AN ABILITY TO ROLL OVER ON HIS OWN.	WearableBlanket	NonWeighted
136	230428HCC3690 I2340417A	2023-Apr	3 MOM	HI	A 3-MONTH-OLD MALE WAS FOUND UNRESPONSIVE AFTER HAVING BEEN DOUBLE SWADDLED AND PLACED IN A IN-BED SLEEPER ON A BED. MEDICAL EXAMINER AND POLICE DEPARTMENT REPORT THAT INVESTIGATIONS ARE STILL ONGOING, AND NO REPORTS ARE AVAILABLE AT THIS TIME.	Swaddle	NonWeighted
137	I2340398A	2023-Apr	2 MOF	IA	Consumer's 2 MOF was wearing a swaddle and the material around the neck bunched up around her neck, while moving around during light sleep, causing her to have difficulty breathing causing a potential strangulation incident. Swaddle was removed. Child was not injured.	TransitionSwaddle	Weighted
138	230509HCC3710 X2350236A	2023-May	3 MOM	TX	A 3-MONTH-OLD MALE WAS FOUND UNRESPONSIVE BY A CARETAKER, WITH HIS FACE AGAINST A CRIB MATTRESS. HE WAS LYING IN A SUPINE POSITION INSIDE A COMPACT ADJUSTABLE CRIB AT A DAYCARE FACILITY AND WEARING A [SLEEP SACK]. THE CARETAKER CALLED 9-1-1 FOR HELP AND ADMINISTERED CPR. EMERGENCY CREWS TRANSPORTED THE VICTIM TO A LOCAL HOSPITAL, AND HE WAS PRONOUNCED DECEASED BY DOCTORS A SHORT TIME LATER. THE AUTOPSY REPORT LISTED THE CAUSE OF DEATH AS CHRONIC BRONCHIOLITIS AND THE MANNER OF DEATH AS NATURAL.	WearableBlanket	Unknown
139	H2350032A	2023-May	Unk	MA	The Consumer reported that her husband was putting the infant clothing [SLEEP SACK] on their child and the zipper fell off. The Consumer stated that there was no injury but this presented a definite choking hazard.	WearableBlanket	NonWeighted
140	I2360307A	2023-Jun	5 MOF	CA	The Consumer reports the [SLEEP SACK] was washed before it was worn by their 5-month-old baby. The following morning they found the dye was on the crib and on their baby's hands. Concerned their baby was in contact with potentially toxic chemicals rubbed off on to her hands.	WearableBlanket	NonWeighted
141	240110HCC1701 I2410127A Mfr/Retailer Report	2023-Jun	2 MOF	TN	A 2-MONTH-OLD FEMALE WAS PLACED IN A SWADDLE SACK AND IN AN INFANT SWING. THERE WAS A FLEECE BLANKET THAT COVERED THE SEAT OF THE SWING. THE INFANT WAS IN THE SWING FOR APPROXIMATELY 8 HOURS. SHE WAS FOUND UNRESPONSIVE BY HER FATHER. SHE WAS LAYING SLIGHTLY ON HER LEFT SIDE; THERE WERE PORTIONS OF THE FLEECE BLANKET GATHERED AROUND HER FACE. THE CAUSE OF DEATH IS UNDETERMINED. A COMPONENT OF ASPHYXIA CANNOT BE EXCLUDED DUE TO THE PRESENCE OF THE WEIGHTED [SLEEP SACK] AND SLEEPING IN AN INFANT SWING.	TransitionSwaddle	Weighted
142	I2380049A	2023-Jul	1 MOF	MI	Consumer's 1 MOF daughter had pieces of swaddle all over her body when she was unswaddled. These pieces are small and can get anywhere. She was not injured.	Swaddle	NonWeighted
143	230918HCC1312 X2390301A	2023-Aug	UnkM	SC	AT [REDACTED: evening/night], THE ONE-YEAR-OLD MALE VICTIM WAS PLACED DOWN TO BED BY HIS PARENTS ON A TWIN MATTRESS WITH FITTED SHEET THAT WAS ON THE FLOOR WITH A CRIB MATTRESS AND PILLOW WEDGED AT THE HEAD OF THE BED TO FILL THE GAP BETWEEN THE WALL AND THE TWIN MATTRESS. THE VICTIM WAS WEARING A [SLEEP SACK], COVERED WITH A BLANKET, AND WAS POSITIONED IN THE CENTER OF THE MATTRESS WITH A U-SHAPED PREGNANCY PILLOW SURROUNDING HIM. THE VICTIM'S MOTHER WENT TO WAKE UP THE VICTIM AT APPROXIMATELY [10 and a half hours later] AND THE VICTIM WAS FOUND DECEASED FACE DOWN WEDGED ON TOP OF THE PILLOW BETWEEN THE CRIB MATTRESS AND TWIN MATTRESS. THE VICTIM'S CAUSE OF DEATH WAS DETERMINED TO BE POSITIONAL ASPHYXIA DUE TO ENTRAPMENT IN BEDDING AND BED CLOTHING.	Swaddle	Unknown
144	240104HCC1661 X23C0592A	2023-Aug	3 MOM	FL	A 3-MONTH-OLD BOY WAS FOUND UNRESPONSIVE ON HIS SIDE IN A BEDSIDE SLEEPER. THE VICTIM WAS SWADDLED IN THE BEDSIDE SLEEPER. HE WAS TAKEN TO THE HOSPITAL WHERE HE WAS PRONOUNCED DEAD.	Swaddle	Unknown
145	I23C0160A	2023-Aug	UnkM	KS	Mother of male infant shared that her son experienced an adverse event while using a [Redacted] Weighted Sleep Sack with an interior swaddle band. The stitched to the back panel fixed swaddle band was found tightly wound around baby's neck after he began crying in extreme duress posing a both a potential suffocation hazard and directly showing a submarining hazard. She reports informing company whom asked for product to be shipped back and as a remedy they provided mother with a free sleep training course. Mother states she thinks the product is unsafe for infant use.	TransitionSwaddle	Weighted
146	I23A0022A	2023-Oct	Unk	CA	Consumer indicated that during overnight sleep the zipper broke on the wearable blanket of 1 YO baby.	WearableBlanket	NonWeighted
147	231023HCC3102 H23A0057A	2023-Oct	2 MOM	TX	A TWO-MONTH-OLD BOY WAS DRESSED IN A SWADDLE SLEEPER GARMENT AND PLACED IN A SUSPENDED BASSINET AT [REDACTED] THAT NIGHT. THE MOTHER OF THE CHILD HEARD THE BOY MAKING NOISES AND WHEN SHE LOOKED IN THE BASSINET, SHE DID NOT SEE HIM. AFTER A QUICK SEARCH SHE DISCOVERED THE BOY ON THE FLOOR OF THE PLAY YARD UNDER THE BASSINET PORTION, LYING FACE DOWN ON THE METAL SLATS OF THE PRODUCT. THE BOY SLIPPED BETWEEN THE SIDE OF THE SUSPENDED BASSINET AND THE FRAME OF THE PRODUCT, LANDING ON THE BOTTOM SURFACE. THE BOY WAS NOT INJURED AND THERE WERE NO PROPERTY DAMAGES.	TransitionSwaddle	Unknown

5 USC 552(a)(2)(D)(ii) Posting

Incident #	Document #	Date	Age/ Sex	State	Narrative	Wearable Infant Sleep Products	Weighted / NonWeighted / Unknown
148	I2440369A	2023- Oct	2 MOM	AK	My nearly three month old son was wearing a [REDACTED] product, the [REDACTED] weighted sleep swaddle. I laid him to sleep and when I left the room I was able to see his face. When I returned, he was face down. I believe he turn and couldn't turn back from the weight of the sleep sack. He passed away.	TransitionSwaddle	Weighted
149	I23B0139A	2023- Nov	10 MOF	CA	10 MOF was put to sleep in sleep suit & when consumer went to get her up, both zippers on suit were detached from suit & loose in crib creating major choking hazard. Consumer stated incident was result of design flaw. They were able to prevent any serious harm to baby.	Sleep Suit	NonWeighted
150	H23B0075A I23B0449A	2023- Nov	Unk	UT	Consumer has safety concern about baby sleeping bag. She was zipping baby in baby sleeping bag when zipper came completely off track. She contacted company & was advised to discard product. Company refused to replace product.	WearableBlanket	NonWeighted
151	I23B0196A	2023- Nov	Unk	CA	The Submitter reports that a large retailer is selling full body children's sleepwear which violates the tight-fitting flammability requirements for children's sleepwear.	WearableBlanket	NonWeighted
152	240111HCC3369 I23C0090A	2023- Nov	1 MOF	TX	A 34-YEAR-OLD FEMALE CONSUMER COMPLAINED THE ARMBAND FROM HER SECONDHAND BASSINET STRANGLER HER 6-WEEK-OLD DAUGHTER AFTER USING IT WITH COORDINATING NEW LEG LIFTERS IN HER HOME. THE DAUGHTER HAD SLID DOWN THE BASSINET DURING SLEEP, CAUSING THE ARMBAND TO WRAP AROUND HER NECK AND OBSTRUCT HER AIRWAY. THE DAUGHTER'S BREATHING MONITOR NOTIFIED THE CONSUMER OF HER DAUGHTER'S CONDITION, AND NO INJURIES WERE REPORTED. NO DAMAGE TO PROPERTY WAS REPORTED.	TransitionSwaddle	NonWeighted
153	I2410327A	2023- Nov	Unk	CA	The Consumer reports that they bought a baby [SLEEP SACK] and the sleeves on the [SLEEP SACK] are too puffy for a baby product and present a choking/suffocation hazard.	WearableBlanket	NonWeighted
154	I23C0120A	2023- Dec	18 MO	OH	Consumer purchased this [SLEEP SACK] & after about week of use she woke up to find that zipper portion was faulty & her 18 MO child had wiggled down into it & had the front flap over his face, unable to get it off. She caught it in time. Replacement did same thing. No injuries.	WearableBlanket	NonWeighted
155	240325CBB1213 Mfr/Retailer Report	2023- Dec	1 MOF	WI	DURING MULTIPLE OCCURRENCES IN EARLY DECEMBER 2023, THE VICTIM, A 3WOF, EXPERIENCED HEAVIER THAN NORMAL BREATHING WHEN SLEEPING IN A WEIGHTED SLEEP SACK. THE VICTIM DID NOT SUSTAIN ANY INJURIES.	WearableBlanket	Weighted
156	I2420214A	2024- Feb	5 MOM	TX	Consumer's 5 MOM almost suffocated in a [SLEEP SACK] when he was sitting up being held in this sack, and his neck was bunched into the sack and caused him to lose oxygen, he stopped breathing momentarily and vomited. Consumer got him out. Sack cut off air around his neck.	TransitionSwaddle	Weighted
157	X2420563A	2024- Feb	2 MOM	TX	2 MOM decedent was found unresponsive supine in his crib laying swaddled in baby [LOUNGER] with blanket partially covering his face. Decedent was taken to ER and his death was pronounced soon after arrival.	Swaddle	Unknown
158	I2430009A	2024- Feb	UnkF	PA	Consumer bought baby [SLEEP SACK] in XS, after watching very carefully while putting their daughter in they noticed it covered her face and mouth within seconds. Immediately fixed it and showed the company the issue with the design, stating it should be fixed.	TransitionSwaddle	NonWeighted
159	I2430325A	2024- Mar	13 MOM	FL	Broken zipper on baby clothing, purchased through online stores, consumer's 1 YOM became dangerously entangled while sleeping, around the neck on 3 different occasions with 2 separate ones.	TransitionSwaddle	NonWeighted
160	I2450224A I2450225A	2024- Apr	1 MOM	PA	A death of a baby occurred. The mother stated she laid the decedent on his back, dressed in a onesie and a weighted sleep sack ([REDACTED] Weighted Sack) on the breast feeding pillow ([REDACTED]) and woke up to find the decedent in the same position, not responsive.	TransitionSwaddle	Weighted

5 USC 552(a)(2)(D)(ii) Posting
(NEISS Data)

**Wearable Infant Blanket Related Incidents
Treated 1/1/2011 to 3/01/2024*
Ages 2 Years and Younger
NEISS Database**

*Based on reports entered into CPSC's NEISS database no later than 04/11/2024.

For the incomplete year 2024 still in progress, any included data is preliminary.

Disclaimer: CPSC does not guarantee the accuracy, completeness, or adequacy of these data particularly with respect to information submitted by people outside of CPSC. This spreadsheet was prepared by the CPSC staff. It has not been reviewed or approved by, and may not represent the views of, the Commission.

Incident #	Document #	Date	Age/Sex	Narrative	Product Type	Weighted
1	131037859	Aug-13	1 MOM	1MOM SLEEPING IN [SLEEP SACK] ON COUCH WITH MOM AND AUNT, FOUND BLUE, NOT BREATHING; CARDIAC ARREST	wearable blanket	Unk
2	171075358	2017-Oct	14 MOM	14MOM AT HOME BEING ROCKED BY DAD IN SLEEP SACK WHEN STARTED BREATHING DIFFERENTLY. DX: SEIZURE CONCERNS, SPELLS OF DECREASED ATTENTIVENESS	wearable blanket	Unk
3	181069112	2018-Oct	18 MOF	18 MOF WEARING A SLEEP SACK TRIPPED TWISTED R LEG DX CLOSED TIBIA FRACTURE	wearable blanket	Unk
4	190506352	2019-Apr	1 MOM	3 dom mother breast feeding him, he was in sleep sack (he is very small for sleep sack) she was repositioning him from left breast to right heard a pop in arm dx closed displaced fracture r humerus	wearable blanket	Unk
5	210956810	2021-Sep	2 YOF	2YOF WAS AT HOME TODAY TAKING A NAP IN HER CRIB WHILE WEARING A SLEEP SACK WITH THE RAILS UP AND MATTRESS SET AT THE LOWEST LEVEL. SHE SOMEHOW MANAGED TO CLIMB OVER THE RAILS AND OUT OF THE CRIB, FALLING TO THE HARDWOOD FLOOR COVERED BY A RUG. DX: CHI	wearable blanket	Unk
6	211231337	2021-Dec	4 MOM	4MOM was being taken out of a sleep sack at daycare today when the daycare worker pulled out his left arm backward and injured it. DX: Oblique fracture of shaft of left humerus.	wearable blanket	Unk
7	240206578	2024-Jan	5 MOM	5mom mom was trying to take the "sleep sack" off of her child and felt a pop in right forearm DX: fractured forearm	wearable blanket	Unk

Definitions from April 2024 balloted standard (w/ CPSC staff proposed additions in red underline, deletions in strikethrough)	CPSC Staff Comments/Questions:
<p>3.4.10. Wearable Blanket, n – A product made of fabric that is intended to be worn over sleepwear; <u>may have a fitted neck hole</u> and / or arm holes and sleeves (short or long); products include sleep sacks, sleep bags, swaddles, sleep suits, and transition swaddles.</p>	
<p>3.4. Sleep Bag, n – A product that is used to contain an infant's body during sleep that has a closure and encloses the infant's body and legs in a singular, bag-like structure; may or may not include arm holes and sleeves (short or long); also known as a sleep sack.</p>	<p>Suggest wearable blanket as umbrella term</p>
<p>3.5 Sleep Suit, n – A product that is used to contain an infant's body during sleep for the purpose of adding warmth, which has an opening for hands and feet.</p>	<p>Isn't the purpose to keep hands away from face? Product has added structure not just quilting? If purpose is keeping warm during sleep, I would argue this definition describes pajamas</p>
<p>3.6. Strap, n – A narrow strip of flexible material that is wider than it is thick, for fastening or holding things together, which may or may not be looped to hold or secure. This is not a drawstring or other piece of fabric used to cinch an opening smaller.</p>	
<p>3.7. Swaddle, n – A product that restrains the movement of the arms by either the fabric of the garment or use of fasteners, such as a swaddle band, snaps, hook-and-loop, etc., which may include holes for the infant's arms or legs.</p>	
<p>3.8. Swaddle Band, n – A strip of fabric which is attached to a swaddle and is designed to wrap around a swaddled infant to secure/restrict limbs.</p>	
<p>3.9. Transition Swaddle <u>Blanket</u>, n – A wearable <u>product that converts from a</u> swaddle that converts to a <u>wearable</u> blanket through opening or unzipping of arm holes or through a repositioning of the swaddle and arm positions; designed to bridge the gap between <u>a swaddle swaddling</u> and a loose-fitting sleep sack.</p>	<p>Suggest capturing mode of use as follows: Transition swaddle (swaddle mode) Transition swaddle (blanket mode)</p>
<p>3.10 Sleep sack, n - A product made of fabric that is intended to be worn over sleepwear with a head opening contoured to child's neck size and may have arm holes or sleeves (short or long)</p>	
<p>3.10. Wearable Blanket, n – A product made of fabric that is intended to be worn over sleepwear with a fitted neck hole; and may have arm holes and sleeves (short or long); products include sleep sacks, sleep bags, swaddles, sleep suits, and transition swaddles.</p>	<p>Are we good with not distinguishing short vs. long sleeved sleep sacks? N/A</p>
<p>3.10. Wearable Blanket, n – A product made of fabric that is intended to be worn over sleepwear with a fitted neck hole; and may have arm holes and sleeves (short or long); products include sleep sacks, sleep bags, swaddles, sleep suits, and transition swaddles.</p>	
<p>3.114. Sleep Bag, n – A product that is used to contain an infant's body during sleep that has a closure and encloses the infant's body and legs in a singular, bag-like structure; may or may not include arm holes <u>and sleeves (short or long); also known as a sleep sack.</u></p>	

weighted - not currently defined in standard