

CPSC FOIA 19-F-00215 Production Part II of III pp 256-515 of 765

Attachment 1

Mold Assessment for Fisher Price PSA

I. Background

Mold is a fungus that is ubiquitously found in both indoor and outdoor environments. The number of species of fungi is unknown; however, it is estimated to be in the range of tens of thousands to upwards of hundreds of thousands¹. Common mold species found in homes are Cladosporium, Penicillium, Alternaria, and Aspergillus. These fungal species are considered opportunistic fungi, in that if there is sufficient moisture and oxygen, these species can grow on any organic substance^{2, 3}.

Mold exposure has been associated with health effects, including allergic reactions, asthma, and other respiratory issues³. Some people may react to mold and experience nasal stuffiness, eye and skin irritation, and wheezing. More severe reactions include shortness of breath and fever. Those individuals who are immuno-compromised and/or have chronic lung diseases are at increased risk for opportunistic infections upon mold exposure⁴. Some molds produce mycotoxins, which are cytotoxic or have other toxic properties¹. Stachybotrys, the species classically thought of as "toxic mold", can be found in buildings and homes, although to a lesser extent than Cladosporium, Penicillium, Alternaria, and Aspergillus⁴. In addition, mold cell walls contain β -D-glycans which have inflammatory properties, and mold spore and mycelia fragments contain allergens⁵.

II. Discussion

A. Review Reports

A review by the Institute of Medicine (IOM) in 2004, found associations between two risk factors, exposure to indoor dampness and presence of mold, and upper respiratory tract symptoms, cough, wheeze, and asthma symptoms in sensitized persons, but no association for the development of asthma. The World Health Organization (WHO) in 2009, reviewed epidemiological, clinical, and laboratory studies and found associations between dampness and dampness related agents, including mold, and the development of asthma, a current diagnosis of asthma, dyspnea (shortness of breath), and respiratory infections. In the WHO review, associations were found in atopic and non-atopic individuals. Neither review reported finding causal relationships between indoor dampness or mold and the development of and/or appearance of health effects.

¹ http://www.edc.gov/mold/basics.htm

² http://ww5.stlouisco.com/doh/pollen_site/MoldInfo.html

³ http://www.epa.gov/mold/index.html

⁴ http://www.edc.gov/mold/stachy.htm

⁵ Health Canada (2007) Residential Indoor Air Quality Guideline for Moulds; Canada Gazette; 141(13).

Mendell et al. (2011) reviewed all currently available evidence, including studies reviewed in the IOM report, recently published studies, and findings from quantitative meta-analysis studies. Mendell et al. classified hundreds of studies into the following four categories based on the strength of evidence between dampness, mold, dampness related agents and health: 1) sufficient evidence of a causal relationship, 2) sufficient evidence of an association, or 4) inadequate or insufficient evidence to determine if an association existed. An association was found between indoor dampness or mold and the four health outcomes defined in the IOM report. In addition, the authors concluded that the studies were, "...strongly suggestive of causality" between asthma exacerbation and dampness or mold in children. This latter finding was especially evident in a controlled experimental intervention study on the exacerbation of asthma in homes with highly symptomatic children (Kercsmar et al., 2006). In this study removal of sources of dampness and visible mold resulted in dramatic reductions in the exacerbation of asthma.

Mendell et al. also found sufficient evidence of associations between indoor dampness or mold and the development of asthma, a current diagnosis of asthma, having ever been diagnosed with asthma, dyspnea, respiratory infections, bronchitis, allergic rhinitis, and eczema.

The measured microbiological agents had limited associations with health effects; this was thought to be due to measurement errors in exposure assessment (i.e., non-standardized methods of measurement used in the different studies) as well as other factors such as age at exposure and interaction effects that occur with multiple chemical exposures. Limitations in the measurement techniques themselves were also highlighted. Although the authors report that their current findings cannot define causal microbiological exposure or dose-response relations that can be used to determine safe levels of exposure, quantifying dampness objectively has shown some promise for future research. In the meantime, the present method of subjectively assessing dampness or presence of mold has the most consistently documented associations with respiratory and allergic disease. Therefore, HS staff believes that it is appropriate to utilize this approach for assessing the potential for health effects due to exposure to mold.

B. Studies on Specific Mold Species

Health Sciences staff reviewed the current literature related to the mold species found in

(b) (3) (A), (b) (4)

The literature review consisted of primary, peer reviewed studies that specifically identified one or more of the four mold species of interest.

Studies published within the last 11 years with sufficient data related to mold . concentrations, species, and health outcomes were reviewed. The studies revealed limited information for the four mold species of interest (See Table 1). These mold

species included Cladosporium, Alternaria, Aspergillus, and Phoma. Four relatively recent epidemiological studies were also reviewed.

All epidemiological studies showed a statistically significant association between increased mold exposure and respiratory effects. Stark et al. (2003) showed that exposure during the first year of life to high mold concentrations increases the incidence of doctor diagnosed lower respiratory illness (LRI)¹⁴.

In addition, the authors found specific connections to "LRI without wheezing" and airborne Penicillium exposure, and "LRI with wheezing" and Alternaria and Zygomycetes exposures. The relationship between Penicillium exposure and "LRI without wheezing" showed the strongest association through relative risk (RR). "LRI with wheezing" might represent an early allergic response. However, for many children in infancy wheezing can represent a non-allergic inflammation of the small airways. Therefore, although children who show repeated "LRI with wheezing" during infancy are more likely to develop allergic asthma, the trigger for developing this type of LRI during infancy is likely to be non-allergic.

When the authors investigated any associations between visible mold or mildew (a thin, discoloring growth pattern produced by mold in damp environments) and increased mold exposure, they found that there was little to no correlation between the two variables. This lack of correlation suggests that dampness-related factors in addition to increased mold exposure, are also important in the development of adverse health effects. However, the visible presence of mold, mildew, or water damage did show a strong trend (b)(5) for association with increased LRI, though less of an association compared to the statistically significant association between high mold exposure and LRI. Therefore, these two variables, the visible presence of mold or mildew and high mold exposure, are independent predictors of LRI during infancy.

In a paper describing the continuation of their 2003 study, Stark et al. (2005) found an association between the presence of high levels of mold and the development of doctor diagnosed allergic rhinitis by the age of 5 years. The authors controlled for factors significantly associated with allergic rhinitis, including the presence of water damage, mold and mildew during the first year of life, and LRI during the first year of life. Therefore, these findings are independent of these factors. During a multivariate adjusted proportional hazards regression analysis, the authors found that some mold species were highly correlated with each other, meaning that when one species is found, it is likely that the second species will also be found, increasing the levels of mold exposure. These species included Alternaria with Aureobasidium, as well as Cladosporium with Alternaria.

In a previous paper by Gent et al. in 2002, the authors found that Penicillium and Cladosporium were significantly associated with persistent cough. Only Penicillium was associated with wheezing. Upon further review of the data, high exposure to Penicillium was also associated with an increase in the number of days in the first year of life that persistent cough is experienced (statistics not shown). When controlled for confounding

Studies

factors, including water leaks, humidifiers or dehumidifiers, and smoking in the home, the Penicillium and Cladosporium associations with persistent cough remained.

Taskinen et al. (2001) studied school children, ages 7 – 13, who attended either schools with moisture problems (index group) or schools with no moisture problems (i.e., healthy, control schools) to determine if associations existed between moisture problems and sensitization of the children. Sensitization was identified by mold specific serum IgE, as well as other clinical outcomes. The authors noted that more children from the index group showed mold specific serum IgE to at least one of the ten species studied. However, the number of children with elevated IgE was low, 14 (15%) out of 93, with 2 children being from control schools. However, 12 of the 14 children with elevated IgE also showed some reaction (positive or weak) to mold specific skin prick testing (SPT). In examining associations with specific clinical outcomes, the authors found increased IgE to be significantly associated with doctor diagnosed asthma and parent reported wheezing, but not persistent cough as reported by parent. In addition, other allergic manifestations, such as allergic rhinitis, conjunctivitis, or eczema, and sensitization to common inhalation allergens, dander, pollen, and mites, were also significantly associated. Although the authors found that those with mold specific IgE or SPT reactions were mostly from the schools with moisture problems (84%), they found no species specific mold associations with any of the responses. It is important to note that this study did not control for confounding factors, such as home environment considerations, exposure to smoking, parental atopy status, or other mold exposures, during their statistical analysis. (b)(5)

(b)(5)

Upon reviewing these studies, HS staff concludes that (b)(5)

There is a known association with parental sensitization and allergic responses in children. Although the Stark et al. (2005) study did control for parental sensitization during the statistical analysis, due to lack of supporting studies, the conclusion (b)(5)

Given that two of the four studies reviewed showed respiratory responses in infants, it is likely that (b)(5)

Therefore, HS staff concludes (b)(5)	
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Table 1: Reviewed Mold Studies

Author	Study Type	Mold Concentration	Species	Health Outcome
Stark, et al. (2003)	Epidemiological (First year of life)	High (189 cfu/m³)	Airborne Penicillium	LRI (RR=1.73)
		High ⁷ (31,579 cfu/g)	Dust-borne Cladosporium	LRI (RR=1.52)
		High ⁷ (870 cfu/g)	Dust-borne Zygomycetes	LRI (RR=1.96)
		High ⁷ (8,333 cfu/g)	Dust-borne Alternaria	LRI (RR=1.51)
		Multiple High ⁷	Multiple Species	LRI (RR=1.86)
		High ⁷	Any Species	LRI Wheezing (RR=1.58) Non-wheezing (RR=3.88)
Stark, et al. (2005)	Epidemiological (By 5 years of age)	High ⁷ (8,333 cfu/g)	Dust-borne Alternaria	DDAR (HR=2.34)
		High ⁷ (33,333 cfu/g)	Dust-borne Aspergillus	DDAR (HR=2.57) ¹⁰
		High ⁷ (24,000 cfu/g)	Dust-borne Aureobasidium	DDAR (HR=3.12) ¹⁰
		High ⁷ (250,000 cfu/g)	Total Dust-borne	DDAR (HR=3.13) ¹⁰
Gent, et al. (2002)	Epidemiological (First year of life)	High	Airborne Penicillium	Wheeze (RR=2.46) Persistent cough (RR=1.84) ¹²
		Medium	Airborne Cladosporium	Persistent cough (RR=1.62) ¹²
			Reported Mold	Persistent cough (RR=1.49)

		High ¹¹	Airborne Penicillium	Wheeze (RR=2.15) Persistent cough (RR=2.06) ¹⁴
		Medium ¹³	Airborne Cladospoium	Persistent cough (RR=1.45) ¹⁴
Taskinen et al. (2001)	Epidemiological (School children ages 7 – 13)	Elevated Serum IgE Antibodies	10 molds mixture	Respiratory morbidity (asthma and/or wheezing) – 86% Clinical Atopy (rhinoconjuntivitis and/or eczema) – 71% SPT reactivity (danders, pollens, and/or mites) – 93%

III. Conclusions		
(b)(5)		

Works Cited

Gent et al. (2002) Levels of Household Mold Associated with Respiratory Symptoms in the First Year of Life in a Cohort at Risk for Asthma. Environmental Health Perspectives. 110:A781-A786.

Kercsmar et al. (2006) Reduction in Asthma Morbidity in Children as a Result of Home Remediation Aimed at Moisture Sources. Environmental Health Perspective. 114:1574-1580.

Mendell et al. (2011) Respiratory and Allergic Health Effects of Dampness, Mold, and Dampness Related Agents: A Review of the Epidemiologic Evidence. Environmental Health Perspectives. 119:748-756.

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Stark et al. (2002) Fungal Levels in the Home and Lower Respiratory Tract Illnesses in the First Year of Life. American Journal of Respiratory and Critical Care Medicine. 168:232-237.

Stark et al. (2005) Fungal Levels in the Home and Allergic Rhinitis by 5 Years of Age. Environmental Health Perspectives. 113:1405-1409.

Taskinen et al. (2001) Mold-specific IgE Antibodies in Relation to Exposure and Skin Test Data in Schoolchildren. Allergology International. 50:239-245.

Attachment 2

Fisher-Price Data

Fisher-Price (FP) provided two sources of data on microbial contamination of Rock 'n Play (RNP) sleepers: (1) four Bureau Veritas reports; and (2) one Building Dynamics, LLC report dated March 1, 2012 which is summarized in two Goldberg Segalla reports dated February 24, 2012 and March 5, 2012

Bureau Veritas (BV) Reports

- (1) Report #(5111)164-0165, dated June 20, 2011
- (2) Report #(5111)336-0079, dated December 12, 2011
- (3) Report #(5111)354-0251, dated January 4, 2012
- (4) Report #(5112)005-0086, dated January 17, 2012

(1) In the first BV report, (b)(4); (b)(3):CPSA Section 6(a); (b)(3):CPSA Section 6(b)	
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Due to	the poor quality of the pictures provided in the four reports, a determination
cannot	he made whether the microbial growth is located in the same area of each RNP
sleene	For some of the full-size RNP sleepers, (b)(4); (b)(3):CPSA Section 6(a); (b)(3):CPSA Section 6(b)
(b)(4); (b)(3)	CPSA Section 6(a); (b)(3):CPSA Section 6(b) (b)(5)
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	mary purpose of the cape-lift sampling method is to confirm the existence of mo
growth	and to identify the type of fungi at the sampling site, referred to as source
sampli	ng. In this case, the "source" is the RNP sleeper, since we have no information
	sumers from whom FP received the samples. Tape sampling is also the simples
	of source sampling. Compared with swab sampling, tape-lift sampling better
preserv	es fungal structure, which may allow for higher resolution identification.
	er, tape-lift sampling is destructive testing and thus the samples are neither
	le nor suitable for subsequent culture analysis.
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Bureau	Veritas indicates (b)(4); (b)(3):CPSA Section 6(a); (b)(3):CPSA Section 6(b)
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¹ Swab sampling in an indoor air quality (IAQ) investigation is usually done in combination with other methods, such as air and bulk sampling. It is normally done when the surface is a non-porous (smooth) material, and cutting it is undesirable or not an option (countertops, poles, floors, etc.). Swab sampling is most commonly done by wiping or swabbing a designated area. Surface samples can be analyzed for microbial identification and semi-quantification by direct microscopy, quantitative polymerase chain reaction (qPCR), and/or culture methods. The analysis of surface samples can provide information about whether a suspect area is supporting microbial growth.

Building Dynamics, LLC (BD)

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(b)(5)	It is well known that seasonal variation will occur with not
only the type of microbial s	pecies collected but also the total counts of microbiota (i.e.,
increased in warmer months	5), (0),0)
Discussion	
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A sensitizer is a substance that will induce an immunologically-mediated (allergic) response, including allergic photosensitivity. This allergic reaction will become evident upon re-exposure to the same substance. Occasionally, a sensitizer will induce and elicit an allergic response on first exposure by virtue of active sensitization.

	****FOR OFFICIAL	USE ONLY****			24	PSA ACTION (FOR PSA	OR PSA
PRODUCT S.	PRODUCT SAFETY ASSESSMENT (PSA) 1	ECHNICAL	TECHNICAL EVALUATION REQUEST	N REQU	EST	PSA Number	: 0481.12
					3	Date Processed	: 3/20/12
Requested by :Theresa Nelson,	Nelson, G	Org. Code	de :CRC	Field Off : FOER	FOER	Date Requested	: 3/27/12
Date Submitted : 3/20/2012	12	Priority	q;	Case #	:PI110066	Due Date:	
Requested Completion Date	: 3/27/2012 (Staff has agreed to completion date.)	n date.)					
PRODUCT INFORMATION:	NC:					Assigned to	
Manufacturer : Fishe	: Fisher-Price, Inc.		City :East Aurora	ra	State :NY	Organization:	: HS
Product : Fisher-Pr	: Fisher-Price Rock 'N Play Sleeper		NEISS Code	:1549, 1537, 1558	7, 1558	Technical Off.	••
Brand name, model, etc.	: Fisher-Price					Request Summary:	
Sample number :							
Sample Disposition:	Return to Requester Store at Warehouse	arehouse	_Other :				
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EVALUATION REQUESTED: current research and literature. product.	ED: rature. Also include staff's assessment of the firm's study disputing the hazards of mold in this	of the firm's stu	old icense with this product as it relates to n's study disputing the hazards of mold i	ct as it relat azards of m	es to old in this	Comments:	
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LOCATIONS OF	Samples: SSF	Files:				(MSWordRe	(MSWordRev 2/99 tp/jb/bh)

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Thank you for your cooperation.

Regards,

Terri Nelson

Compliance Officer
Office of Compliance & Field Operations
U.S. Consumer Product Safety Commission

Phone: 301-504-7509 or 1-800-638-8095 ext. 7509

Fax: 301-504-0359 tnelson@cpsc.gov

SIGN UP FOR RECALL NOTICES: http://www.cpsc.gov/cpsclist.aspx

Page 272 Withheld pursuant to exemption (b)(4); (b)(3):CPSA Section 6(a) of the Freedom of Information Act

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TO: Theresa Nelson, CRC FROM: Ted Yang, EPHA

DATE: 6/5/2012

RE: Data Review for PSA # 0621.12 Case # PI110066

Date due: 6/6/2012

Priority: c

Request: Determine any incidents to children (victims 6-and-under) in which the word

"mold" was present in reports received from 1/1/2009 - 5/15/2012. Sort by mfr.

Hazard Pattern: mold in products

Selection Criteria:

Product Code(s):

Manufacturer/Model Text:

Narrative Text: mold

Time Frame: 09/01/2008 - 05/15/2012 (covers dt_ent: 1/1/2009 - 5/15/2012)

NFIRS Search Criteria:

Incidents Identified:

Databases	Incident Count* (see notes below)	Death Count*
Incident Investigations (INDP)	2	0
Reported Incidents (IPII)	26 (43)	0
Death Certificates (DTHS)	0	0
NEISS reports (count)	N/A	N/A
Fire reports (NFIRS)	N/A	N/A
Total	28	0

^{*} For INDP, IPII and DTHS, duplicate reports have been removed, i.e. counted only once, in the database listed first. The reports enumerated in the table have been identified from CPSC databases on the date the search was completed. These should be considered neither a statistical sample nor a complete count of all such incidents, but only a count of those in CPSC databases on the search date.

NOTES:

Search yielded 2 INDP records and 26 IPII reports involving incidents to children (victims 6-and-under) in which the word "mold" was present in reports received from 1/1/2009 - 5/15/2012. All records indicating incidents with children ages 6-and-under include age of victim in bold.

Also, 43 additional IPII reports involving mold were retained; the incidents described in these reports either mention mold with respect to a children's product, involve a consumer expressing concern of a product's danger to children, or involve a child victim whose age is unknown.

Mold Incidents (age \leq 6) Dt _ent:: 1/1/2009 - 5/15/2012

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evitarian	CONSUMER REPORTS THAT THE BOTTOM OF THE WOODEN ACTIVITY TOYHER 11-46WITH-OLD MODELN ACTIVITY TOYHER 11-46WITH-WIS FOUND COVERED IN A THICK IA VER ON MICH. WAS WOOSWARD RE USUSHING IF HEAD MASS NGESTER WAS INCESTING IN CONSUMER BUSING IF THE WAS INCESTING IN CONSUMER BUSING IN SHE WAS INCESTING IT.	THE 10 MOF CHL D'S HICHCHAIR TRAY BS 2 PECES PUT TOGETHER BY SCREWS THERE IS A SEEM THAT BLUNS ALL AROUND THE TRAY. WHEN OWNER TRED TO LOSSEN THE SCREWS TO CLENT THE SEAM SHE NOTICED IT FAD THUNED BLACK & DARK DISLORATION ON THE	THE CONSUMER NOTICED MOLD ON THE SIDE OF THE CONSUMER AT HET NIME OF PURCHASE. THE CONSUMER STATED THAT HERA WONTH OLD SON HAS BEEN GETTING SICK A LOT WHILE HE HAS BEEN SLEEPING IN THE CRIB.	26 VOF. HER 3 YOM SON AND HER B MOF DAUGHTER ARE EXPERIENCING SKIN RASHES, FEVERS WITH SRUDS INFECTIONS, & OTHER RESPIRATIONS FROBE ENSO DUETO BLACK MOLD GROWNEG IN HER MASHER, WHICH TURNED LIGHTER WHITE GREEN WASHER FOR	6 YOM HAS ASTHMA, AND EXPOSURE TO MOLD WORBENG HAS WARFORD. DISCOVERED A LARGE ANGUNT OF MALD BUNDER THE FRONT SEAL OF FRONT LOAD WASHER THE FRONT SEAL OF FRONT LOAD WASHER THAT SHE CANNOT GET RID OF. HAZARD TO HER TSON.	CONSUMER REPORTS THAT 18 MOM AND 3 YOM WEER PLAYING WITH A WATER SQUEEZE TOY WHEN THE CONSUMER NOTICED DISCOLORATION YHE WATER BEING SQUEEZED OUT COMISMER BEINGS SQUEEZED OUT COMISMER BEINGS THAT WATER LETT TRAPPED IN THE TOYS AND CAUSE MOD TO GROW CONSUMER CONSIDERS THE	BLACK MOLD CONTINLOSILY FORMS ON THE OUTSOE RUBBER HOS OF FORM! LOAD WASHING MACHINE, 36 YEAROLD FEWALE CLEANS IT & IT RETURNS WORSE THAN BEFORE. SHE ATTRIBUTES HER SINUS IN FECTIONS & HER AYEAROLD SON'S SEVERE ALLERGIES & ASTHMAT TO THE MOLD.	WASHING MACHNE HAS LEFT CLOTHES WITH MOLDY ODGS THEFE'S BLOCK GUNKON RM. WASHER HAD STOPPED DRAINING WATER 5 MITHES & LACK SEEN FEPAIGE FOR THAT & YOM THES ALLERGY MASTHIMMCEZEM & HAD SEVERAL ATTACKS OVER LAST FEW YEARS & REGISTED AT FERST A FEGINED.	CUSTOMER IS STATING THAT HE PURCHASED A WASHER AND DIFFE FROM THE STORE. HE STATES HIS UNITS ARE INFESTED WITH MOLD AND ML DEW AND CAUSING HEALTH ISSUES WITH HIS 3 CHLDREN UNDER THE AGE OF 5 WITH HIS 3 CHLDREN UNDER THE AGE OF 5	CONSUMER USED LOTION DALLY ON 2 CHLUREN. AGES 2.4 FOR SEVETAL MONTHS. ABOUT WEEK AGO. CONSUMER SIARTED NOTICING WHAT LOCKED. LKF FEW PIECES OF LATIONT. CONSUMER OPERING CAP & SAW LAYER OF DOBLACK MOLD ONLOTION.	CONSUMERS REPORT THAT THEY NOTICED MOLD GROWING IN A RUBBERZED STRAW THAT IS A PART OF A SIPPING CUP USED BY 1 YOF 47 CONSUMERS STOPED USING THE CUP
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Mold Incidents (age ≤ 6) Dt_ent:: 1/1/2009 - 5/15/2012

Mold Incidents (age ≤ 6) Dt_ent:: 1/1/2009 - 5/15/2012

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Mold incidents (age ≤ 6) Dt_ent:: 1/1/2009 - 5/15/2012

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Apecon	GREN BRETTATION / RAJET GOT BAFECTION AFTER LISING PRODUCT. USBD 300 of 120 PAPERS, OCCUPED BY THE PRINTE PART OF THE BASY. TREED & CHEANS LIKEAND WITH ALCE VERA.	SUT WEEGITH SHE EMESSANT, BLACK MOLD TO CONFICH FACH PART BY EXTRA PADONIG.	THE CONNECT REPORTS THAT THE FRONT LOAD MASSING MASSING SCHOOLS CONNECT THE CONNECT THAT THE FRONT LOAD CONNECT THE CONNECT TO TH	COMBLAKER REPORTS THAT SHE HAS FOUN OF THESE PAGETS AND NOTICEDE JACK MOLD IN THE BASE OF OWN OF THE PAGETS THESH SHE CACCACED ALL THE PAGETS AND ALL FOUN OF 21 THESH HAS THE BLACK MOLD.	THE CONSUMED STATED AFTER BLEEFING IN THIS PRODUCT HER GRAWSON BECAUSE, FEW AS YACKITY OF THE REPRAINTS YESSEE, FEW AS YACKITY OF THIS PRODUCT HE ARANGE DIRECTHAN THE ATMENT FOR ABSTRANCE OF A BLANK SUBSTANCE CAME OUT THE FARIST OFFER A BLANK SUBSTANCE CAME OUT.	THE CONSUMER EXPRESSED CONCERN THAT IS THE THE WITH THE LIMER.	THE CONSIMER EXPRESSED CONCERN THAT MOUD HAS DEVELOPED BETWEEN THE LANER (QUAND THE FABRIC PAD.		THE CONSUMEN EXPRESSED CONCERN THAT MOLD HAS FORMED ON THE PAD AND LINER OF SOTHER PRODUCT.		MOLD BEGAW TO ADPEAR ON THE SEAT AND STRAPS, CONSUMER PEOPLESSED CONCERN BECAUSE SHE CANNOT PERMOVE THE SEAT POR LAUNDERWIC CONSUMER OWNIES 28 ESPERS 8.	MOLD BEGAN TO APPEAR ON THE SEAT & STRINGS. CONSUMER EXPERSED CONCERN. SECULACE SHE CANNOT SEALVE THE SEAT FOR LANDERING. CONSUMER OWNS TWO THE WORLD SHEED SHOW SO RECORTING THE CONSUMER SPACE WITH EACH ONE.	THE CONSUMER EXPRESSED CONCERN THAT HERS! CEPER 144S DEVELOPED MOLD ON THE 10 SEAT.	THE CONSUMER IS CONCERNED BECAUSE. 10 THERE IS MOLD ON THE LINER OF THE PRODUCT.	THE CONSUMEN EXPRESSED CONCERN THAT THE ROCKING SLEEPERS PAD AND SEAT ARE TO MOLDY.	THE CONSUMER EXPRESSED CONCERN RECAUSE THERE IS MOUD ON THE ROCKING TO SEEPLEPS LINER MEAN THE SUPPORT	THE CONSTANCE EXPRESSED CONCERN. BECAUSE THERE IS MALD ON THE ROCKING. 10 BLEEPER'S LINER NEAR THE SUPPORT.	THE CONSUMEN EXPRESSED CONCERN THAT MOUD IS ON THE PAD AND LINER OF THE TO POCKING SLEEPER.	THE CONSUMED EXPRESSED CONCERN THAT THE CONSUMED THE PART AND THE SEAT ON THE ROCKING SLEEPES THE CONSUMED AND STATED THAT THE READ DHAS HAND PRESENTED PROSE LENG FOR TWO MANATINES AND SHE IS NOW ATTRIBUTING THIS TO THE
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w a nbom		UPCA SBODOGROSOB	OSSZOLJANJOHOZ, REJ DI RESPONTA	MANA PROFEES	PROPER TENDER	MA REOTO / HENEBORN ROCK N PLAY BLEEPER	MM RB070 / NEWBORN ROCK 'N PLAY SLEEPER	MA REGION / NEWBORN ROCK N PLAY SLEEPER	MA PRIOTO/NEWBORN ROCK N PLAY SI EEPER	METROTO/NEWBORN FOCK IN PLAY BLEEPER	MA REDZOZ/NEWIGORN ROCK N PLAY	MA PROTO/NEWBOTN ROOK N FLAY	MF RED/O/NEWBORN ROCK WPLAY SLEEPER	M# PEGZG / NEWBORN FOCK N PLAY SLEEPER	MAR PROTO/NEWBORN FOCK NPLAY SLEEPER	ME PROTO / NEWBORN ROCK 'N PLAY SE FERFER	MAI PROTO/MEWBORN ROCK IN PLAY SU. EFFER	MAR REOTO / NEW BOOKN ROCK IN PLAY SLEEPER	MERGOTG VIEWBORN POCK IN PLAY
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Mold Incidents (age ≤ 6)

очоор	Y116666A	VOLUME TO THE PARTY OF THE PART	¥11656657A	115206634	Acabean Y	H10E0302A	HOSTOTAL	OBSOZOWA	00S1 (13A	POLOGESA	70946123A	M-10000000	1
o Alexandra Alex	THE CONFIDENCE IS CONCEINED BECAUSE THE PAID AND THE LINEH ON THE ROCKING BLEEFER IN AND MICH DY.	THE RETALLERS REPORT STATED THAT WHEN THE CONSUMER RESIDENCE TO CONSUMER RESIDENCE THE ROCKERS BE NOTICED WILL DE ANOLD WAS THE WALL AND THE WELL AND THE WALL DINN BE THE CAUSE TO WAS THE WALL DINN BE THE CAUSE TO THE WALL DINN BE THE CAUSE OF A THE WALL DINN BE THE CAUSE TO THE WALL DINN BE THE CAUSE TO THE AND THE WALL DINN BE THE CAUSE TO THE AND THE WALL DINN BE THE CAUSE TO THE AND THE WALL DINN BE THE CAUSE TO THE AND THE WALL DINN BE THE CAUSE T	THE DOWINMER EXPRESSED CONCERN THAT THE WASTERNAL ON THE SEAT OF THE ROCKING SLEEPER HAS DEVELOPED MICLD MEAR THE TO PARESTED SLEPPONT.	CONSUMER REPORTED ABOUT BLACK MOLD GROWING DATHER ROSE FLUBER BISAL OF THE FRONT LAND WASHER CHOSLINES HARS CHLITERED ABOUT THE 21 EURY CONNEINER DADOUT THE 21 EURY CONNEINER DADOUT THE	PRODUCT HOLES/DRISHE WANTED TO FETURN THE BATH TOY, SHE SAD THAT RECERTLY CAN THE TY THE TOYS THAT HAVE HOLES GET BLACK AGGOOF THE SHOWN TOWN THAT BATH SHE SHOWN THAT SHOWN THAT THE SHOWN THAT SHOWN THAT THE SHOWN THAT SHOWN THAT THE SHOWN THAT THE SHOWN THAT THE SHOWN THAT THE SHOWN THE SHOWN THAT THE SHOWN THE SH	COMBLIMER REPORTS THAT WHEN SHE RECENTO THE TOY WHISTLE CHDERED ONLINE. SHE NATIVED THAT IT HAD BLACK MALD.	TODDILER WIFES HAD BLACK MOLD IN THE 47 MEDIS E OF THE PACK.		EXTRIBATE MIX. D PROBLEM COCKURS AFTER EACH PANEARLL, YERONG WAS CONTACTED LAST YEAR & THEY ADVISED TO CLEAN WITH REACH. THE STILL HAS MIX.D STORES WHICH WILL APPEAR LEALLY AFTER CLEANME. CHAUPES TO USE THE DECKNOT DAY & DECKNO MAY BE THE DECKNOT DAY & DECKNO MAY BE	CONSUMER FOLND MOLD GN THE GABRET OF THE WASHING MACHINE AND ALSO IN THE DISTERNED TO SEPENSES. SHE FOLMD SEVERAL CHU DEBARS SOCK THAT WHERE COVERED WITH A MOLD, AS WELL AS OTHER MOLDY DEBARS.	CONSUMER REPORTS THAT MOLD BUILDS UP CONSUMEDURARY IN THE WASHING AMCHINE. CAUSING SIGNADOSAY TO BECOME IL WITH MOLD PELATED STRAM. CONSUMER PEOPITS THAT HIS GRANDOSW WAS HOSFITALEED AS A THE LANESS.	WHEN THE BOX CONTANNES THE TOY WAS OPENED, THERE WAS STRONG SWELL SHRAPH TO MAKE STRONG SWELL SHRAPH TO MAKE SAME BOX & METEROR PACKING WITHOUTHE SAME BALOX POWIDEN SHESTINES THAT CONSUMER BEILE IN ES BUCD. THE CONSUMER SIRE IN THE SAME STATES THAT THE TOWN MAY THE CONSUMER SHAPE THE TOWN SHAPE SHOPE.	CONSTANCE REPORTES THAT AFTER RELACIVING THE ACTIVITY CALE TOF THAN THE BOX IT WAS HOTTED TO HAVE SEVERE MOLE ON THE UNDERSIDE. COMBUNER SAYS THE SIDES OF THE TO'S VERM TO MADE FROM A MATERIAL THAT IS SHOREPTER. FTO MAD IN CROWTH.
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FOR OFFICIAL USE ONLY



TO: Theresa Nelson, CRC FROM: Angie Qin, EPHA

DATE: 7/11/11

Page 279

RE: Data Review for PSA # 0792.11 Case # PI110066
Date due: 7/12/11
Priority: c
Request: Data search for all incidents involving Fisher-Price Rock N Play Sleeper mode
2.60.70 ^{(b)(5)}
Jozard Pattern: Infants can fall from Sleeper, even when buckled in. Also, concern of
nfant's developing head plagiocephaly and/or neck torticollis from sleeping in product
chech 3 product coles
Selection Criteria:
/ 1 12 12 14 1
Product Code(s): 1549 1537 1558 Manufacturer/Model Text: fisher-price/fisher price 6070 Narrative Text: (b)(5)
Narrative Text: (b)(5)
Time Frame: 6/1/09-6/15/11

Incidents Identified:

NFIRS Search Criteria: N/A

Databases	Incident Count* (see notes below)	Death Count*
Incident Investigations (INDP)	2.	0
Reported Incidents (IPII)	14	0
Death Certificates (DTHS)	0	0
NEISS reports (count)	N/A	N/A
Fire reports (NFIRS)	N/A	N/A
Total	16	0

^{*} For INDP, IPII and DTHS, duplicate reports have been removed, i.e. counted only once, in the database listed first. The reports enumerated in the table have been identified from CPSC databases on the date the search was completed. These should be considered neither a statistical sample nor a complete count of all such incidents, but only a count of those in CPSC databases on the search date.

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Search found	16 incidents	associated with	Fisher-Price	Rook 'N	Play	Sleeper	R6070.
Search follow	TO Including	associated with	I I IDIICI I IICC	Troops 1		p	

b)(5)		

SUMMARY

itemNum	item
1	Epidemiology Data Search by AQin 06JUL11
1	Search time frame of 6/1/09-6/15/11
1	
	Investigations database searched
	Previous search data cleared
	Included product codes 1549 1537 1558
	Included manufacturers and models FISHER-PRICE/FISHER PRICE/6070
	9 observations saved in data set psa0792_11Indp
	Injury and Patential Injury database searched
	Injury and Potential Injury database searched Previous search data cleared
_	Included product codes 1549 1537 1558
	Included manufacturers and models FISHER-PRICE/FISHER PRICE/6070
	834 observations saved in data set psa0792_11lpii

4	Death Certificate database searched
4	Previous search data cleared
4	Included product code(s) 1549 1537 1558
4	Included narrative text FISHER-PRICE/FISHER PRICE/6070
4	0 observations saved in data set psa0792_11Dths
•	
	INDP repulled for task numbers found elsewhere
	8 investigations added to psa0792_11Indp
-	B. P. J. A. J.
	Duplicate task numbers removed
	10 observations kept in data set psa0792_11Indp
	825 observations kept in data set psa0792_11lpii 0 observations kept in data set psa0792_11Dths
_	Death reports counted
	0 death reports in DTHS
	1 death reports in INDP
	2 death reports in IPII
8	Excel export attempted
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9 Total processing time was 0:34

Fisher-Price Rock N Play Sleepr (IPII Data) 6/1/09-6/15/11

					<u> </u>					10.00
	typecon	CONSUMER REPORTS THAT AFTER JUST 3 WEEKS OF THE BABY SLEEPER'S OVERNIGHT USE. BUT NOT DIAGNOSED UNTIL 4 MONTHS. USAUSED HER 3-WEEKS-OLD DAUGHTER TOTALION IS BEFAILED OF IT EXPONED.	TO TURN HEAD TO ONE SIDE. SHE ALSO DEVELOPED FLAT HEAD CAUSED BY ITS HARD 21 PLASTIC BACKING.	THE CONSUMER STATED ONE OF THE BUCKI ON THE PAD OF THE BABY BASSINET BROKE 10 OFF.	CONSUMER REPORTED THAT SHE FEELS TH' NEWBORN ROCKER SLEEPER CONTRIBUTED SIGNIFICANTLY TO HER SON'S PLAGIOCEPHALY OVER HEAD). SHE USED THE ROCKER FOR OVER NIGHT SLEEPING AS ADVERTISED ON THE PACKAGING. HERSON IS NOW IN PHYSICAL THERAPY 3 TIMES A WEEK & HAS A CORRECTIVE 10 HELM	CONSUMER'S SON HAS DEVELOPED FLATTENING ON THE BACK OF HIS HEAD FROM SING THE SLEEPER. HE ALSO HAS FROM SING THE MUSCLES IN HIS NECKAND FAVORS ONE SIDE WHEN SLEEPING. HE USED THE PRODUCT 12 HOURS PERDAY FOR 4 MONTHS. DOCTOR RECOMMENDED PHYSICAL 10 THERAPY AND HELMET.	THE RETAILER'S REPORT STATED THAT WHEN THE CONSUMER REMOVED THE ROCKING SLEPPER'S PAD FOR LAUNDERING SHE NOTIC SALEPPER'S PAD FOR LAUNDERING SHE NOTIC MACLD AROUND THE HEAD ANDLEG AREA. THE MOLD WAS YELLOW IN COLOR. CONCERN WAS EXPRESSED THAT THE MOLD MAY BE THE CAUSE OF A COUGH THAT THE BABY HAS TO DEVELOPED.	THE CONSUMER EXPRESSED CONCERN THAT THE MATERIAL ON THE SEAT OF THE ROCKING ALEEPER HAS DEVELOPED MOLD NEAR THE PRESTIC SUPPORT.	THE CONSUMER IS CONCERNED BECAUSE THE LINES ON THE ROCKING SLEEPER 194RE WOLDY.	THE CONSUMER EXPRESSED CONCERN THAT THE ROCKING SLEEPER'S FABRIC SEAT IS TO WOLD'S. THE BABY IS 6 WEEKS OLD.
	Semanbom	9	NEWBORN ROCK IN PLAY SLEEPER, MODEL NO. R6070 /UPC 027084834	M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER	M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER	M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER	M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER	M# R6070 / NEWBORN ROCK 'N PLATE	M# R6070 / NEWBORN ROCK 'N PLAN	M# R6070 / NEWBORN ROCK 'N PLAY
	£9M8H11M		FISHER PRICE / FISHER-PRICE BRANDS	MATTEL / FISHER-PRICE	MATTEL / FISHER-PRICE	MATTEL / FISHER-PRICE	MATTEL / FISHER-PRICE / MATTEL / FISHER-PRICE	MATTEL / FISHER-PRICE / MATTEL / FISHER-PRICE	MATTEL / FISHER-PRICE / MATTEL / FISHER-PRICE	MATTEL / FISHER-PRICE / MATTEL / FISHER-PRICE
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Fisher-Price Rock N Play Sleepr (IPII Data) 6/1/09-6/15/11

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Fisher-Price Rock N Play Sleepr (INDP Data) 6/1/09-6/15/11

evitanan	A FEMALE CONSUMER PUT HER FOUR MONTH OLD SON IN AN INFANT SEAT DESIGNED FOR NIGHTIME IN AN INFANT SEAT DESIGNED FOR HIM IN THE SEAT WITH THE THREE-POINT WAIST RESTRAINT. WHILE SHE WAS OUT OF THE BEDROOM, THE INFANT GOT OUT OF THE RESTRAINT AND FELL FROM THE SEAT. THE INFANT SUFFERED A CONTUSION AND SCRATCH TO HIS HEAD. THE INJURIES HAVE HEALED. A FOUR MONTH OLD MALE WAS DIAGNOSED A CONTUSION AND SCRATCH OF THE INJURIES HAVE HEALED. A FOUR MONTH OLD MALE WAS DIAGNOSED A CONTUSION AND SCRATCH OF THE INJURIES THREE MONTHS.	204 OF PLAYPEN/SLEEPEH USE.
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Fisher-Price Rock N Play Sleepr (INDP Data) 6/1/09-6/15/11

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١.		A FEMALE CONSUMER PUT HER FOUR MONTH OLD SON IN AN INFANT SEAT DESIGNED FOR NIGHTTIME AND DAYTIME USE. SHE BUCKLED HIM IN THE SEAT WITH THE THREE-POINT WAIST RESTRAINT. WHILE SHE WAS OUT OF THE BEDROOM, THE INFANT GOT OUT OF THE RESTRAINT AND FELL FROM THE SEAT. THE INFANT SUFFERED A CONTUSION AND SCRATCH, TO HIS HEAD. THE INJURIES HAVE HEALED.	A FOUR MONTH OLD MALE WAS DIAGNOSED WITH PLAGIOCEPHALY AFTER THREE MONTHS OF PLAYPEN/SLEEPER USE.
		A FEMALE CONSUMER PUT HER FOUR MONTH OLD SON IN AN INFANT SEAT DESIGNED FOR NIGHTTIME AND DAYTIME USE. SHE BUCKLED HIM IN THE SEAT WITH THE THREE-POINT WA!! RESTRAINT. WHILE SHE WAS OUT OF THE BEDROOM, THE INFANT GOT OUT OF THE RESTRAINT AND FELL FROM THE SEAT. THE INFANT SUFFERED A CONTUSION AND SCRATO HIS HEAD. THE INJURIES HAVE HEALED.	S Q
l	l	A FEMALE CONSUMER PUT HER FOUR MOY OLD SON IN AN INFANT SEAT DESIGNED FOUGHTTIME AND DAYTIME USE, SHE BUCK HIM IN THE SEAT WITH THE THREE-POINT RESTRAINT, WHILE SHE WAS OUT OF THE BEDROOM, THE INFANT GOT OUT OF THE RESTRAINT AND FELL FROM THE SEAT. TO HIS HEAD, THE INJURIES HAVE HEALET	N H
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Page 2

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ock N Play Slee 6/1/09-6/15/11		101221CNE0795	110426CNE9000
Fisher-Price Rock N Play Sleepr (INDP Data) 6/1/09-6/15/11	<u> </u>		<u></u>

(ii)

Nelson, Theresa

From:

Wanna-Nakamura, Suad

Sent:

Page 286

Tuesday, November 08, 2011 11:43 AM

To: Cc: Nelson, Theresa

Subject:

Moore, Kelly RE: Favor RE: FP Rock N Play Sleeper incident - FW: IDI Number: 110906CCC1997

(b)(5)

Suad Wanna-Nakamura, PhD
Physiologist
U.S Consumer Product Safety Commission
4330 East West Highway
Suite 600-E
Bethesda MD 20814-4421
Tel 301 504 7252
Mobile (b)(6)
Fax 301 504 0079
mailto:snakamura@cpsc.gov

----Original Message----

From: Nelson, Theresa

Sent: Tuesday, October 18, 2011 8:20 AM

To: Wanna-Nakamura, Suad

Subject: FW: Favor RE: FP Rock N Play Sleeper incident - FW: IDI Number: 110906CCC1997

(b)(5)

Thanks, Terri

----Original Message----

From: Nelson, Theresa

Sent: Tuesday, October 04, 2011 9:34 AM

To: Wanna-Nakamura, Suad

Cc: Moore, Kelly

Subject: RE: Favor RE: FP Rock N Play Sleeper incident - FW: IDI Number: 110906CCC1997

Thanks Suad, I'll look forward to your response on this IDI. This is the one with 51 pages that cannot be emailed due to the size. Do you want me to scan it today and send it to you?

Terri

----Original Message-----From: Wanna-Nakamura, Suad

Sent: Tuesday, October 04, 2011 9:28 AM

To: Nelson, Theresa

Subject: RE: Favor RE: FP Rock N Play Sleeper incident - FW: IDI Number: 110906CCC1997

(b)(6)and respond to you sometime today.. yesterday was a very busy day here with play yards crios bassinets etc Suad Suad Wanna-Nakamura, PhD **Physiologist** U.S Consumer Product Safety Commission 4330 East West Highway Suite 600-E Bethesda MD 20814-4421 Tel 301 504 7252 Mobile 301 768 2915 Fax 301 504 0079 mailto:snakamura@cpsc.gov ----Original Message-----From: Nelson, Theresa Sent: Tuesday, September 27, 2011 5:18 PM To: Wanna-Nakamura, Suad Subject: FW: Favor RE: FP Rock N Play Sleeper incident - FW: IDI Number: 110906CCC1997 Suad Can you let me know if you're in this week? I need your review of the IDI linked below based on your PSA on this product. Terri ----Original Message----From: Nelson, Theresa Sent: Tuesday, September 20, 2011 1:36 PM To: Wanna-Nakamura, Suad Subject: FW: Favor RE: FP Rock N Play Sleeper incident - FW: IDI Number: 110906CCC1997 Suad - When I try to send it via pdf, I get the message "over size limit" (it's 50 pages with lots of pictures) and it won't attach. Could you wait and view it_via the link below when you get back in the office? I could scan it and send it to you, but [b)(6) Terri ----Original Message-----From: Wanna-Nakamura, Suad Sent: Tuesday, September 20, 2011 1:15 PM To: Nelson, Theresa Subject: Favor RE: FP Rock N Play Sleeper incident - FW: IDI Number: 110906CCC1997 Terri, I do not have access to CPSC net yet when I am off site ... I only get email could you please send me the pdf version... (b)(6) ____thanks a lot Suad Suad Wanna-Nakamura, PhD U.S Consumer Product Safety Commission 4330 East West Highway Suite 600-E Bethesda MD

age 288

20814-4421 Tel 301 504 7252 Fax 301 504 0079 mailto:snakamura@cpsc.gov

From: Nelson, Theresa

Sent: Tuesday, September 20, 2011 11:23 AM

To: Wanna-Nakamura, Suad

Cc: Moore, Kelly

Subject: FW: FP Rock N Play Sleeper incident - FW: IDI Number: 110906CCC1997

(b)(5)

Terri

----Original Message-----

From: cca,

Sent: Friday, September 16, 2011 3:32 PM

To: Nelson, Theresa

Subject: IDI Number: 110906CCC1997

IDI is from investigator ID: 2118 - Shawn M. Cerruti

A two week old male victim began sleeping overnight inside a portable rocking sleeper. After several months his mother noticed that his head was becoming flat on the back and right side. A specialist diagnosed him with severe brachycephaly and plagiophaly (flattening of the head). He wore a medical helmet for 23 hours a day for three months and his head has resumed its normal shape.

If you wish to view the entire IDI click on the link below.



DRAFT - FOR OFFICIAL USE ONLY - DRAFT

PSA No. 0933.11 **FOER** CONSUMER PRODUCT SAFETY COMMISSION PRODUCT SAFETY ASSESSMENT CASE No: PI110066 **TECHNICAL EVALUATION** REQUESTER: Theresa Nelson **DIVISION FOR HEALTH SCIENCES** SAMPLE No: DRAFT - FOR OFFICIAL USE ONLY - DRAFT CPSC SEAL: IDI No: 01221CNE0795, 110426CNE9000, 110524CCC2557 FIRM: Fisher-Price, Inc. PRODUCTS: Fisher-Price Rock 'N Play Sleeper REQUEST: Concern of infant's developing head plagiocephaly and/or neck torticollis from sleeping in product. Infants can fall from Sleeper, even when buckled in. POTENTIAL HAZARD: Plagiocephaly and/or neck torticollis INCIDENTS: The CPSC staff is aware of three incidents. PREPARED BY: Suad Wanna-Nakamura, PhD, Physiologist, 301 504 7252 DATE:9/12/2011

Health Sciences Staff (HS) Assessment:

The subject product Fisher-Price Rock 'N Play Sleeper (Figure. 1) is advertised as a child seat and a rocking cradle. The firm suggests consumers use the product from birth until the child is able to pull-up or sit unassisted. The manufacturer's suggested weight limit is twenty-five pounds. The Consumer Product Safety Commission's (CPSC) staff is aware of 3 consumer incidents associated with the product; one incident involved the fall of a 4.5 month old child from the product (101221CNE0795) and two concerned children diagnosed with plagiocephaly and torticollis (110426CNE9000 and 110524CCC2557). The incidents occurred between the period of July 2010 and December 2010. The infants' age ranged from 4.5 to 6 months.



Figure 1. Fisher-Price Rock 'N Play Sleeper.

Plagiocephaly and Muscular Torticollis: Positional or deformational plagiocephaly (DP), commonly known as flat head, is a condition that may be present at birth due to mechanical constraint of fetal head in the womb, especially in multiple birth infants¹. It may also develop after birth in the first few months of life². The incidence of DP has increased since 1992 and it has been suggested that it is associated with the introduction of the "Back to Sleep" campaign³⁻⁵, which recommends that infants be placed in the supine position for sleeping because of evidence that this reduces the risk for SIDS. Although the flattened appearance of an infant's head

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DRAFT - FOR OFFICIAL USE ONLY - DRAFT

can be worrying to parents there is no current scientific evidence to show that plagiocephaly interferes with brain development or function. This condition appears to improve with time and it is often reversible; the only lasting effect may be the physical shape/deformity of the head⁶. Muscular torticollis (turtle neck) is a known risk factor sometimes associated with plagiocephaly and is caused by constraint of head neck movement or congenital defect⁷⁻⁸.

Despite the increase in the number of children with plagiocephaly and the risk of physical deformity associated with this condition, the American Academy of Pediatrics has not reversed its recommendations to place infants to sleep on their backs, mostly because the condition can be reversed and has no lasting health effects on children.

However, to help prevent the development of flat head the AAP presently recommends a certain amount of prone positioning, or "tummy time," during the day while the infant is awake and under supervision. Alternating the orientation of supine head position from right to left is another effective measure; i.e., sleeping with head turned to the right side one night and changing to the left side position on a consecutive night.

Falls: The injury potential of any fall is dependent on several factors including height of the fall, nature of the impact surface, and orientation of the body at impact. The orientation of the body at impact is one of the most important factors in determining the type and severity of injury. Injuries could range from minor abrasions, lacerations and contusions, to more severe injuries such as bone fractures, concussions, spine and/or skull fractures, possibly resulting in death. HS staff notes that the likelihood of severe head injury is possible should a child fall head first onto a hard floor surface.

b)(5)	HS Conclusion: (b)(5)	
	(b)(5)	
0)(5)	(b)(5)	

References:

- 1. Littlefield TR, Kelly KM, Pomatto JK, Beals SP. Multiple-birth infants at higher risk for development of deformational plagiocephaly. Pediatrics 1999; 103:565-569
- 2. Argenta LC, David LR, Wilson JA, Bell WO. An increase in infant cranial deformity with supine sleeping position. Journal of Craniofacial Surgery 1996; 7:5–11
- 3. Turk AE, McCarthy JG, Thorne CH, Wisoff JH. The 'back to sleep campaign' and deformational plagiocephaly: is there cause for concern? Journal of Craniofacial Surgery 1996; 7:12–18

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- 4. Christy M. McKinney, Cunningham ML, Holt VL, Leroux B, Starr JR. A case-control study of infant, maternal and perinatal characteristics associated with deformational plagiocephaly. Article first published online: 21 APR 2009
 http://www.familyop.com/Library/Cranial%20Research%20Articles/Characteristics%20of%202733%20cases%20of%20DP%20and%20changes%20in%20risk%20factors...pdf
- 5. Peitsch WK, Keefer CH, LaBrie RA, Mulliken JB. Incidence of cranial asymmetry in healthy newborns. Pediatrics 2002; 110:e72
- 6. Pollack IF, Losken WH, Fasick P. Diagnosis and Management of Posterior Plagiocephaly. February 1, 1997 Pediatrics Vol. 99 No. 2 pp. 180-185
- 7. Dunn PM. Congenital postural deformities. British Medical Bulletin 1976; 32:71-76
- 8. Öhman A, Mårdbrink EL, Stensby J, Beckung E. Evaluation of treatment strategies for muscle function in infants with congenital muscular torticollis. October 2011; **27**(7): 463-470
- Persing J, James H, Swanson J, Kattwinkel J. Prevention and management of positional skull deformities in infants. American Academy of Pediatrics Committee on Practice and Ambulatory Medicine, Section on Plastic Surgery and Section on Neurological Surgery. Pediatrics 2003; 112:199– 202

		**** ****	****FOR OFFICIAL USE	USE ONLY***				PSA ACTION (FOR PSA COORDINATOR USE ONLY)	OR PSA R USE ONLY)
PRODU	JCT SAI	PRODUCT SAFETY ASSESSMENT (PSA) 7		HNICAL]	TECHNICAL EVALUATION REQUEST	N REOU	TEST	PSA Number	: 0933.1.1
					:			Date Processed	: 8/11/11
Requested by	Theresa Ne	Theresa Nelson, (301) 504-7509		Org. Code	de :CRC	Field Off	FOER:	Date Requested	9/7/11
Date Submitted	: 8/10/2011			Priority	ɔ :	Case #	:PI110066	Due Date:	
Requested Completion Date	tion Date	: 9/07/2011							
PRODUCT INFORMATION:	RMATION	i,						Assigned to	
Manufacturer	:Fisher-Price, Inc.	rice, Inc.			City :East Aurora	ora	State :NY	Organization:	: HS
Product :F	Fisher-Price	Fisher-Price Rock 'N Play Sleeper			NEISS Code	:1549		Technical Off.	
Brand name, model, etc.	ıl, etc.	: Fisher-Price, R6070						Request Summary:	y:
Sample number	: 11-810	: 11-810-6684 (ask CO prior to requesting sample)	sting sample)						
Sample Disposition:	•	X_Return to Requester	Store at Warehouse	nse	_Other :				
IDI Number	: 1012210	: 101221CNE0795, 110426CNE9000, 110524CCC25	110524CCC2557 &	Amazon produ-	57 & Amazon product reviews (see Compliance Officer)	pliance Office	er)		
EVALUATION REQUESTED: HS-Reproduct and determine likelihood of injung Product Safety Assessment Report form.	KEQUESTE nine likeliho sessment Rej	EVALUATION REQUESTED: HS- Review incident reports, IDI's, product reviews and product sample. Conduct a HS evaluation on product and determine likelihood of injury and severity of injury. Discuss your safety concerns. Please provide a written report using the Product Safety Assessment Report form.	orts, IDI's, product rinjury. Discuss you	eviews and prod r safety concerns	fuct sample. Conducs. Please provide a v	t a HS evalua vritten report	tion on using the	Comments:	
EPI ASSESSMENT: Dates:	T: Dates:	From :	To :	Sort by Mfg.:	Yes	No			
IDI	_IPI	NEISS Comments	_NEISS Estimates	es	_Death	_NFIRS			
HAZARD : fr	Concern of rom sleeping	: Concern of infant's developing head plagiocephaly and/or neck torticollis from sleeping in product. Infants can fall from Sleeper, even when buckled in.	giocephaly and/or ne from Sleeper, even w	ck torticollis vhen buckled in.	HAZARD CODE	: 203			
LOCATIONS OF		Samples: Rm. 613-28		Files: 613-28				(MSWordRe	(MSWordRev 2/99 rp/jb/bh)

	# 10 m		M# R6070 / NEWBORN ROCK 'N	MATTEL/ MATTEL/ MATTEL/	Ass as assess)	8		e e
4	Y1165859A mold	THE CONSUMER EXPRESSED CONCERN THAT THE ROCKING SLEEPER'S FABRIC SEAT IS MOLDY. THE BABY IS 6 WEEKS OLD.	M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER	MATTEL/ FISHER- PRICE/ MATTEL/ FISHER- PRICE	1537	8	41/2011	6/22/2011	201	N	2		Y1165859A
0	Y1165662A mold	THE CONSUMER EXPRESSED CONCERN BECAUSE THERE IS MOLD ON THE ROCKING SLEEPER'S LINER NEAR THE SUPPORT.	M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER	MATTEL / FISHER- PRICE / MATTEL / FISHER- PRICE	1597	2	1/1/2011	6/22/2011	0	- 2	F		Y1165662A
<u> </u>	Y1185742A mold	THE CONSUMER EXPRESSED CONCERN THAT MOLD HAS FORMED ON THE PAD AND LINER OF THE PRODUCT.	M# R6070 / NEWBORN ROCK N PLAY SLEEPER	MATTEL / FISHER- PRICE	1537	o	7/14/2011	12/9/2011	o c		₽		Y1185742A
ď.	Y11B5741A mod	THE CONSUMER EXPRESSED CONCERN THAT THERE IS MOUD ON THE SEAT PAD AND LINER.	N# R6070 / NEWBORN ROCK 'N PLAY SLEEPER	MATTEL / FISHER- PRICE	1537	0	9/3/2011	12/9/2011	0		2		<u>Y1185741A</u>
ž	Y11B5737A, mold	THE CONSUMER IS CONCERNED BECAUSE THERE IS MOLD ON THE LINER OF THE PRODUCT.	N# R8070 / NEWBORN ROCK 'N PLAY SLEEPER	MATTEL / FISHER- PRICE	1537	0	11/1/2011	12/9/2011	o o	.	Ÿ .		Y1185737A
¥	Y11B5743A mold	THE CONSUMER EXPRESSED CONCERN THAT MOLD HAS DEVELOPED BETWEEN THE LINER AND THE FABRIC PAD.	M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER	MATTEL / FISHER- PRICE	1537	o	6/30/2011	12/9/2011	0	9	7	95	Y1185743A
mold	Y11B5745A m	I CONSUMER EXPRESSED CONCERN THAT THE SLEEPER DEVELOPED BLACK IN MILDEW &MOLD SPOTS BETWEEN THE PAD & LINER. THIS HAPPENED BECAUSE SHE ALLOWED HER 4 MONTH-OLD SON TO SLEEP DIAPER-FREE FOR SEVERAL DAYS IN PRODUCT, USING ONLY A RECEIVING BLANKET TO ABSORB ANY URINE.	M# 96070 / NEWBORN ROCK 'N PLAY SLEEPER	MATTEL / FISHER- PRICE	1537	*	6/16/2011	12/9/2011	204	In ·	S		Y1185745A
mo l d.	Y1165660A m	THE CONSUMER EXPRESSED CONCERN THAT SHE FOUND BLACK MOLD N BETWEEN THEPAD AND THE SEAT ON THE ROCKING SLEEPER, THE CONSUMER ALSO STATED THAT HER CHILD HAS HAD RESPRITORY PROBLEMS FOR TWO MONTHS AND SHE IS NOW ATTRIBUTING THIS TO THE SLEEPER.	M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER	MATTEL/ FISHER- PRICE/ MATTEL/ FISHER- PRICE	1537	0	4/23/2011	6/22/2011	9	1	\$		Y1165660A
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Clear	inghouse Format - With	Manufacturer	(b)(5)	
9	Reported Incident			b)(5)
U.S. 0	Consumer Product Safety		11/2/2012	5/(5/
	onal Injury Information Cl		Page 1	77.75
cument Number : H1220229A	Task Number :		Issue: 0	(b)(5)
Date Received : 02/17/2012	Confirmed :		Date Entered : 02/22/201	,
City:	State :	Zip:	Date Notified :	F
Source : 0	Type Of Contact : 21	979		
Prod : 1537	BASSINETS OR CRADLES	OOMOOMEN OOM	ii Criiiv. C	
Prod: 0	NO SECOND PRODUCT INVO	DLVEMENT		
Date Injured : 02/15/2012	D Work Related	: N		
Age: 0	Sex			
Disposition : 0 0=NO INJ	IURY Haz	Type: F OTHER	1	
Brand : FISHER-PRI		eened?:		
Model : ROCK 'N PL	AY SLEEPER / R6070			
larrative :				
CONSUMER STATED THAT CHILD	REN WHO USE THE BASSINE	T DEVELOP TORTIO	COLLI	
, WHICH IS A FLATTENING OF T				Ĩ.
VEAR A HELMET TO SUPPORT T	HE AFFECTED AREA. HER CH	ILD HAS NOT DEVE	ELOP	
D THIS CONDITION BUT FEARS	IT CAN HAPPEN.PRODUCT HA	AS HARD SURFACE	i.	
cument Number: 11280549A	Task Number :		Issue: 0	
Date Received: 08/26/2012	Confirmed :	(h) (6	Date Entered: 08/28/201	2
City: SACRAMEN	TO State: CA	Zip :	Date Notified :	
Source: 0	Type Of Contact: 21	CONSUMER CON	MPLAINTS	
Prod : 1537	BASSINETS OR CRADLES			
Prod: 0	NO SECOND PRODUCT INVO	DLVEMENT		
Date Injured: 08/20/2012	M Work Related	: N		
Age: 203	Sex			
Disposition: 1 1=TREAT	ED & RELEASED, OR EX/Haz	Type: F OTHER	ľ	21
Brand : FISHER PRI	CE / MATTEL, INC. Scre	eened?:		
Model:				
Narrative :				
CONSUMER NOTICED THAT 3 YO				
ONSUMER ATTRIBUTING THIS TO VAS BORN. DOCTOR IS TREATI	열대 경기 경기 그리고		MARTINE .	
PEIT.	NO FLAT HEAD WITH FILLOWS	S INTING TO BESE	' A	
	Tarthernous			
cument Number : 11290178A	Task Number : 120 Confirmed :	913CCC2975	Issue: 0 Date Entered: 09/11/201.	0
Date Received : 09/09/2012 City : (0)(6)	State : AL	Zip : (b) (6	Date Entered: 09/11/201	4
Source: 0	Type Of Contact : 21	CONSUMER CON		
Prod : 1537	BASSINETS OR CRADLES	CONSCIVILA COM	III LAINTO	
Prod : 0	NO SECOND PRODUCT INVO	NVEMENT		
THE STATE OF STATE SHOWS AND ADDRESS OF STATE OF				
Date Injured: 09/08/2012	D Work Related	· IN		

Age: 205

Sex: 2 FEMALE

Disposition: 1 1=TREATED & RELEASED, OR EX/Haz Type: F OTHER

Brand: FISHER PRICE / FISHER-PRICE BRANScreened?:

Model: R6070

Narrative:

5 MOF HAD FALLEN OUT OF SLEEPER BUT HAD HER LEG TANGLED IN THE SAFETY RESTRAINT. THE RESTRAINT HAD CUT OFF THE CIRCULATION TO HER LEFT LEG FROM HER KNEE DOWN. SHE WAS HANGING UPSIDE DOWN & HER HEAD WAS BAREL Y TOUCHING THE GROUND. SHE HAD A BURN MARK ON HER LEG.

U.S. Consumer Product Safety Commission **National Injury Information Clearinghouse**

11/2/2012

Page 2

Document Number: I1290333A Task Number: Issue: 0

Date Received: 09/15/2012

Confirmed:

Date Entered: 09/18/2012

City: (b)(6)

State: SC

Date Notified:

Source: 0

Type Of Contact: 21 CONSUMER COMPLAINTS

Prod: 1537

BASSINETS OR CRADLES

Prod: 1807

FLOORS OR FLOORING MATERIALS

Date Injured: 09/15/2012

Work Related: N

Age: 206

Sex: 1 MALE

Disposition: 0 0=NO INJURY

Haz Type: 9 FALLS

Model: 3040SPR

Brand: SIMPLICITY (BY GRACO) / SIMPLICIT' Screened?:

Narrative:

CONSUMER SAYS THE BAR ON THE BASSINET THAT COLLAPSES TO CONVERT IT TO A CO-SLEEPER DOESN'T SEEM LONG ENOUGH TO BE SECURE WHEN USED AS A RE GULAR BASSINET, SHE SAYS SHE HEARD HER 6-MONTH-OLD SON CRYING AND FOU ND THE BAR WAS HANGING DOWN AND THE BABY WAS ON THE FLOOR.

Document Number: Y1225729A

Task Number:

Issue: 0

Date Received: 02/15/2012

Source: 6

Confirmed:

Date Entered: 02/24/2012

City: (b)(6)

State : MI

Date Notified: Type Of Contact: 10 OFFICE OF COMPLIANCE

Prod: 1537

BASSINETS OR CRADLES

Prod: 0

NO SECOND PRODUCT INVOLVEMENT

Date Injured: 09/01/2011

Work Related: N

Age: 202

Sex: 1 MALE

Brand: MATTEL/FISHER-PRICE

Disposition: 1 1=TREATED & RELEASED, OR EX/Haz Type: F OTHER Screened?:

Model: M# V9197 / RNP SLEEPER-CIRCLES

Narrative:

THE CONSUMER STATED HER SON HAS BEEN DIAGNOSED WITH PLAGIOCEPHALY SIN CE USE IN THIS SLEEPER. IT WAS FIRST NOTICED WHEN HE WAS TWO MONTHS OLD. THE CHILD HAS SEEN A REHABILITATION SPECIALIST, WHO PRESCRIBED A HELMET TO CORRECT THE ISSUE.

Document Number: Y1225926A

Task Number:

Issue: 0

Date Received: 02/23/2012

Confirmed:

Date Entered: 03/03/2012

City: (b)(6)

State: LA

Date Notified:

Source: 6

Type Of Contact: 10 OFFICE OF COMPLIANCE

Prod: 1537

BASSINETS OR CRADLES

Prod: 0

NO SECOND PRODUCT INVOLVEMENT

Date Injured: 12/01/2011

Work Related: N

Age: 204

Sex: 2 FEMALE

Brand: MATTEL/FISHER-PRICE

Disposition: 1 1=TREATED & RELEASED, OR EX/Haz Type: F OTHER

Model: M# V9102 / ROCK 'N PLAY SLEEPER

Screened?:

Narrative :

THE CONSUMER STATED THAT THE BACK OF HER DAUGHTER'S HEAD HAS FLATTENE DISINCE USE OF THIS PRODUCT. SHE HAS SEEN HER PEDIATRICIAN REGARDING. THE ISSUE. SHE HAS A PRESCRIPTION TO TAKE HER FOR X-RAYS AND SCANS FOR POSSIBLE HELMET USAGE IF NEEDED.

age 297

Clearinghouse Format - With Manufacturer Reported Incidents

U.S. Consumer Product Safety Commission National Injury Information Clearinghouse

11/2/2012

Page 3

Document Number: Y1225927A Task Number: Issue: 0

Date Received: 02/23/2012 Confirmed: Date Entered: 03/03/2012

City: (D)(6) Date Notified:

Source: 6 Type Of Contact: 10 OFFICE OF COMPLIANCE
Prod: 1537 BASSINETS OR CRADLES

Prod: 0 NO SECOND PRODUCT INVOLVEMENT

Date Injured: 07/01/2011 D Work Related: N

Age: 203 Sex: 2 FEMALE

Disposition: 1 1=TREATED & RELEASED, OR EX/Haz Type: F OTHER

Brand : MATTEL / FISHER-PRICE Screened? :

Model: M# V9102 / ROCK 'N PLAY SLEEPER

Narrative:

THE CONSUMER STATED THAT HER DAUGHTER DEVELOPED A FLAT SPOT ON HER HE AD WHILE USING THE SLEEPER. SHE USED THE SLEEPER 2-3 HOURS PER DAY D URING THE WEEK AND MORE DURING THE WEEKENDS. THE CHILD WAS TAKEN TO THE PEDIATRICIAN.

Document Number: Y1225928A Task Number: Issue: 0

Date Received: 02/23/2012 Confirmed: Date Entered: 03/03/2012

City: State: LA Zip: Date Notified:

Source: 6 Type Of Contact: 10 OFFICE OF COMPLIANCE

Prod: 1537 BASSINETS OR CRADLES

Prod: 0 NO SECOND PRODUCT INVOLVEMENT

Date Injured: 12/07/2010 D Work Related: N

Age: 202 Sex: 1 MALE

Disposition: 1 1=TREATED & RELEASED, OR EX/Haz Type: F OTHER

Brand: MATTEL/FISHER-PRICE Screened?:

Model: M# V9102 / ROCK 'N PLAY SLEEPER

Narrative:

THE CONSUMER STATED THAT HE HAS USED THE SLEEPER FOR HIS CHILD TO SLE EP IN. THIS HAS RESULTED IN HIS SON RECEIVING A FLAT SPOT ON THE LEF T SIDE OF THE BACK OF HIS HEAD. HE WAS TAKEN TO THE DOCTOR & TOLD TO USE A CRIB.

Document Number: Y1235488A Task Number: Issue: 0

Date Received: 03/01/2012 Confirmed: Date Entered: 03/06/2012

City: (b)(6) State: AR Zip: Date Notified:

State . An Zip . Date Notified .

Source: 6 Type Of Contact: 10 OFFICE OF COMPLIANCE

Prod: 1537 BASSINETS OR CRADLES

Prod: 0 NO SECOND PRODUCT INVOLVEMENT

Date Injured: 08/01/2011 D Work Related: N

Age: 202 Sex: 1 MALE

Disposition: 1 1=TREATED & RELEASED, OR EX/Haz Type: F OTHER

Brand: MATTEL/MATTEL/FISHER-PRICE Screened?:

Model: M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER

Narrative:

THE CONSUMER STATED THAT THE BACK OF HER SON'S HEAD HAS BECOME FLATTE NED SINCE THE USE OF THE PRODUCT. THE CHILD HAS SEEN THE PEDIATRICIA N AND A NEUROLOGIST, AND HAD X-RAYS. SHE OWNS TWO OF THE SAME PRODUCT S WITH THE SAME ISSUE WITH HER TWIN BOYS.

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Y11B5738A	Y1215512A IDI not yet completed 120109CCC1407	Y1165958A	Y11B5740A	Y1165657A	Y1186746A	Y1185856A	111123HCC1188	Y1165654A	Y1185665A
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9/15/2011	12/25/2011	5/1/2011	10/13/2011	5/31/2011	5/1/2011	5/31/2011	9/18/2011	10/11/2010	9/15/2010
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MATTEL / FISHER- 1537 PRICE	FISHER- PRICE	MATTEL/ FISHER- PRICE/ MATTEL/ FISHER- PRICE	MATTEL/ FISHER- PRICE	MATTEL/ FISHER- PRICE/ MATTEL/ FISHER- PRICE	MATTEL/ FISHER- PRICE	MATTEL/ FISHER- PRICE/ MATTEL/ FISHER- PRICE	PRICE P	MATTEL/ FISHER- PRICE/ MATTEL/ FISHER- PRICE	PRICE / MATTEL / FISHER- PRICE
R6070	M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER	M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER	M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER	M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER	M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER	M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER	FISHER- PRICE POCK N PLAY V9197	M# R8070 / NEWBORN ROCK 'N PLAY SLEEPER	HOCK 'N PLAY SLEEPER
CONSUMER REPORTED MOLD BEGAN TO APPEAR ON THE SEAT AND THE STRAPS. CONSUMER EXPRESSED CONCERN BECAUSE SHE CANNOT REMOVE THE SEAT FOR LAUNDERING. THE CONSUMER OWNS TWO NEWBORN ROCK N PLAY SLEEPERS AND IS REPORTING THIS DAME ISSUE WITH EACH ONE.	WIFE NOTICED HIVES ON BACK OF 5MOM'S LEGS. SHE CHANGED HIS DAIPER IS A HE WAS TAKEN TO EMERGENCY ROOM WHERE HE WAS GIVEN MEDICATION. WHEN THEY ARRIVED HOME THEY NOTICED MOLE ON SEAT. THEY TOOK HIM TO PEDIATRICIAL FOLLOWING DAY FOR FOLLOW UP EXAM. High undergoing testing for allergies. Firm collected sample steeper with mold growth.	THE CONSUMER IS CONCERNED BECAUSE THE PAD AND THE LINER ON THE ROCKING SLEEPER ARE MOLDY.	THE CONSUMER EXPRESSED CONCERN THAT HER SLEEPER HAS DEVELOPED MOLD ON THE SEAT.	THE CONSUMER EXPRESSED CONCERN THAT THE MATERIAL ON THE SEAT OF THE ROCKING SLEEPER HAS DEVELOPED MOLD NEAR THE PLASTIC SUPPORT.	THE CONSUMER EXPRESSED CONCERN THAT THERE IS MOLD ON THE LINER.	THE RETAILER'S REPORT STATED THAT WHEN THE CONSUMER REMOVED THE ROCKING SLEEPER'S PAD FOR LAUNDERING SHE NOTICED MOLD AROUND THE HEAD ANDLEG AREA. THE MOLD WAS YELLOW IN COLOR. CONCERN WAS EXPRESSED THAT THE MOLD MAY BE THE CAUSE OF A COUGH THAT THE BABY HAS DEVELOPED.	A CONSUMER REPORTED THAT MOLD BEGAN TO GROW ON THE FABRIC OF TWO IDENTICAL BASSINETS AFTER THEY HAD BEEN USED FOR SEVERAL MONTHS. THE CONSUMER'S SIX MONTH OLD SON DOES NOT SHOW ANY SIGNS OF ILLNESS AS A RESULT OF BEING EXPOSED TO THE NOLD.	CONSUMER NOTICED BLACK MOLD UNDER THE SEAT PAD AND IN THE SEAT LINING WHEN SHE WENT TO REMOVE THE PAD TO WASH IT FOR THE FIRST TIME. CONSUMER STATED HER 2 MONTH OLD DAUGHTER HAS HAD RESPIRATORY ISSUES SINCESHE WAS 10 DAYS OLD, AND SHE BELIEVES IT IS RELATED TO THE MOLD.	THE CONSUMER EXPRESSED CONCERN THAT THE ROCKING SLEEPER'S PAD AND SEAT ARE MOLDY.
Y1185738A mold		Y1165858A	Y11B5740A	Y1165657A	Y11B5746A	Y1165656A		Y1165064A	Y1165665A
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M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER	M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER	M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER	M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER	M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER	M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER	M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER	M# R6070 / NEWBORN ROCK'N PLAY SLEEPER	M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER	70 Y XX H EE
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THE CONSUN BACK OF HEF USE OF THE O	VORTI NOREE NORTHS	THE CONSUN TOO HARD. A BACK OF HIS OVER NIGHT.	EPS AC S	NG TH	sume proc	sume	NEW-BORN FEMAL WEEKS CONSUMER & HER NECK SEEM WAS BIG. AT 16WE HYDROCEPHALUS.	SSINE	EMAL SIGNE BED E SEA
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THE CONSUMER STATE BACK OF HER HEAD. H USE OF THE SLEEPER. DIMINISHING.	REPORTED VIA EMAIL: HEADRESTIS TOO HAR MONTHS OLD DAUGHT DAUGHTER HAS A SLIC	THE CONSUMER STATE TOO HARD. AS A RESU BACK OF HIS HEAD. TH	THE CONSUMER STATED THAT HIS DAUGHT THE BACK OF HER HEAD FROM SLEEPING IN SLEEPS ANYWHERE FROM 2-6 HOURS IN IT.	THE FOLLOWING REPORT WAS RECEIVED STATED THAT HER BABY HAS DEVELOPED USING THE BABYHAMMOCK TO SLEEP IN.	Consumer stated that while in the product, as a result.	Consumer reported chair	EEMALE 6WEI	THE CONSUMER STATI	A FEMALE CONSUMER PUT HER FOL DESIGNED FOR NIGHTTIME AND DAY SEAT WITH THE THREE-POINT WAIS THE BEDROOM, THE INFANT GOT OL THE SEAT. THE INFANT SUFFERED A
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ELOPED A FLAT S THE FLAT SPOT	THE PLATE	PED PORT	SOOT	AIL: T	s kick	*.	NIGHT GHT:	≥	D SO HE BU STRA AND
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ID THAT HER BABY DEVELOPED A FLAT SPOT ON T HER PEDIATRICIAN ADVISED HER TO DISCONTINUE AFTER STOPPING USE, THE FLAT SPOT IS	REPORTED VIA EMAIL: CONSUMER STATED THAT THE BABY HAMMOCK'S HEADRESTIS TOO HARD, RESULTING IN A SLIGHT FLAT SPOT ON HER 2-MONTHS-OLD DAUGHTER'S HEAD. THE CONSUMER STATED THAT HER DAUGHTER HAS A SLIGHT FLATSPOT ON THE RIGHT SIDE OF HER HEAD.	THE CONSUMER STATED THAT THE PLASTIC SUPPORT UNDER THE LINE TOO HARD. AS A RESULT, HER SON HAS DEVELOPED A FLAT SPOT ON T BACK OF HIS HEAD. THE CHILD ONLY USES THE PRODUCT TO SLEEP IN OVER NIGHT.	THE CONSUMER STATED THAT HIS DAUGHTER RECEIVED A FLAT SPOT ON THE BACK OF HER HEAD FROM SLEEPING IN THE SOOTHER. HIS DAUGHTE SLEEPS ANYWHERE FROM 2-6 HOURS IN IT.	THE FOLLOWING REPORT WAS RECEIVED VIA EMAIL: THE CONSUMER STATED THAT HER BABY HAS DEVELOPED A FLAT SPOT ON HIS HEAD USING THE BABYHAMMOCK TO SLEEP IN.	; legs		NEW-BORN FEMALE HAS BEEN USING PRODUCT NIGHTLY SINCE BIRTH. WEEKS CONSUMER NOTICED THAT SHE HAD DIFFICULTY LIFTING HER H & HER NECK SEEMED STIFF. PEDIATRICIAN THOUGHT THE BABY'S HEAD WAS BIG. AT 16WEEK CHECK UP, PEDIATRICIAN DIAGNOSED BABY WITH HYDROCEPHALUS.	THE CONSUMER STATED ONE OF THE BUCKLES ON THE PAD OF THE BABY BASSINET BROKE OFF.	A FEMALE CONSUMER PUT HER FOUR MONTH OLD SON IN AN INFANT SEAT DESIGNED FOR NIGHTTIME AND DAYTIME USE. SHE BUCKLED HIM IN THE SEAT WITH THE THREE-POINT WAIST RESTRAINT. WHILE SHE WAS OUT OF THE BEDROOM, THE INFANT GOT OUT OF THE RESTRAINT AND FELL FROM THE SEAT. THE INFANT SUFFERED A CONTUSION AND SCRATCH TO HIS HEAD. THE INJURIES HAVE HEALED.
OTO O	HER HER	EEP S	SPO	#MER HEAD	while		S HEF S HEF S HEF S HEF	蓝	WIN I
THE CONSUMER STATED THAT HER BABY DEVELOPED A FLAT SPOT ON THE BACK OF HER HEAD. HER PEDIATRICIAN ADVISED HER TO DISCONTINUE USE OF THE SLEEPER. AFTER STOPPING USE, THE FLAT SPOT IS DIMINISHING.	p PS	THE CONSUMER STATED THAT THE PLASTIC SUPPORT UNDER THE LINER IS TOO HARD. AS A RESULT, HER SON HAS DEVELOPED A FLAT SPOT ON THE BACK OF HIS HEAD. THE CHILD ONLY USES THE PRODUCT TO SLEEP IN OVER NIGHT.	THE CONSUMER STATED THAT HIS DAUGHTER RECEIVED A FLAT SPOT ON THE BACK OF HER HEAD FROM SLEEPING IN THE SOOTHER. HIS DAUGHTER SLEEPS ANYWHERE FROM 2-6 HOURS IN IT.	THE FOLLOWING REPORT WAS RECEIVED VIA EMAIL: THE CONSUMER STATED THAT HER BABY HAS DEVELOPED A FLAT SPOT ON HIS HEAD SINCE USING THE BABYHAMMOCK TO SLEEP IN.	Consumer stated that while her 3 week on, 8 lb. son was kicking his legs while he was in the product, as a result, the sleeper tipped over.		NEW-BORN FEMALE HAS BEEN USING PRODUCT NIGHTLY SINCE BIRTH. AT 8 WEEKS CONSUMER NOTICED THAT SHE HAD DIFFICULTY LIFTING HER HEAD. & HER NECK SEEMED STIFF. PEDIATRICIAN THOUGHT THE BABY'S HEAD WAS BIG. AT 16WEEK CHECK UP, PEDIATRICIAN DIAGNOSED BABY WITH HYDROCEPHALUS.	ЗАВҮ	A FEMALE CONSUMER PUT HER FOUR MONTH OLD SON IN AN INFANT SEAT DESIGNED FOR NIGHTTIME AND DAYTIME USE. SHE BUCKLED HIM IN THE SEAT WITH THE THREE-POINT WAIST RESTRAINT. WHILE SHE WAS OUT OF THE BEDROOM, THE INFANT GOT OUT OF THE RESTRAINT AND FELL FROM THE SEAT. THE INFANT SUFFERED A CONTUSION AND SCRATCH TO HIS HEAD. THE INJURIES HAVE HEALED.
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Y1215805A p-flat head	Y1215804A p-flat head	Y1215807A p-flat head	Y1215808A p-flat head	Y1215802A p-flat head	9		Y1215684A Other -Frydrocephalus	Y1065872A Other -buckle	10C0687A
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Y11A5703A płagłocephały	Y11A5703A	A 2 MOM WAS DIAGNOSED WITH PLAGIOCEPHALY BY THREE (3) DIFFERENT MEDICAL FACILITIES. THE MOTHER OF THE VICTIM BELIEVES THE CAUSE OF THE CONDITION IS FROM SLEEPING, RESTING, AND PLAYING IN THE SUBJECT SLEEPEN/BASSINET DURING A 4 TO 5 MONTH PERIOD.	NEWBORN ROCK 'N PLAY SLEEPEH R6070	FISHER- PRICE, 1537 INC.	M 15	1102/2017	12/14/2011 7/2	202	(b)(6)	OK .	111114HCC3129	39
Y11B5441A plagiocephaty	Y1185441A	THE CONSUMER STATED THAT HER SON HAS DEVELOPED A FLAT HEAD FROM USING THE ROCKER. THE CHILD WAS EXAMINED BY A DOCTOR WHO HAS RECOMMENDEDTHAT THE CHILD RECEIVE PHYSICAL THERAPY TO ALLEVIATE THE SYMPTOMS. HE HAS ALWAYS TILTED HIS HEAD TO ONE SIDE.	M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER	MATTEL / FISHER- 1558 PRICE	X	10/25/2011	11/18/2011 10	204 1 1	×	OK.	Y11B5441A	38
Y11B5735A płagiocephały	Y11B5735A	THE CONSUMER STATED THAT HER CHILD WAS DIAGNOSED WITH FLAT HEAD AT HIS TWO MONTH CHECKUP WITH THEIR PEDIATRICIAN. THE DOCTOR ADVISED THECONSUMER TO DISCONTINUE USE OF THE SLEEPER.	M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER	MATTEL / FISHER- 1537 PRICE	M d	7/1/2011	12/9/2011 7/1	203	J. T.	<u>≅</u>	Y11B5735A	37
Y11B5734A plagiocephaly	Y11B5734A	A LAW FIRM REPRESENTS GUARDIAN AND NATURAL PARENT OF MALE TWINS ALLEDGING BABIES SKULLS BECAME MISSHAPEN AND/OR FLATTENED AS A RESULT OF USING THE SLEEPER FROM 4/29/2011 - 6/29/2011.	M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER	MATTEL / FISHER- 1537 PRICE	M 18	5/1/2011	12/9/2011 5/1	0 91		<u>κ</u>	Y11B5734A	36
plagiocephaly	Y1215801A	THE CONSUMER STATED THAT THE BACK OF HER 5-MONTHS-OLD SON'S HEAD WASFLAT FROM THE USE OF THE BABY HAMMOCK. THE CONSUMER ADDRESSED HER CONCERN WITH THE PEDIATRICIAN. SHE DISCONTINUED USE OF THE PRODUCT AND HAS NOTICED AN IMPROVEMENT IN THE AREA OF CONCERN.	M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER	MATTEL/ FISHER- PRICE/ MATTEL/ FISHER- FISHER- PRICE	M 18	11/1/2011	1/21/2012	205 1	В	MD	<u>Y1215801A</u>	35
Y11B5733A płagłocephały	Y11B5733A	CONSUMER STATED THAT THE HARD SLEEPING SURFACE OF THE PRODUCT HAS CAUSED LEFT SIDE OF HER SON'S HEAD TO BE FLAT. HE HAS BEEN DIAGNOSED WITH PLAGIOCEPHALY. HE HAS SEEN A PLASTIC SURGEON, AND HAS HAD EXTENDED TREATMENT AT CHILDREN'S HOSPITAL.	M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER	MATTEL / FISHER- 1537 PRICE	<u> </u>	7/22/2010	12/9/2011 7/5	205	>	MA	<u> </u>	34
p-head flatness	Reported to firm - not to CPSC	THE CONSUMER STATED THAT HER SON HAS DEVELOPED A FLAT SPOT ON THE RIGHT SIDE OF HIS HEAD. SHE ALSO STATED HIS NECK HAS THE ROPORTED TO TURN TO ONE SIDE. THE CHILD WAS TAKEN FOR A CHECK UP firm - not to RECENTLY AND THE PEDIATRICIAN NOTED THESE ISSUES.	V9197	MATTEL/ FISHER- PRICE/ MATTEL/ FISHER- PRICE	3		8/11/2011 ns	202 18	 >	MA	Firm not CPSC	33
p-head flatness	ap geologistasses hous	Consumer reported that his son received a flat spot on left side of back of his head. Doctor evaluated on Jan 5, 2010 and stated to use a regular crib to have him sleep in, using a wedge to force him to sleep on the other side of his head. They are to do this for two mornths and have him re-evaluated.	V9102 Rock N Play Sleeper	MATTEL/ FISHER- PRICE/ MATTEL/ FISHER- PRICE	3		1/10/2011 call to FP NS	0	,	ğ S	to CPSC	32
p-head flatness		THE CONSUMER STATED THAT AFTER TAKING HER SON TO THE PEDIATRICIAN, HE WAS DIAGNOSED WITH A FLAT HEAD. STATED SHE BELIEVES THIS IS FROM THE USE OF THIS PRODUCT SINCE IT IS THE ONLY PLACE HE SLEEPS. THE PEDIATRICIAN STATED HE WOULD LIKE TO SEE HER BABY IN A FEW WEEEKS AND MAY NEED TO PRESCRIBE A HELMET TO CORRECT THE SITUATION.	V9102 Rock N Play Steeper	MATTEL/ FISHER- PRICE/ MATTEL/ FISHER- PRICE	2		11/8/2011 NS		*	₹ 2	to CPSC	31
Y11B5/36A p-flat head	Y11B5736A	THE CONSUMER EXPRESSED CONCERN THAT HER SON'S HEAD IS FLATTENED FROMSLEEPING IN THE PRODUCT. THIS WAS NOTICED IN DECEMBER OF 2010.	M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER	MATTEL / FISHER- 1537 PRICE	≤	12/1/2010	129/2011 12	202	*	Ŋ	Y11B5736A	30

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Y1215840A	Y11B5538A	Y1185515A	110426CNE9000	Y11C4336A	Y11C5648A	Firm not CPSC	110906CCC1997	Y11C5646A
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1/20/2012	11/23/2011	6/4/2011	5/16/2011	12/23/2011	er 1000 20		9/20/2011	12/24/2011
9/1/2011	7/23/2011	3/1/2011	7/1/2010	3/13/2011	8/1/2011	11/16/2011	12/26/2010	9/1/2011
Ti.	3	₹	3	₹	Z	→ π	2	3
1543	1537	1537	1537	1529	1537		<u> </u>	1537
MATTEL / FISHER- PRICE	MATTEL / FISHER- PRICE	MATTEL / FISHER- PRICE	MATTEL,	FISHER- PRICE	MATTEL / FISHER- PRICE		FISHER PRICE	MATTEL / FISHER- PRICE
M# V9196 / ROCK 'N PLAY SLEEPER-BUTTERFL	M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER	M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER	FISHER PRICE POCK N PLAY P6070	FISHER- PRICE NEWBORN ROCK'N PLAY SLEEPER M# N/A / UPC# N/A	ROCK N' PLAY SLEEPER R6070	V9102	ROCK N' PLAY SLEEPER R6070	M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER
THE CONSUMER STATED THAT HER 6 MOF DAUGHTER HAS ACID REFLUX AND HAD BEEN SLEEPING IN SLEEPER. AT THIS TIME, SHE NOTICED THAT THE SIDE OF HER CHILD'S HEAD WAS FLAT AND SHE LEANED HER HEAD TO ONE SIDE. SHE WAS DIAGNOSED WITH TORTICOLLIS AND PLAGIOCEPHALY.	THE CONSUMER STATED THAT HER SON HAS BEEN SLEEPING IN THE PRODUCT 10-14 HOURS PER DAY SINCE BIRTH. HE DEVELOPED A FLAT HEAD AT 2 MONTHS OLD & DEVELOPED TORTICOLLIS AT 4 MONTHS OLD. HIS DOCTOR REFERRED HIMTO A SPECIALIST WHO STATES ISSUES ARE FROM SLEEPER.	CONSUMER'S SON HAS DEVELOPED FLATTENING ON THE BACK OF HIS HEAD IN FROMUSING THE SLEEPER. HE ALSO HAS WEAKENING OF THE MUSCLES IN HIS NECKAND FAVORS ONE SIDE WHEN SLEEPING. HE USED THE PRODUCT 12 HOURS PERDAY FOR 4 MONTHS. DOCTOR RECOMMENDED PHYSICAL THERAPY AND HELMET.	A FOUR MONTH OLD MALE WAS DIAGNOSED WITH PLAGIOCEPHALY AFTER THREE MONTHS OF PLAYPEN/SLEEPER USE. Mold also reported on sleeper by this consumer.	CONSUMER NOTICED THAT 3 MOM SLOUCHING DOWN & LOOKED CRUNCHED UP IN SLEEPER. CONSUMER IMMEDIATELY STOPPED USING IT. BABY WAS DIAGNOSED WITH SEVERE BRACHYCEPHALY & MODERATE PLAGIOCEPHALY. CONSUMER BELIEVES THAT THIS SLEEPER CAUSED THESE PROBLEMS.	THE CONSUMER STATED THAT HER SON RECEIVED A FLAT HEAD DURING THE USE OF ROCK N PLAY SLEEPER. HE WAS IN IT ABOUT TEN HOURS A DAY ON AND OFF INCLUDING NIGHTTIME SLEEP. HE AS TAKEN TO THE PEDIATRICIAN AND WAS GIVEN INSTRUCTIONS ON TUMMY TIME AND POSITIONING TO DO BUT HE ENDED UP HAVING TO GET A HELMET. THE CONSUMER HAS TWO SLEEPERS BECAUSE SHE HAS TWINS.	0 0 2	A TWO WEEK OLD MALE VICTIM BEGAN SLEEPING OVERNIGHT INSIDE A PORTABLE ROCKING SLEEPER. AFTER SEVERAL MONTHS HIS MOTHER NOTICED THAT HIS HEAD WAS BECOMING FLAT ON THE BACK AND RIGHT SIDE. A SPECIALIST DIAGNOSED HIM WITH SEVERE BRACHYCEPHALY AND PLAGIOPHALY (FLATTENING OF THE HEAD). HE WORE A MEDICAL HELMET FOR 23 HOURS A DAY FOR THREE MONTHS AND HIS HEAD HAS RESUMED ITS NORMAL SHAPE.	CONSUMER'S SON RECEIVED FLAT HEAD DURING USE OF THE SLEEPER. WHEN HEWAS TAKEN TO PEDIATRICIAN CONSUMER WAS GIVEN SUGGESTIONS TO HELP THECONDITION LIKE TUMMY TIME & POSITIONING HIM DIFFERENTLY. THE CONDITION HASN'T IMPROVED & THEY MEASURED FOR HELMET.
płagiocer Y1215840A torticollis	płagiocer Y11B553BA torticollis	Y1165515A	1090528A	/11C4336A	Y1105648A	Reported to firm - not to CPSC	Y11C5439A	Y11C5646A
plagioceptaly & torticollis	plagiocephaly &	plagiocephaly & torticolis	plagiocephaly & MOLD	plagiocephaly & Y11C4336A brachycephaly	Y11C5648A plagiocephaly	plagiocephaty	Y11C5439A plagfocephaly	Y11C5646A Plaglocephaly

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57	56	—	54	53	52	51	50	49
Firm not CPSC - CPSC H11C0183A	Firm not CPSC- CPSC-H11C0183A	Y11C5645A	Y1185809A	110524CCC2557	Y1215803A	Y1215513A	Y1215799A	Y11 <u>C5649A</u>
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(b)(6)			<u></u>	<u> </u> -		<u> </u>	Γ	
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12/14/2011	12/14/2011	12/24/2011	8/25/2011	7/12/2011	1/21/2012	1/12/2012	1/21/2012	12/24/2011
NS .	NS.	9/1/2011	12/20/2010	12/1/2010	12/1/2011	12/21/2011	10/1/2011	1/1/2011
TI .	7	TT	0	Ti Ti	Π	n	0	Z
1537	1537	1537	1558	1537	1537	1537	1537	1537
FISHER- PRICE, INC.	MATTEL/ FISHER- PRICE/ MATTEL/ FISHER- PRICE	MATTEL / FISHER- PRICE	MATTEL/ FISHER- PRICE	FISHER- PRICE, INC.	MATTEL/ FISHER- PRICE / MATTEL/ FISHER- PRICE	MATTEL / FISHER- PRICE	MATTEL/ FISHER- PRICE / MATTEL / FISHER- PRICE	MATTEL / FISHER- PRICE
V9197	V9197	M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER	M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER	NEWBORN ROCK 'N PLAY SLEEPER R6070	M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER	M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER	M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER	N# R6070 / NEWBORN ROCK 'N PLAY SLEEPER
SEE INCIDENT REPORT ABOVE.	CONSUMER STATED THAT HER TWIN DAUGHTERS HAVE BOTH BEEN DIAGNOSED WITH TORTICOLLIS AND PLAGIOCEPHALY. THEY ARE CURRENTLY UNDERGOING HELMET THERAPY. THE DOCTOR HAS ADVISED THAT THIS COULD BE A RESULT OF USING THE ROCK N PLAY SLEEPER. THE CONSUMER HAS TWIN DAUGHTERS AND TWO PRODUCTS. A SEPARATE CASE WILL BE ESTABLISHED.	THE CONSUMER STATED THAT SHE STARTED USING THIS PRODUCT WHEN HER DAUGHTER WAS 6 WEEKS OLD & WHEN SHE WAS ALMOST 4 MONTHS OLD SHE TOOK HERTO THE DOCTOR BECAUSE SHE NOTICED SOME HEAD ISSUES. SHE WAS DIAGNOSED WITH TORTICOLLIS & HAS STARTED PHYSICAL THERAPY.	CPSC REPORT STATED THAT CHILD DEVELOPED TORTICOLLIS AFTER USING THE SLEEPER EVERYDAY FOR 6 MONTHS. SLEEPER WAS USED FOR NAPS AND OVERNIGHT SLEEP. THE TORTICOLLIS WAS EVIDENT AT THREE WEEKS OLD BUT NOT DIAGNOSED UNTIL 4 MONTHS OLD. CHILD WAS SEEN BY PEDIATRICIAN & P.T.	A SIX-MONTH-OLD FEMALE DEVELOPED TORTICOLLIS AFTER SLEEPER USE. THE VICTIM WAS PLACED IN THE SLEEPER AT VICTIM'S HOME FOR NAPS AND OVERNIGHT SLEEP EVERYDAY FROM ZERO TO SIX MONTHS OLD. THE TORTICOLLIS WAS EVIDENT AT THREE WEEKS OLD BUT VICTIM WAS NOT DIAGNOSED WITH TORTICOLLIS UNTIL FOUR MONTHS OLD. THE CONNECTION BETWEEN THE SLEEPER AND THE TORTICOLLIS WAS NOT DISCOVERED UNTIL VICTIM WAS SIX MONTHS OLD.	THE CONSUMER STATED THAT HER DAUGHTER'S UPPER TORSO AND NECK LEANS FORWARD SINCE USING THE BABY HAMMOCK. THE CONSUMER AND HER HUSBAND BELIEVE IT MAY HAVE BEEN CAUSED FROM CONTINUED USAGE WITH THIS PRODUCT.	THE CONSUMER STATED THAT HER DAUGHTER WAS DIAGNOSED BY THE PEDIATRICIAN WITH TORTICOLLIS AND WILL REQUIRE PHYSICAL THERAPY, HER PEDIATRICIAN ADVISED HER THAT IT IS A DIRECT RESULT OF USING THE SLEEPER.	THE CONSUMER STATED THAT SHE HAS 4-MONTHS-OLD TRIPLETS THAT HAVE VARYING DEGREES OF PLAGIOCEPHALY (FROM USE OF THE BABY HAMMOCK), THEIR DOCTOR HAS EXAMINED THE CHILDREN AND ADVISED HER THAT THEY WILL GROW AND DEVELOP OUT OF THE FLAT SPOTS. THE BABIES ARE 16, 15, AND 10 LBS.	BOTH OF CONSUMER'S SONS HAVE BEEN DIAGNOSED BY THEIR PEDIATRICIAN WITH FLAT HEAD & HAVE BEEN REFERRED TO A SPECIALIST. CONSUMER BELIEVES THIS IS FROM USE OF THE SLEEPER. BOTH CHILDREN'S CONDITION IMPROVED ONCE USE OF THE SLEEPER WAS DISCONTINUED.
Reported to film - not to CPSC	Reported to firm - not to CPSC	Y11C5645A torticollis	Y1185609A torticollis	11150455A	Y1215803A torticollis	Y1215513A torticollis	/1215799A	Y11C5649A
torticollis/plagiocephaly	torticollis/plagiocephaly	tortico#is	torticollis	torticollis	toritodis	torticollis	Y1215799A plagiocephaly X3	Y11C5649A plagiocephaly x2

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Task Number: Document Number: Y1235489A

Date Received: 03/01/2012

Confirmed:

Date Entered: 03/06/2012

Issue: 0

City: (b)(6)

State : AR

Date Notified:

Source: 6

Type Of Contact: 10 OFFICE OF COMPLIANCE

Prod: 1537

BASSINETS OR CRADLES

Prod: 0

NO SECOND PRODUCT INVOLVEMENT

Date Injured: 08/01/2011

Work Related: N

Age: 202

Sex: 1 MALE

Disposition: 1 1=TREATED & RELEASED, OR EX/Haz Type: F OTHER

Brand: MATTEL/MATTEL/FISHER-PRICE Screened?:

Model: M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER

Narrative :

THE CONSUMER STATED THAT THE BACK OF HER SON'S HEAD HAS BECOME FLATTE NED SINCE THE USE OF THE PRODUCT. THE CHILD HAS SEEN THE PEDIATRICIA N AND A NEUROLOGIST, AND HAD X-RAYS. SHE OWNS TWO OF THE SAME PRODUC TS WITH THE SAME ISSUE WITH HER TWIN BOYS.

Document Number: Y1235854A

Task Number:

Issue: 0

Date Received: 03/29/2012

Confirmed:

Date Entered: 04/04/2012

City: SANTA CLARITA

State: CA Type Of Contact: 10 OFFICE OF COMPLIANCE

Date Notified:

Source: 6

BASSINETS OR CRADLES

Prod: 1537 Prod: 0

NO SECOND PRODUCT INVOLVEMENT

Date Injured: 03/22/2012

Work Related : N

Age: 0

Sex: 1 MALE

Disposition: 1 1=TREATED & RELEASED, OR EX/Haz Type: F OTHER

Brand: MATTEL/FISHER-PRICE

Screened?:

Model: M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER

Narrative:

THE CONSUMER STATED THAT HER SON USED THE PRODUCT FOR 4 MONTHS FOR NA PS AND OVERNIGHT SLEEPING. THE CHILD DEVELOPED TORTICOLLIS AND PLAGE OCEPHALY WHICH RESULTED IN 18 MONTHS OF PHYSICAL THERAPY & 2 DIFFEREN T HELMETS

Document Number: Y1235887A

Task Number:

Issue: 0

Date Received: 03/29/2012

Confirmed:

Date Entered: 04/04/2012

City: SAN JOSE

State : CA

Date Notified:

Source: 6

Type Of Contact: 10 OFFICE OF COMPLIANCE

Prod: 1537

BASSINETS OR CRADLES

Prod: 0

NO SECOND PRODUCT INVOLVEMENT

Date Injured: 01/10/2012

Work Related: N

Age: 207

Sex: 1 MALE

Disposition: 1 1=TREATED & RELEASED, OR EX/Haz Type: F OTHER

Brand: MATTEL/FISHER-PRICE

Model: M# V9197 / RNP SLEEPER-CIRCLES

Screened?:

Narrative:

CONSUMER'S CHILD SLEPT IN THE SLEEPER EVERY NIGHT BEGINNING AUGUST 10 , 2011 UNTIL JANUARY 10, 2012. THE CHILD WAS DIAGNOSED HIM WITH OCC IPITAL PLAGIOCEPHALY & PRESCRIBED AN ORTHOPEDICS HELMET TO RESHAPE HI S HEAD. THE PEDIATRICIAN STATED THAT THE SLEEPER CAUSED FLAT SPOTS

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Document Number: Y1245544A Task Number: Issue: 0

Confirmed: Date Received: 04/05/2012

State: CA

Date Entered: 04/10/2012

City: (b)(6)

Date Notified:

Source: 6

Type Of Contact: 10 OFFICE OF COMPLIANCE

Zip:

Prod: 1537

BASSINETS OR CRADLES

Prod: 0 Date Injured: 12/15/2011 D

NO SECOND PRODUCT INVOLVEMENT

Work Related : N

Age: 202

Sex: 1 MALE

Disposition: 1 1=TREATED & RELEASED, OR EX/Haz Type; F OTHER

Brand: MATTEL/FISHER-PRICE

Screened?:

Model: M# V9197 / RNP SLEEPER-CIRCLES

Narrative:

CONSUMER'S SON SLEPT IN THE SLEEPER 8 HOURS A NIGHT FROM BIRTH UNTIL 8 WEEKS OLD. HE NOW HAS BRACHYCEPHALY & THE PEDIATRICIAN SAID THAT I T WILL NOT CORRECT ITSELF & TO TRY RE-POSITIONING FOR A PERIOD OF TIM E AND IF IT DID NOT SELF-CORRECT A HELMET WILL BE NEEDED.

Document Number: Y1245545A

Task Number:

Issue: 0

Date Received: 04/05/2012

Confirmed:

Date Entered: 04/10/2012

City: LEXINGTON

State: KY

Date Notified: Type Of Contact: 10 OFFICE OF COMPLIANCE

Source: 6 **Prod**: 1537

BASSINETS OR CRADLES

Prod: 0

NO SECOND PRODUCT INVOLVEMENT

Date Injured: 10/01/2011

Work Related: N

Age: 203

Sex: 1 MALE

Disposition: 1 1=TREATED & RELEASED, OR EX/Haz Type: F OTHER

Brand: MATTEL/FISHER-PRICE

Screened?:

Model: M# V9197 / RNP SLEEPER-CIRCLES

Narrative:

CONSUMER'S SON WAS DIAGNOSED BY PEDIATRICIAN WITH A FLAT HEAD. SHE B ELIEVES THIS IS FROM THE USE OF THIS PRODUCT SINCE IT IS THE ONLY PLA CE HE SLEEPS. THE PEDIATRICIAN STATED HE WOULD LIKE TO SEE THE HER B ABY IN A FEW WEEKS AND MAY NEED TO PRESCRIBE A HELMET TO CORRECT IT.

Document Number: Y1245546A

Task Number:

Issue: 0

Date Received: 04/05/2012

Confirmed:

Date Entered: 04/10/2012

City: (b)(6)

State: MA

Zip : Date Notified :

Source: 6

Type Of Contact: 10 OFFICE OF COMPLIANCE

Prod: 1537

BASSINETS OR CRADLES

Prod: 0

NO SECOND PRODUCT INVOLVEMENT

Date Injured: 07/01/2011

Work Related: N

Age: 202

Sex: 1 MALE

Disposition: 1 1=TREATED & RELEASED, OR EX/Haz Type: F OTHER

Brand: MATTEL/FISHER-PRICE

Screened?:

Model: M# V9197 / RNP SLEEPER-CIRCLES

Narrative:

THE CONSUMER STATED THAT HER SON HAS DEVELOPED A FLAT SPOT ON THE RIG HT SIDE OF HIS HEAD. SHE ALSO STATED HIS NECK HAS THE TENDENCY TO TU RN TO ONE SIDE. THE CHILD WAS TAKEN FOR A CHECK UP RECENTLY AND THE PEDIATRICIAN NOTED THESE ISSUES.

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Document Number: Y1245843A

Task Number:

Issue: 0

Date Received: 04/26/2012

Confirmed:

Date Entered: 05/02/2012

City: (b)(6) Source: 6

Type Of Contact: 10 OFFICE OF COMPLIANCE

Zip : (b) (6) Date Notified :

Prod: 1537

BASSINETS OR CRADLES

Prod: 0 Date Injured: 02/01/2012

NO SECOND PRODUCT INVOLVEMENT Work Related: N

State: VA

Age: 208

Sex: 0 UNKNOWN

Disposition: 1 1=TREATED & RELEASED, OR EX/Haz Type: F OTHER Brand: MATTEL/FISHER-PRICE

Screened?:

Model: M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER

Narrative :

THE CONSUMER STATED THAT HER 8 MONTH OLD CHILD WAS DIAGNOSED WITH PHA GIOCEPHALY. IT WAS DETERMINED THAT THE CHILD NEEDED A HELMET.

Document Number: Y1265488A

Task Number:

Issue: 0

Date Received: 06/07/2012

Confirmed:

Date Entered: 06/13/2012

City: (b)(6)

State: CA

Date Notified:

Source: 6

Type Of Contact: 10 OFFICE OF COMPLIANCE

BASSINETS OR CRADLES

Prod: 1537 Prod: 0

NO SECOND PRODUCT INVOLVEMENT

Date Injured: 05/24/2012

Work Related: N

Age: 204

Sex: 0 UNKNOWN

Disposition: 1 1=TREATED & RELEASED, OR EX/Haz Type: F OTHER

Brand: MATTEL/FISHER-PRICE

Screened?:

Model: M# V9197 / RNP SLEEPER-CIRCLES

Narrative :

CONSUMER STATED THAT 4 MONTH OLD CHILD SLEPT IN THE SLEEPER EVERY NIG HT. THE CHILD HAD 4 MONTH CHECK UP & DOCTOR STATED THAT CHILD HAS A FLAT SPOT ON HEAD & TORTICOLLIS FROM THE USE OF THE SLEEPER. HE PRESC RIBED IN-HOME STRETCHING EXCERCISES & ADVISED TO STOP USING THE UNIT.

Document Number: Y1265709A

Task Number: 120627CCC1774

Issue: 0

Date Received: 06/21/2012

Confirmed:

Date Entered: 06/26/2012

City: STATEN ISLAND

State: NY

Date Notified:

Source: 6

Type Of Contact: 10 OFFICE OF COMPLIANCE

Prod: 1537

BASSINETS OR CRADLES

Prod: 0

NO SECOND PRODUCT INVOLVEMENT

Date Injured: 06/07/2012 D

Work Related: N

Age: 201

Sex: 1 MALE

Disposition: 1 1=TREATED & RELEASED, OR EX/Haz Type: 7 ALLERGIC REACTION

Zip:

Brand: MATTEL/MATTEL/FISHER-PRICE Screened?: Model: M# X3840 / NEWBORN ROCK 'N PLAY SLEEPERT

Narrative:

THE CONSUMER STATED THAT 1 MOM HAS BEEN TAKEN TO THE DOCTOR ON SEVERA LOCCASIONS FOR CONGESTION AND COUGHING, THE DOCTOR PRESCRIBED A LIQU ID MEDICATION TO TREAT THE CONGESTION. SHE BELIEVES IT HAS BEEN CAUS ED BY MOLD FOUND ON THE BACK OF THE PAD OF THE BASSINET.

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Document Number: Y1265790A Task Number: Issue: 0

City: (b)(6) State: KY Zip: Date Notified:

Work Related : N

Source: 6 Type Of Contact: 10 OFFICE OF COMPLIANCE
Prod: 1537 BASSINETS OR CRADLES

Prod: 1537 BASSINETS OR CRADLES
Prod: 0 NO SECOND PRODUCT INVOLVEMENT

FIDE : O HO GEOGRAP I HODGOT INTOEVEMENT

Age: 203 Sex: 1 MALE

Disposition: 1 1=TREATED & RELEASED, OR EX/Haz Type: F OTHER

Brand : MATTEL / FISHER-PRICE Screened? :

Model: M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER

Narrative:

Date Injured: 06/12/2012

THE CONSUMER STATED THAT 3 MOM WAS TAKEN TO THE DOCTOR AND DIAGNOSED WITH PLAGIOCEPHALY. THE CHILD IS IN THE PRODUCT ABOUT 10 HOURS A DAY. HE IS REQUIRED TO WEAR A HELMET. THE CONSUMER IS LOOKING FOR COMPENSATION FOR THE COST OF THE HELMET.

Document Number: Y1265836A Task Number: Issue: 0

Date Received: 06/28/2012 Confirmed: Date Entered: 07/04/2012

City: (b)(6) State: AR Zip Date Notified:

Source: 6 Type Of Contact: 10 OFFICE OF COMPLIANCE

Prod: 1537 BASSINETS OR CRADLES

Prod: 0 NO SECOND PRODUCT INVOLVEMENT

Date Injured: 12/01/2011 D Work Related: U

Age: 202 Sex: 2 FEMALE

Disposition: 1 1=TREATED & RELEASED, OR EX/Haz Type: F OTHER

Brand: MATTEL / FISHER-PRICE Screened?:
Model: M# X3840 / NEWBORN ROCK 'N PLAY SLEEPERT

Narrative:

CONSUMER STATED THAT HER DAUGHTER DEVELOPED A FLAT SPOT ON THE BACK OF HER HEAD FROM SLEEPING IN THE ROCKER FOR MORE THAN 12 HOURS PER DAY. SHE WAS REFERRED TO A SPECIALIST AT FOUR MONTHS OLD, & WAS PRESCRIBED AN ORTHODIC HELMET TO WEAR FOR 23 HOURS PER DAY.

Document Number: Y1275888A Task Number: Issue: 0

Date Received: 07/26/2012 Confirmed: Date Entered: 08/09/2012

City: (0)(6) State: CA Zip: Date Notified:

Source: 6 Type Of Contact: 10 OFFICE OF COMPLIANCE

Prod: 1537 BASSINETS OR CRADLES

Prod: 0 NO SECOND PRODUCT INVOLVEMENT

Date Injured: 07/19/2012 D Work Related: N

Age: 204 Sex: 2 FEMALE

Disposition: 1 1=TREATED & RELEASED, OR EX/Haz Type: F OTHER

Brand: MATTEL / FISHER-PRICE Screened?:
Model: M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER

Narrative:

GENDER: FEMALE; INJURY TYPE: PLAGIOCEPHALY/FLATHEAD; THE CONSUMER STA TED THAT HER 4 MONTHS OLD GRANDDAUGHTER'S HEAD IS DEFORMED FROM SLEEP ING IN THIS SLEEPER. THE BABY'S PEDIATRICIAN STATED THAT AN ORTHOTIC HELMET WILL BE NECESSARY TO RESHAPE HER HEAD.

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Task Number: **Document Number: Y1275889A** issue: 0

Date Received: 07/26/2012 Confirmed: Date Entered: 08/09/2012

City : (b)(6) Date Notified: State: PA

Work Related : N

Type Of Contact: 10 OFFICE OF COMPLIANCE Source: 6

Prod: 1537 BASSINETS OR CRADLES

Prod: 0 NO SECOND PRODUCT INVOLVEMENT

Sex: 1 MALE Age: 218

Disposition: 9 9=UNKNOWN, NOT STATED, ETC. Haz Type: F OTHER

Brand: MATTEL/FISHER-PRICE Screened?:

Model: M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER

Narrative:

Date Injured: 04/23/2011

AGE AT THE TIME OF INCIDENT: 1YEAR(S) 6MONTH(S); GENDER: MALE; DATE OF INCIDENT: 04/23/2011; INJURY FLAG: YES; INJURY # 1 INJURY TYPE: P

LAGIOCEPHALY/FLATHEAD; THE CONSUMER STATED THAT SHE USED THE SLEEPER

AND AFTER A FEW MONTHS OF USE HER SON'S HEAD STARTED TO FLATTEN.

Document Number: Y1275890A Task Number: Issue: 0

Confirmed: Date Entered: 08/09/2012 Date Received: 07/26/2012

City: (b)(6) State: TX Date Notified:

Type Of Contact: 10 OFFICE OF COMPLIANCE Source: 6

Prod: 1537 BASSINETS OR CRADLES

NO SECOND PRODUCT INVOLVEMENT Prod: 0

Date Injured: 07/10/2012 D Work Related: N

Age: 0 Sex: 2 FEMALE

Disposition: 1 1=TREATED & RELEASED, OR EX/Haz Type: F OTHER

Model: M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER

Brand: MATTEL / FISHER-PRICE

Narrative:

INJURY FLAG: YES: INJURY TYPE: PLAGIOCEPHALY/FLATHEAD: THE CONSUM ER STATED THAT AFTER CONTINUOUS USE OF THE SLEEPER THE BACK OF HER DA UGHTER'S HEAD FLATTENED. HER DOCTOR ADVISED THAT SHE DISCONTINUE USE

OF THE PRODUCT.

Document Number: Y1275891A Task Number: Issue: 0

Confirmed: Date Received: 07/26/2012 Date Entered: 08/09/2012

Screened?:

City: (b)(6) State: SC Date Notified:

Source: 6 Type Of Contact: 10 OFFICE OF COMPLIANCE

Prod: 1537 BASSINETS OR CRADLES

Prod: 0 NO SECOND PRODUCT INVOLVEMENT

Date Injured: 03/01/2012 D Work Related : N

Age: 202 Sex: 1 MALE

Disposition: 9 9=UNKNOWN, NOT STATED, ETC. Haz Type: F OTHER

Brand: MATTEL/FISHER-PRICE

Model: M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER

Narrative:

THE CONSUMER STATED THAT HER 2 MONTHS OLD SON DEVELOPED A FLAT SPOT O NITHE BACK OF HIS HEAD FROM USING THIS SLEEPER.

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Ocument Number : Y1275892A	lask Number :	issue: 0
18-18 No.	1921 22 1 121	CLE CT CLN TO THE SECONDOCTOR

Date Received : 07/26/2012 Date Entered: 08/09/2012 Confirmed:

Date Notified: City: (b)(6) State: FL

Work Related: N

Source: 6 Type Of Contact: 10 OFFICE OF COMPLIANCE

BASSINETS OR CRADLES Prod: 1537

Prod: 0 NO SECOND PRODUCT INVOLVEMENT

Sex: 1 MALE Age: 202

Disposition: 1 1=TREATED & RELEASED, OR EX/Haz Type: F OTHER

Brand: MATTEL/FISHER-PRICE Screened?:

Model: M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER

Narrative :

Date Injured: 02/01/2012

THE CONSUMER STATED THAT HER 2 MONTHS OLD SON HAS DEVELOPED A FLAT SP OT ON THE RIGHT SIDE OF HIS HEAD FROM SLEEPING IN THE SLEEPER FOR APP ROXIMATELY 6-7 HOURS PER DAY. HER PEDIATRICIAN EXAMINED THE CHILD AN D ADVISED HER TO DISCONTINUE USE OF THE ITEM.

Document Number: Y1275893A Task Number: Issue: 0

Date Received : 07/26/2012 Confirmed: Date Entered: 08/09/2012

City: (b)(6) Date Notified: State : CA

Type Of Contact: 10 OFFICE OF COMPLIANCE Source: 6

Prod: 1537 BASSINETS OR CRADLES

Prod: 0 NO SECOND PRODUCT INVOLVEMENT Work Related : N Date Injured: 03/01/2012 D

Sex: 2 FEMALE Age: 201

Disposition: 9 9=UNKNOWN, NOT STATED, ETC. Haz Type: F OTHER

Brand: MATTEL/FISHER-PRICE Screened?:

Model: M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER

Narrative:

THE CONSUMER STATED THAT THE BACK OF HER 1 MONTH OLD DAUGHTER'S HEAD HAS FLATTENED SINCE USE OF THIS SLEEPER.

Document Number: Y1275894A Task Number: Issue: 0

Date Received: 07/26/2012 Confirmed: Date Entered: 08/09/2012

Sex:1

MALE

City: (b)(6) State: SC Date Notified:

Type Of Contact: 10 OFFICE OF COMPLIANCE Source: 6

Prod: 1537 **BASSINETS OR CRADLES**

NO SECOND PRODUCT INVOLVEMENT Prod: 0

Date Injured: 12/01/2010 Work Related: N

Disposition: 1 1=TREATED & RELEASED, OR EX/Haz Type: F OTHER

Brand: MATTEL/FISHER-PRICE Screened?: Model: M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER

Narrative:

Age: 202

THE CONSUMER STATED THAT AT HER SON'S TWO MONTH CHECKUP, HER PEDIATRI CIAN NOTICED THAT THE CHILD HAD DEVELOPED A FLAT SPOT ON HIS HEAD. T HE DOCTOR TOLD HER TO DISCONTINUE USING THE SLEEPER. SINCE THAT TIME , THE FLAT SPOT HAS BECOME MORE ROUNDED NATURALLY.

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Document Number: Y1275895A Task Number: Issue: 0

Date Received: 07/26/2012 Confirmed: Date Entered: 08/09/2012

Type Of Contact: 10 OFFICE OF COMPLIANCE

City: (b)(6) Date Notified:

Source: 6 Type Of Contact: 10
Prod: 1537 BASSINETS OR CRADLES

Prod: 0 NO SECOND PRODUCT INVOLVEMENT

Date Injured: 01/11/2012 D Work Related: N

Age: 204 Sex: 2 FEMALE

Disposition: 1 1=TREATED & RELEASED, OR EX/Haz Type: F OTHER

Brand: MATTEL/FISHER-PRICE Screened?:

Model: M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER

Narrative:

THE CONSUMER STATED THAT HER 4 MONTHS OLD DAUGHTER HAS BEEN DIAGNOSED WITH FLATHEAD AND NECK ISSUES. THE CONSUMER'S PEDIATRICIAN IS ATTRIBUTING THIS TO USE OF THE SLEEPER. THE CHILD HAS BEEN REFERRED TO A PHYSICAL THERAPIST.

Document Number: Y1275896A Task Number: issue: 0

Date Received: 07/26/2012 Confirmed: Date Entered: 08/09/2012

City: Date Notified:

Source: 6 Type Of Contact: 10 OFFICE OF COMPLIANCE
Prod: 1537 BASSINETS OR CRADLES

Prod: 0 NO SECOND PRODUCT INVOLVEMENT

Date Injured: 12/01/2011 D Work Related: N

Age: 203 Sex: 2 FEMALE

Disposition: 9 9=UNKNOWN, NOT STATED, ETC. Haz Type: F OTHER

Brand: MATTEL/FISHER-PRICE Screened?:
Model: M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER

Narrative:

THE CONSUMER STATED THAT HER 3 MONTH OLD DAUGHTER HAS DEVELOPED A FLA T SPOT ON THE BACK OF HER HEAD WHERE HER HEAD RUBS ON THE PLASTIC SEA T INSERT OF THE SLEEPER.

Document Number: Y1275897A Task Number: Issue: 0

Date Received: 07/26/2012 Confirmed: Date Entered: 08/09/2012

City: (6)(6) State: NY Zip: Date Notified:

Source: 6 Type Of Contact: 10 OFFICE OF COMPLIANCE

Prod: 1537 BASSINETS OR CRADLES

Prod: 0 NO SECOND PRODUCT INVOLVEMENT

Date Injured: 10/01/2011 D Work Related: N

Age: 204 Sex: 0 UNKNOWN

Disposition: 1 1=TREATED & RELEASED, OR EX/Haz Type: F OTHER

Brand: MATTEL/FISHER-PRICE Screened?:
Model: M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER

Narrative:

THE CONSUMER STATED THAT SHE HAS 4 MONTH OLD TRIPLETS THAT HAVE VARYING DEGREES OF PLAGIOCEPHALY. THEIR DOCTOR HAS EXAMINED THE CHILDREN AND ADVISED HER THAT THEY WILL GROW AND DEVELOP OUT OF THE FLAT SPOTS DUE TO SLEEPER. THE BABIES ARE 16, 15, AND 10 LBS.

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Document Number: Y1275961A

Task Number:

Issue: 0

Date Received: 07/26/2012

Confirmed:

Date Entered: 08/03/2012

City: SPOKANE

State: WA

Date Notified:

Source: 6

Prod: 1537

BASSINETS OR CRADLES

Type Of Contact: 10 OFFICE OF COMPLIANCE

Prod: 0

NO SECOND PRODUCT INVOLVEMENT

Date Injured: 04/01/2012

Work Related: U

Age: 203

Sex: 2 FEMALE

Disposition: 1 1=TREATED & RELEASED, OR EX/Haz Type: F OTHER

Brand: MATTEL/FISHER-PRICE

Screened?:

Model: M# W9443 / NEWBORN ROCK N' PLAYT SLEEPER

Narrative :

CONSUMER STATED THAT HER DAUGHTER HAS DEVELOPED A FLAT SPOT ON THE BA CK OF HER HEAD SINCE USE OF THIS PRODUCT. THE PRODUCT WAS USED FOR N APS & NIGHT TIME SLEEPING. SHE TOOK HER DAUGHTER TO THE PEDIATRICIAN, NEUROLOGIST & AN ORTHOTIC SPECIALIST. SHE WAS FITTED FOR HELMET.

Document Number: Y1285566A

Task Number:

Issue: 0

Date Received: 08/09/2012

Confirmed:

Date Entered: 08/18/2012

City: (b)(6)

Date Notified:

Source: 6 **Prod**: 1537

BASSINETS OR CRADLES

Prod: 0

NO SECOND PRODUCT INVOLVEMENT

Date Injured: 04/01/2012

Work Related: N

Age: 207

Sex:1 MALE

Disposition: 1 1=TREATED & RELEASED, OR EX/Haz Type: F OTHER

Brand: MATTEL/FISHER-PRICE

Screened?:

Type Of Contact: 10 OFFICE OF COMPLIANCE

Model: M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER

Narrative:

AGE AT THE TIME OF INCIDENT: 7MONTH(S); MALE; DATE OF INCIDENT: 04/0 1/2012; THE CONSUMER STATED THAT HER SON DEVELOPED A FLAT HEAD FROM USING THE SLEEPER. HE WAS TAKEN TO THE DOCTOR WHEN HE WAS 4 MONTHS OL DIAND WAS PRESCRIBED A HELMET TO CORRECT THE SHAPE OF HIS HEAD.

Document Number: Y1285589A

Task Number:

Issue: 0

Date Received: 08/09/2012

Confirmed:

Date Entered: 08/15/2012

City: (b)(6)

State: OH

Date Notified:

Source: 6

Type Of Contact: 10 OFFICE OF COMPLIANCE BASSINETS OR CRADLES

Prod: 1537

NO SECOND PRODUCT INVOLVEMENT

Prod: 0

Date Injured: 02/01/2012

Work Related: N

Age: 201

Sex: 1 MALE

Disposition: 1 1=TREATED & RELEASED, OR EX/Haz Type: F OTHER

Brand: MATTEL/FISHER-PRICE

Screened?:

Model: M# V9102 / ROCK 'N PLAY SLEEPER

Narrative :

AGE 1MONTH; WEIGHT: 9LBS; MALE; DATE: 02/01/2012; INJURY: PLAGIOCEPHA LY/FLATHEAD; THE CONSUMER STATED THAT HER SON DEVELOPED A FLAT HEAD A FTER USING THE SLEEPER. HE HAS BEEN PRESCRIBED A HELMET TO RESHAPE HI S HEAD, HE USED THE SLEEPER OVERNIGHT FOR THE FIRST MONTH THEN NAPS.

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Task Number: Document Number: Y1285701A Issue: 0 Date Entered: 08/24/2012 Date Received: 08/16/2012 Confirmed: Date Notified: City: (b)(6) State: L Type Of Contact: 10 OFFICE OF COMPLIANCE Source: 6 BASSINETS OR CRADLES **Prod**: 1537 NO SECOND PRODUCT INVOLVEMENT Prod: 0 Date Injured: 08/03/2012 Work Related: N Age: 206 Sex: 2 FEMALE Disposition: 1 1=TREATED & RELEASED, OR EX/Haz Type: F OTHER Brand: MATTEL/FISHER-PRICE Screened?: Model: M# V9196 / ROCK 'N PLAY SLEEPER-BUTTERFLY Narrative: 6 MOF: CONSUMER STATED THAT HER DAUGHTER SLEPT IN THE PRODUCT EVERY N IGHT FOR 2 MONTHS & THEN TOOK NAPS IN IT. SHE WAS DIAGNOSED BY A PLAS TIC SURGEON WITH TORTICOLLIS & PLAGIOCEPHALY. SHE WILL BE IN PHYSICAL THERAPY AND WILL UNDERGOCRANIAL HELMET THERAPY FOR 4-6 MONTHS Document Number: Y1285702A Task Number: 120824CCC2930 Issue: 0 Confirmed: Date Entered: 08/24/2012 Date Received: 08/16/2012 City: (b)(6) Zip (0) (6) Date Notified: State: MN Source: 6 Type Of Contact: 10 OFFICE OF COMPLIANCE **BASSINETS OR CRADLES Prod**: 1537 NO SECOND PRODUCT INVOLVEMENT Prod: 0 Work Related: N Date Injured: 07/11/2012 Age: 206 Sex: 1 MALE Disposition: 1 1=TREATED & RELEASED, OR EX/Haz Type: 7 ALLERGIC REACTION Brand: MATTEL/FISHER-PRICE Screened?: Model: M# W9443 / NEWBORN ROCK N' PLAYT SOOTHER Narrative: 6 MOM; MOLD HAS FORMED ON THE LINER OF THEIR SLEEPER. CONSUMER BELIEV ES HER SON ACQUIRED A COUGH AND UNEXPLAINABLE VOMITING FROM USAGE WIT HITHIS PRODUCT. THEY HAVE BEEN TO THEIR EMERGENCY ROOM ON THREE OCCAS IONS FOR THIS ISSUE. HER SON RECEIVED A CHEST X-RAY. Document Number: Y1285710A Task Number: Issue: 0 Date Received: 08/16/2012 Confirmed: Date Entered: 08/24/2012 Date Notified: State: NY City: BRONX Type Of Contact: 10 OFFICE OF COMPLIANCE Source: 6 Prod: 1537 BASSINETS OR CRADLES Prod: 0 NO SECOND PRODUCT INVOLVEMENT Date Injured: 07/01/2012 D Work Related: N Sex: 1 MALE Age: 205 Haz Type: 7 ALLERGIC REACTION Disposition: 0 0=NO INJURY Brand: MATTEL/FISHER-PRICE Screened?: Model: M# W9443 / NEWBORN ROCK N' PLAYT SOOTHER Narrative: AGE: 5MONTH(S); WEIGHT: (6)(6) BENDER: MALE; DATE OF INCIDENT: 07/01/2012; INJURY FLAG: NO; EVENT DESCRIPTION: THE CONSUMER EXPRES SED CONCERN THAT WHEN SHE REMOVED THE PAD FROM THE SLEEPER SHE DISCOV

ERED THAT THE BACK OF THE PAD AND THE SEAT WERE COVERED IN MOLD.

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Document Number: Y1285787A Task Number: Issue: 0 Date Received: 08/23/2012 Confirmed: Date Entered: 08/31/2012 Date Notified: City: State: NC Type Of Contact: 10 OFFICE OF COMPLIANCE Source: 6 **BASSINETS OR CRADLES Prod**: 1537 Prod: 0 NO SECOND PRODUCT INVOLVEMENT Work Related: N Date Injured: 01/12/2012 D Age: 202 Sex: 2 FEMALE Disposition: 1 1=TREATED & RELEASED, OR EX/Haz Type: F OTHER Brand: MATTEL/FISHER-PRICE Screened?: Model: M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER Narrative: THE CONSUMER STATED THAT AFTER USING THE PRODUCT FOR TWO MONTHS SHE B EGAN NOTICING A FLAT SPOT ON THE BACK OF 2 MOF'S HEAD. AT HER CHECK-U PITHE DOCTOR DIAGNOSED THE ISSUE AS PLAGIOCEPHALY AND PRESCRIBED HELM ET FOR THE CHILD. Task Number: Document Number: Y1285956A issue: 0 Confirmed: Date Received: 08/30/2012 Date Entered: 09/12/2012 Date Notified : City: (b)(6) State : CA Type Of Contact: 10 OFFICE OF COMPLIANCE Source: 6 **Prod**: 1537 BASSINETS OR CRADLES Prod: 0 NO SECOND PRODUCT INVOLVEMENT Work Related: N Date Injured: 07/19/2012 D Sex: 2 FEMALE Age: 203 Disposition: 1 1=TREATED & RELEASED, OR EX/Haz Type: F OTHER Brand: MATTEL/FISHER-PRICE Screened?: Model: M# V9196 / ROCK 'N PLAY SLEEPER-BUTTERFLY Narrative: AGE AT THE TIME OF INCIDENT: 3MONTH(S); GENDER: FEMALE; DATE OF INCID ENT: 07/19/2012; INJURY LOCATION: HEAD/NECK: THE CONSUMER STATED THA THER DAUGHTER SLEEPS IN THIS PRODUCT EVERY NIGHT AND HAS DEVELOPED T ORTICOLLIS. SHE IS CURRENTLY RECEIVING PHYSICAL THERAPY. Document Number: Y1285978A Task Number: 120910CCC3836 Issue: 0 Date Received: 08/30/2012 Confirmed: Date Entered: 09/07/2012 City: (b)(6) Date Notified : MOUD State : CA Source: 6 Type Of Contact: 10 OFFICE OF COMPLIANCE **Prod**: 1537 **BASSINETS OR CRADLES** NO SECOND PRODUCT INVOLVEMENT Prod: 0 Work Related : N Date Injured: 08/09/2012 Sex: 2 FEMALE Age: 203 Disposition: 1 1=TREATED & RELEASED, OR EX/Haz Type: 7 ALLERGIC REACTION Brand: MATTEL/FISHER-PRICE

Screened?:

Narrative:

3 MO MALE & FEMALE TWINS HAD RESPIRATORY ISSUES & X-RAYED AT HOSPITAL . THEY WERE DIAGNOSED WITH BACTERIAL INFECTION. DOCTOR STATEDIT WAS P ROBABLY DUE TO MOLD ON THE PAD OF THE SLEEPER.

Model: M# W9443 / NEWBORN ROCK N' PLAYT SOOTHER

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Document Number: Y1285980A Task Number: Issue: 0

Date Entered: 09/07/2012 Date Received: 08/30/2012 Confirmed:

Work Related : N

City: (b)(6) Date Notified : State: NJ

Type Of Contact: 10 OFFICE OF COMPLIANCE Source: 6

Prod: 1537 BASSINETS OR CRADLES

NO SECOND PRODUCT INVOLVEMENT Prod: 0

Sex: 1 MALE Age: 204

Disposition: 1 1=TREATED & RELEASED, OR EX/Haz Type: F OTHER

Brand: MATTEL/FISHER-PRICE Screened?: Model: M# X3840 / NEWBORN ROCK 'N PLAY SLEEPERT

Narrative:

Date Injured: 08/23/2012

4 MOM SLEPT IN THE SLEEPER FOR 4 MONTHS COULD NOT RAISE HIS HEAD. PED IATRICIAN DIAGNOSED HIM WITH TORTICOLLIS AND PLAGIOCEPHALY AND PUT IN PHYSICAL THERAPY FOR WEAK NECK MUSCLES. HE HAS UNDERGONE OTHER TEST BEÇAUŞE WEAK MUSÇLES HAVE CAUSED DEVELOPMENTAL DELAYS

Document Number: Y1295523A Task Number: Issue: 0

Date Received: 09/05/2012 Confirmed: Date Entered: 09/13/2012

> Zip: (b) (6) Date Notified: City: (b)(6) State: IL

Type Of Contact: 10 OFFICE OF COMPLIANCE Source: 6

Prod: 1537 BASSINETS OR CRADLES

NO SECOND PRODUCT INVOLVEMENT Prod: 0

Work Related: N Date Injured: 04/01/2012 Age: 202 Sex: 1 MALE

Disposition: 1 1=TREATED & RELEASED, OR EX/Haz Type: F OTHER

Brand: MATTEL/FISHER-PRICE Screened?: Model: M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER

Narrative :

THE CONSUMER STATED THAT HER 2 MONTHS OLD SON SLEPT IN THIS SLEEPER F OR ROUGHLY 5 HRS PER DAY, AT 8 WEEKS OLD THE DOCTOR NOTICED THAT HE O NLY TURNED HIS HEAD TO THE LEFT. AT 12 WEEKS OLD HE HAD A FLAT SPOT O N THE BACK OF HIS HEAD AND WAS DIAGNOSED WITH TORTICOLLIS.

Document Number: Y1295524A Task Number: Issue: 0

Date Received: 09/05/2012 Confirmed: Date Entered: 09/13/2012

City: (b)(6) Date Notified: State: KS

Work Related: N

Source: 6 Type Of Contact: 10 OFFICE OF COMPLIANCE

Prod: 1537 BASSINETS OR CRADLES

NO SECOND PRODUCT INVOLVEMENT Prod: 0

Age: 0 Sex: 0 UNKNOWN

Disposition: 0 (=NÓ INJURY Haz Type: 7 ALLERGIC REACTION

Brand: MATTEL/FISHER-PRICE Screened?: Model: M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER

Narrative:

Date Injured: 08/20/2012

AGE AT THE TIME OF INCIDENT: YEAR(S) MONTH(S); DATE OF INCIDENT: 08/2 0/2012; INJURY FLAG: NO; EVENT DESCRIPTION: THE CONSUMER EXPRESSED CONCERN THAT WHEN SHE REMOVED THE PAD FROM HER SLEEPER FOR LAUNDERING , SHE NOTICED MOLD UNDERNEATH THE PAD.

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3 MILD

Document Number: Y1295525A

Task Number:

Issue: 0

Date Received: 09/05/2012

City: (b)(6)

Confirmed:

Date Entered: 09/13/2012

Source: 6

Type Of Contact: 10 OFFICE OF COMPLIANCE

Date Notified:

Prod: 1537 Prod: 0

BASSINETS OR CRADLES

NO SECOND PRODUCT INVOLVEMENT

State : CA

Date Injured: 08/08/2012

Work Related: N

Age: 203

Disposition: 0 0=NO INJURY

Sex: 1 MALE

Haz Type: 7 ALLERGIC REACTION

Brand : MATTEL > FISHER-PRICE

Screened?:

Model: M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER

Narrative:

AGE AT THE TIME OF INCIDENT: YEAR(S) 3MONTH(S); GENDER: MALE; DATE O F INCIDENT: 08/08/2012: INJURY FLAG: NO: EVENT DESCRIPTION: THE CON

SUMER EXPRESSED CONCERN THAT MOLD FORMED ON THE LINER AND BACK OF THE

SEAT PAD.

Document Number: Y1295526A

Task Number:

Issue: 0

Date Received: 09/05/2012

Confirmed:

Date Entered: 09/13/2012

City: (b)(6)

State: MI Type Of Contact: 10 OFFICE OF COMPLIANCE

Date Notified:

Source: 6 **Prod**: 1537

BASSINETS OR CRADLES

Prod: 0

NO SECOND PRODUCT INVOLVEMENT

Date Injured: 07/15/2012

Work Related: N

Age: 203

Sex: 1 MALE

Disposition: 0 0-NO INJURY

Haz Type: 7 ALLERGIC REACTION

Brand : MATTEL / PISHER-PRICE

Screened?:

Model: M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER

Narrative :

AGE AT THE TIME OF INCIDENT: YEAR(S) 3MONTH(S); GENDER: MALE; THE CO NSUMER EXPRESSED CONCERN THAT WHEN SHE REMOVED THE PAD FROM HER SLEEP ER FOR LAUNDERING, SHE NOTICED MOLD ON THE FABRIC UNDERNEATH, IT DID NOT COME OFF IN THE WASH.

Document Number: Y1295527A

Task Number:

Issue: 0

Date Received: 09/05/2012

Confirmed:

Date Entered: 09/13/2012

City: (b)(6)

State: HI

Zip: Date Notified :

Source: 6

Type Of Contact: 10 OFFICE OF COMPLIANCE

Prod: 1537

BASSINETS OR CRADLES

Prod: 0

NO SECOND PRODUCT INVOLVEMENT

Date Injured: 06/01/2012 D

Work Related: N

Age: 205

Sex: 1 MALE

Disposition: 0 0=NO INJURY

Haz Type: 7 ALLERGIC REACTION

Brand: MATTEL/FISHER-PRICE

Screened?:

Model: M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER

Narrative:

AGE AT THE TIME OF INCIDENT: 0YEAR(S) 5MONTH(S); GENDER: MALE; DATE OF INCIDENT: 06/01/2012; INJURY FLAG: NO; EVENT DESCRIPTION: THE CO NSUMER EXPRESSED CONCERN THAT THE SEAT IS MOLDY AND WILL NOT WIPE CLE AN.

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Document Number: Y1295528A

Task Number:

Issue: 0

Date Received: 09/05/2012

Confirmed:

Date Entered: 09/13/2012

City: ST LOUIS

State: MO

Date Notified :

Source: 6

Type Of Contact: 10 OFFICE OF COMPLIANCE

Prod: 1537

BASSINETS OR CRADLES

Prod: 0

NO SECOND PRODUCT INVOLVEMENT

Date Injured: 07/11/2012 M

Work Related: N

Age: 0

Sex: 0 UNKNOWN

Disposition: 0 0=NO INJURY

Haz Type: 7 ALLERGIC REACTION

Brand: MATTEL/FISHER-PRICE

Screened?:

Model: M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER

Narrative:

THE CONSUMER EXPRESSED CONCERN THAT THERE IS MOUD ON THE LINER.

Document Number: Y1295529A

City: HUNTINGTON BEACH

Task Number:

Issue: 0 Date Entered: 09/13/2012

Date Received: 09/05/2012

Confirmed:

State: CA

Date Notified:

Source: 6

Type Of Contact: 10 OFFICE OF COMPLIANCE

Prod: 1537

BASSINETS OR CRADLES

Prod: 0 Date Injured: 06/12/2012 M

NO SECOND PRODUCT INVOLVEMENT Work Related: N

Age: 202

Sex: 0 UNKNOWN Haz Type: 7 ALLERGIC REACTION

Disposition: 0 0=NO INJURY

Brand: MATTEL / FISHER-PRICE

Screened?:

Model: M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER

Narrative :

THE CONSUMER EXPRESSED CONCERN THAT THE LINER IS MOLDY.

Document Number: Y1295530A

Task Number:

issue: 0

Date Received: 09/05/2012

Confirmed:

Date Entered: 09/11/2012

City: (b)(6)

State: TX

Date Notified:

Source: 6

Type Of Contact: 10 OFFICE OF COMPLIANCE

Prod: 1537

BASSINETS OR CRADLES

Prod: 0

NO SECOND PRODUCT INVOLVEMENT

Date Injured: 04/19/2012 D

Work Related: N

Age: 208

Sex: 0 UNKNOWN

Disposition: 0 0=NO INJURY

Haz Type: 7 ALLERGIC REACTION

Brand: MATTEL/FISHER-PRICE

Screened?:

Model: M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER

Narrative: THE CONSUMER EXPRESSED CONCERN THAT THE LINER IS MOLDY. 8 moul

7 model

6 wold

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Document Number: Y1295531A Task Number: 120913CCC3860 Issue: 0 Date Received: 09/05/2012 Confirmed: Date Entered: 09/11/2012 State: TX Zip: Date Notified: City: HOUSTON Type Of Contact: 10 OFFICE OF COMPLIANCE Source: 6 BASSINETS OR CRADLES **Prod**: 1537 NO SECOND PRODUCT INVOLVEMENT Prod: 0 Work Related : N Date Injured: 02/24/2012 9 mod Sex: 1 MALE Age: 0 Disposition: 1 1=TREATED & RELEASED, OR EX Haz Type: 7 ALLERGIC REACTION Brand : MATTEL FISHER PRICE Screened?: Model: M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER Narrative: THE CONSUMER EXPRESSED CONCERN THAT MOLD IS FORMING ON THE LINER. SH E BELIEVES THIS HAS CAUSED HER SON TO BE SICK WITH RESPIRATORY ISSUES FOR FIVE WEEKS. HE HAS BEEN TO THE DOCTORS ON THREE OCCASIONS FOR T HIS ISSUE. Document Number: Y1295532A Task Number: Issue: 0 Date Received: 09/05/2012 Confirmed: Date Entered: 09/11/2012 City: (b)(6) State: NJ Date Notified: Type Of Contact: 10 OFFICE OF COMPLIANCE Source: 6 BASSINETS OR CRADLES Prod: 1537 10 mall NO SECOND PRODUCT INVOLVEMENT Prod: 0 Work Related: N Date Injured: 01/16/2012 Age: 208 Sex: 0 UNKNOWN Haz Type: 7 ALLERGIC REACTION Disposition: 0 0=NO INJURY Brand: MATTEL / FISHER-PRICE Screened?: Model: M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER Narrative: THE CONSUMER EXPRESSED CONCERN THAT THERE IS MOLD ON THE SEAT AND STR APS NEAR THE SEAT. Task Number: 120914CCC1972 Issue: 0 Date Received : 09/05/2012 Confirmed: Date Entered: 09/11/2012

Document Number: Y1295533A

City: (b)(6) State : PA Date Notified: Zip: Type Of Contact: 10 OFFICE OF COMPLIANCE Source: 6

Prod: 1537 BASSINETS OR CRADLES

Prod: 0 NO SECOND PRODUCT INVOLVEMENT

Work Related : N Date Injured: 12/01/2011 D

Disposition: 1 1=TREATED & RELEASED, OB EX/Haz Type: 7 ALLERGIC REACTION

Sex: 1 MALE

Brand: MATTEL/FISHER-PRICE Screened?: Model: M# R6070 / NEWBORN ROCK 'N PLAY SLEEPER

Narrative:

Age: 202

CONSUMER STATED THAT HER 2 MONTH OLD SON HAD FEVERS & VOMITING SO SHE TOOK HIM TO THE DOCTOR AND HE TOLD HER THAT THE CHILD WAS SICK DUE T O MOLD. UPON INSPECTION OF THE SLEEPER SHE DISCOVERED THAT THE PAD H AS BLACK MOLD ON IT WHERE THE CHILD'S BOTTOM SITS.

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Document Number :	Y1295628A		Task Number :	:			Issue :	0		
Date Received :			Confirmed :	:		(b) (c)	Date Entered :	09/15/2012		
City:	(b)(6)		State :	: AL	Zip :	(b) (b)	Date Notified :			
Source :	6	7	ype Of Contact:	: 10 OF	FICE O	F COMPL	LIANCE			
Prod :	1537	BASSI	NETS OR CRADLE	ES						
Prod :	0	NO SE	COND PRODUCT	INVOLVE	MENT					
Date Injured :	07/01/2012	D	Work Rela	ated : N					U	j
Age :				Sex: 1	MALE				U	
NOVEN NO 50			ELEASED, OR EXA	Haz Type	:F	OTHER				
Brand :	MATTEL/FI	SHER-P	RICE	Screene	d? :					
Model :	M# R6070 / N	VEWBO	RN ROCK 'N PLAY	SLEEPER	₹					
Narrative: THE CONSUMER ST. OCEPHALY AND TOR APS DURING THE D. ANIAL BAND.	RTICOLLIS. H	E SLEP	TIN THIS PRODUC	OT AT NIG	HT AND	FOR N				
Document Number :	Y1295923A		Task Number :	:	20250 - 240	3340705-3223	Issue :	0	- 0	
Date Received :	09/27/2012		Confirmed:	:		(b) (6)	Date Entered :	10/03/2012		
City:	(b)(6)		State :	: LA	Zip:	(D) (U)	Date Notified :			
Source :	6	1	Type Of Contact	: 10 OF	FICE O	F COMPI	LIANCE			
Prod :	1537	BASSI	NETS OR CRADLE	ES						10
Prod :	0	NO SE	COND PRODUCT	INVOLVE	MENT					Let.
Date Injured :	09/19/2012	D	Work Rela	ated : N					17	mold.
Age :	204	00-00		Sex: 1	MALE					
Disposition	4 4=TREAT	ED & AD	MITTED FOR HO	Haz Type	; 7	ALLERGI	IC REACTION			
Brand:	FISHER PRI	CE / MA	TTEL/EISHER-PF	Screene	d? :					
Model :	M# W9442 /	NEWBO	RN ROCK 'N PLAY	SLEEPE	RT					
Narrative : THE CONSUMER ST	ATED THAT S	HE BEN	MOVED THE PAD T	O WASH	IT WHE	N SHE N	IOTI			
CED THAT THERE W							100-100-1			
BELIEVES THE MOL	D IN THE PRO	DOUCT	CONTRIBUTED TO	HER 4 M	OM INF	ANT'S H	E			
ALTH ISSUES. HE SI	JFFERS FRO	M INTES	STINAL ISSUES & 1	WAS HOS	PITALIZ	ZED.				
Document Number :	Y12A5460A		Task Number :	: 121025C	CC206	2	Issue :	0		
Date Received :	10/04/2012		Confirmed:	:		(b) (6)	Date Entered :	10/12/2012		
City:	(b)(6)		State	: MN	Zip:	(b) (b)	Date Notified :			
Source :	6	7	ype Of Contact	: 10 O F	FICE O	F COMP	LIANCE			
Prod :	1537	BASSI	NETS OR CRADLE	S						
Prod :	1542	BABY	MATTRESSES OR	PADS						٨
Date Injured :	09/24/2012	D	Work Rela	ated: U					ł	well
Age :	208			Sex: 1	MALE				13	ጥ
Disposition :	1 1=PREAT	ED & RE	ELEASED, OR EXA	Hay Type	:6	POISON	ING			
Brand :	MARTEL/FI	SHER-P	RICE	Screene	d? :					
Model :	M# R6070 / N	VEWBO	RN ROCK 'N PLAY	SLEEPER	}					
Narrative :										

CONSUMER STATED THAT HIS 8-MONTH-OLD SON WAS TAKEN TO THE HOSPITAL FO R BREATHING PROBLEMS. THEY DID AN XRAY, A MUCOUS LAB TEST, ADMINISTER ED STEROIDS AND A NEBULIZER TREATMENT. WHEN THEY GOT HOME AND REMOVED THE PAD FOR LAUNDERING THEY NOTICED MOLD ON THE SEAT.

U.S. Consumer Product Safety Commission **National Injury Information Clearinghouse**

11/2/2012

Page 19

Document Number: Y12A5752A

Task Number:

Issue: 0

Date Received: 10/24/2012

Confirmed:

Date Entered: 10/26/2012

City: HUNTINGTON BEACH

Type Of Contact: 10 OFFICE OF COMPLIANCE

Date Notified:

Source: 6

Prod: 1537 Prod: 0

BASSINETS OR CRADLES

NO SECOND PRODUCT INVOLVEMENT

Work Related: N

State: CA

Age: 205

Sex: 2 FEMALE

Disposition: 0 0=NO INJURY

Haz Type: 7 ALLERGIC REACTION

Date Injured: 10/14/2012 D

Brand: MATTEL/FISHER-PRICE

Screened?:

Model: M# W9443 / NEWBORN ROCK N' PLAYT SOOTHER

Narrative:

AGE AT THE TIME OF INCIDENT: YEAR(S) 5MONTH(S); WEIGHT AT THE TIME OF

GENDER: FEMALE; DATE OF INCIDENT: 10/14/2012; I NJURY FLAG: NO; EVENT DESCRIPTION: THE CONSUMER EXPRESSED CONCERN

THAT THERE WAS MOLD ON THE SEAT OF THE SLEEPER.

14 mild

U.S. Consumer Product Safety Commission **National Injury Information Clearinghouse**

11/2/2012

Page 1

Issue: 0

Document Number: 11230273A

Date Received: 03/13/2012

City: (b)(6)

Source:

Task Number:

Confirmed:

Date Entered: 03/15/2012

State : CA Type Of Contact: 21 CONSUMER COMPLAINTS

Zip : (b) (6) Date Notified :

BABY BOUNCER SEATS (EXCL. JUMPERS)

NO SECOND PRODUCT INVOLVEMENT

Date Injured: 01/10/2012

Work Related : N

Age: 205

Sex:1

Disposition: 1 1=TREATED & RELEASED, OR EX/Haz Type: F OTHER

Brand: FISHER PRICE / FISHER-PRICE BRAIScreened?:

Model: FISHER PRICE ROCK'N PLAY SLEEPER V9102 V9196 V9197 /SN 0097

Narrative:

A 5 MOM'S HEAD WAS DAMAGED FROM THE ROCKER/ SLEEPER. THE CHILD SLEPT IN THE SLEEPER UNTIL HE WAS DIAGNOSED WITH OCCIPITAL PLAGIOCEPHALY. THE SURGEON PRESCRIBED HELMET TO RESHAPE HIS HEAD. AS PER CALLER, TH E SLEEPER HAD A HARD SHELL AS WELL AS NO ROOM FOR HEAD MOVEMENT.

FOR OFFICIAL USE ONLY



TO: Theresa Nelson, CRC FROM: Angie Qin, EPHA

DATE: 11/19/12

RE: Data Review for PSA # 0120.13 Case # CA120159

Date due: 11/20/12

Priority: c

Request: Data search for all incidents regarding Fisher-Price Rock 'N Play Sleeper Hazard Pattern: Development of mold in plastic liner is harmful to infant's respiratory system. Also incidents of head plagiocephaly and neck torticollis reported from infant's

(b)(5)

lying on their back in sleeper.

Selection Criteria:

Product Code(s): 1549 1537 1558 1529 1543

Manufacturer/Model Text: fisher-price/fisher price/sleeper

Narrative Text:

Time Frame: <19/2012-11/9/2012 date of entry)

NFIRS Search Criteria: N/A

Incidents Identified:

	Incident Count*	3 5 °
Databases	(see notes below)	Death Count*
Incident Investigations (INDP)	0	0
Reported Incidents (IPII)	47	0
Death Certificates (DTHS)	0	0
NEISS reports (count)	N/A	N/A
Fire reports (NFIRS)	N/A	N/A
Total	¥ 47	0

^{*} For INDP, IPII and DTHS, duplicate reports have been removed, i.e. counted only once, in the database listed first The reports enumerated in the table have been identified from CPSC databases on the date the search was completed These should be considered neither a statistical sample nor a complete count of all such incidents, but only a count o those in CPSC databases on the search date.

NOTES:

Search found 47 incidents involving Fisher-Price Rock 'N Play Sleepers (including 1 RNP Sleeper-circles). Of these, 12 incidents were related to head plagiocephaly and/or neck torticollis and 35 incidents were related to mold

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CA	MO	Ξ	<u>×</u>	CA	Š
3 MO MALE & FEMALE TWINS HAD RESPIRATORY ISSUES & X-RAYED AT HOSPITAL, THEY WERE DIAGNOSED WITH BACTERIAL INFECTION, DOCTOR STATEDIT WAS PROBABLY DUE TO MOLD ON THE PAD OF THE SLEEPER.	6 MOM; MOLD HAS FORMED ON THE LINER OF THEIR SLEEPER. CONSUMER BELIEVES HER SON ACQUIRED A COUGH AND UNEXPLAINABLE VOMITING FROM USAGE WITH THIS PRODUCT. THEY HAVE BEEN TO THEIR EMERGENCY ROOM ON THREE OCCASIONS FOR THIS ISSUE. HER SON RECEIVED A CHEST X-RAY.	THE CONSUMER STATED THAT SHE REMOVED THE PAD TO WASH IT WHEN SHE NOTICED THAT THERE WAS MOLD GROWING UNDER THE PAD ON THE SEAT LINER. SHEBELIEVES THE MOLD IN THE PRODUCT CONTRIBUTED TO HER 4 MOM INFANT'S HEALTH ISSUES. HE SUFFERS FROM INTESTINAL ISSUES & WAS HOSPITALIZED.	CONSUMER STATED THAT HIS 8-MONTH-OLD SON WAS TAKEN TO THE HOSPITAL FOR BREATHING PROBLEMS. THEY DID AN XRAY, A MUCOUS LAB TEST, ADMINISTERED STEROIDS AND A NEBULIZER TREATMENT. WHEN THEY GOT HOME AND REMOVED THE PAD FOR LAUNDERING THEY NOTICED MOLD ON THE SEAT.	CONSUMER STATED THAT HER 2 MONTH OLD SON HAD FEVERS & VOMITING SO SHE TOOK HIM TO THE DOCTOR AND HE TOLD HER THAT THE CHILD WAS SICK DUE TO MOLD. UPON INSPECTION OF THE SLEEPER SHE DISCOVERED THAT THE PAD HAS BLACK MOLD ON IT WHERE THE CHILD'S BOTTOM SITS.	THE CONSUMER EXPRESSED CONCERN THAT MOLD IS FORMING ON THE LINER. SHE BELIEVES THIS HAS CAUSED HER SON TO BE SICK WITH RESPIRATORY ISSUES FOR FIVE WEEKS. HE HAS BEEN TO THE DOCTORS ON THREE OCCASIONS FOR THIS ISSUE.
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AGE 4MONTH(S); WEIGHT (S) MALE; DATE OF INCIDENT: 07/29/2012; THE CONSUMER EXPRESSED CONCERN THAT WHEN SHE REMOVED THE PAD TO WASH IT SHE DISCOVERED THAT THE SEAT IS MOLDY. SHE TRIED TO CLEAN IT WITH BLEACH BUT THE MOLD WILL NOT COME OUT.	PRODUCT IN CONSUMER POSSESSION: YES; AGE AT THE TIME OF INCIDENT: 0YEAR(S) BMONTH(S); WEIGHT AT THE TIME OF INCIDENT: 17LBS 0OZ; GENDER:MALE; DATE OF INCIDENT: 06/01/2012; INJURY FLAG: NO; EVENT DESCRIPTION: THE CONSUMER EXPRESSED CONCERN THAT MOLD HAS FORMED ON THE LINER	AGE AT THE TIME OF INCIDENT: YEAR(S) 4MONTH(S); WEIGHT AT THE TIME OF INCIDENT: 14LBS 0OZ; GENDER: MALE; DATE DF INCIDENT: 08/02/2012; EVENT DESCRIPTION: THE CONSUMER EXPRESSED CONCERN BECAUSE HIS WIFE FOUND BLACK MOLD ON THE SEAT FABRIC UNDER THE PAD	AGE: 7 MONTH(S); GENDER: FEMALE; DATE OF INCIDENT: 08/08/2012; INJURY FLAG: NO; EVENT DESCRIPTION: THE CONSUMER EXPRESSED CONCERN THAT SHE REMOVED THE THE PAD FOR LAUNDERING AND NOTICED MOLD ON THE PAD AND SEAT. SHE OWNS TWO AND IS NOTICING THE SAME ISSUE WITH EACH ONE.	AGE: YEAR(S) MONTH(S); GENDER: ; DATE OF INCIDENT: 08/08/2012; INJURY FLAG: NO; EVENT DESCRIPTION: THE CONSUMER EXPRESSED CONCERN THAT SHE REMOVED THE THE PAD FOR LAUNDERING AND NOTICED MOLD ON THE PAD AND SEAT. SHE OWNS TWO AND IS NOTICING THE SAME ISSUE WITH EACH ONE.
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	AGE AT THE TIME OF INCIDENT: 0YEAR(S) 6MONTH(S); WEIGHT AT THE TIME OF INCIDENT: 0LBS 0OZ; GENDER: MALE; DATE OF INCIDENT: 07/15/2012; INJURY FLAG: NO; EVENT DESCRIPTION: THE CONSUMER STATED THAT BLACK MOLD HAS GROWN ON THE SEAT LINER.	AGE AT THE TIME OF INCIDENT: YEAR(S) MONTH(S); WEIGHT AT THE TIME OFINCIDENT: OLBS 0OZ; GENDER: ; DATE OF INCIDENT: INJURY FLAG: NO; EVENT DESCRIPTION: THE CONSUMER EXPRESSED CONCERN THAT THERE IS MOLD ON THE SEAT.	AGE AT THE TIME OF INCIDENT: YEAR(S) 5MONTH(S); WEIGHT AT THE TIME OF INCIDENT BENDER: FEMALE; DATE OF INCIDENT: 10/14/2012; INJURY FLAG; EXPRESSED CONCERNTHAT THERE WAS MOLD ON THE SEAT OF THE SLEEPER.	THE CONSUMER EXPRESSED CONCERN BECAUSE SHE REMOVED THE PAD TO WASH IT FOR THE FIRST TIME AND SHE FOUND BLACK COLORED MOLD GROWING ON THE SEAT LINER. WA	THE CONSUMER EXPRESSED CONCERN THAT THERE IS MOLD ON THE LINER OF THE PRODUCT.	AGE: 5MONTH(S); WEIGHT: 13LBS 12OZ; GENDER: MALE; DATE OF INCIDENT: 07/01/2012; INJURY FLAG: NO; EVENT DESCRIPTION: THE CONSUMER EXPRESSED CONCERN THAT WHEN SHE REMOVED THE PAD FROM THE SLEEPER SHE DISCOVERED THAT THE BACK OF THE PAD AND THE SEAT WERE COVERED IN MOLD.	AGE: 3MONTH(S); WEIGHT (S)

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AGE: 2MONTH(S); WEIGHT: 12LBS GENDER: FEMALE; DATE OF INCIDENT:09/01/2012; THE PAD IS WAS NOTICED WHEN CONSUMER REMOVEDTHE PAD FOR LAUNDER	THET (H(S); W (NT:(0); W (DENT: DESCP (SSED C	EAR(S) ENDER 1012; IN. RIPTION RIED TO DELACK JCT.	T THE T	AGE AT THE TI 3MONTH(S); W INCIDENT: (S) OF INCIDENT: (S) EVENT DESCH EVENT DESCH EXPRESSED C ON THE SEAT.	WASHI WASHI VERED OTTOM OTTOM AS BEE HE HAS S.
AGE: 2MONTH(S); WEIGHT: 12LBS GENDER: FEMALE; DATE OF INCIDENT:09/01/2012; THE PAD IS I WAS NOTICED WHEN CONSUMER REMOVEDTHE PAD FOR LAUNDER MOI D IS I OCATED ON THE SFAT	AGE AT THE TIME OF INCIDENT: 0 #MONTH(S); WEIGHT AT THE TIME INCIDENT: OB 002: GENDER: N OF INCIDENT: 08/01/2012: INJURY EVENT DESCRIPTION: THE CONS EXPRESSED CONCERN THAT THE ON THE LINER OF THE PROCUCT	AGE: YEAR(S) 6MONTH(S); WE 00Z; GENDER: MALE; DATE OI 09/16/2012; INJURY FLAG: NO: DESCRIPTION: THE FOLLOW! REPORTED TO US BY E-MAIL. CONSUMER EXPRESSED CON FOUND BLACK MOLD ON THE PRODUCT.	IME OF VEIGHT DOZ: 09/27/2 RIPTION CONCEF	TO/O6/2	XPRESING THE MOLD OF SHE IS N SLEEE HAD BE
IGHT: 1 ATE OF THE PATE OF I CONSI OF LAU	AT THE AT THE O12; INU O12; INU E PROCE	H(S); WDATE (DATE (COLLOW) COLLOW COLLOW ON THE	INCIDE AT THE GENDE 012; INC 1: THE O RN THA:	INCIDE AT THE O12; INC O12; INC THE O	SED CC E PROD ON THE S FRUST PING O
AGE: 2MONTH(S); WEIGHT: 12LBS 0OZ; GENDER: FEMALE; DATE OF INCIDENT:09/01/2012; THE PAD IS MOLDY. T WAS NOTICED WHEN CONSUMER REMOVEDTHE PAD FOR LAUNDERING. THE	AGE AT THE TIME OF INCIDENT: 0YEAR(S) 4MONTH(S); WEIGHT AT THE TIME OF INCIDENT: 08/01/2012; INJURY FLAG: N EVENT DESCRIPTION: THE CONSUMER EXPRESSED CONCERN THAT THERE IS MON THE LINER OF THE PROCUCT	AGE: YEAR(S) 6MONTH(S); WEIGHT: 16LBS 00Z; GENDER. MALE; DATE OF INCIDENT: 09/16/2012; INJURY FLAG: NO; EVENT DESCRIPTION: THE FOLLOWING WAS REPORTED TO US BY E-MAIL. THE CONSUMER EXPRESSED CONCERN THAT. FOUND BLACK MOLD ON THE LINER OF TH PRODUCT.	AGE AT THE TIME OF INCIDENT: 0YEAR(S) 2MONTH(S); WEIGHT AT THE TIME OF INCIDENT: 09 20 20 20 20 20 20 20 20 20 20 20 20 20	AGE AT THE TIME OF INCIDENT: 0YEAR(S) 3MONTH(S); WEIGHT AT THE TIME OF INCIDENT: MALE; DA OF INCIDENT: 10706/2012; INJURY FLAG: NEVENT DESCRIPTION: THE CONSUMER EXPRESSED CONCERN THAT THERE IS MON THE SEAT.	CONSUMER EXPRESSED CONCERN THAT WHILE WASHING THE PRODUCT SHE DISCOVERED MOLD ON THE SEAT STRAPS AND BOTTOM. SHE IS FRUSTRATED THAT HE SON HAS BEEN SLEEPING ON MOLD AND SAYS HE HAS HAD BREATHING ISSUES FOR NIGHTS.
AGE: 2MONTH(S); WEIGHT: 12LBS 0OZ; GENDER: FEMALE; DATE OF INCIDENT:09/01/2012; THE PAD IS MOLDY. THIS WAS NOTICED WHEN CONSUMER REMOVEDTHE PAD FOR LAUNDERING. THE MOLD IS LOCATED ON THE SEAT.	AGE AT THE TIME OF INCIDENT: 0YEAR(S) 4MONTH(S); WEIGHT AT THE TIME OF INCIDENT: (Soc) \$002; GENDER: MALE; DATE OF INCIDENT: 08/01/2012; INJURY FLAG: NO; EVENT DESCRIPTION: THE CONSUMER EXPRESSED CONCERN THAT THERE IS MOLD ON THE LINER OF THE PROCUCT	AGE: YEAR(S) 6MONTH(S); WEIGHT: 16LBS 00Z; GENDER: MALE; DATE OF INCIDENT: 09/16/2012; INJURY FLAG: NO; EVENT DESCRIPTION: THE FOLLOWING WAS REPORTED TO US BY E-MAIL. THE CONSUMER EXPRESSED CONCERN THAT SHE FOUND BLACK MOLD ON THE LINER OF THE PRODUCT.	AGE AT THE TIME OF INCIDENT: 0YEAR(S) 2MONTH(S); WEIGHT AT THE TIME OF INCIDENT: ⑤⑤ DOZ; GENDER: FEMALE; DATE OF INCIDENT: 09/27/2012; INJURY FLAG: NO; EVENT DESCRIPTION: THE CONSUMER EXPRESSED CONCERN THAT MOLD HAS FORMED ON THE LINER OF THE PRODUCT	AGE AT THE TIME OF INCIDENT: 0YEAR(S) 3MONTH(S); WEIGHT AT THE TIME OF INCIDENT: 500 DOZ; GENDER: MALE; DATE OF INCIDENT: 10706/2012; INJURY FLAG : NO; EVENT DESCRIPTION : THE CONSUMER EXPRESSED CONCERN THAT THERE IS MOLD ON THE SEAT.	CONSUMER EXPRESSED CONCERN THAT WHILE WASHING THE PRODUCT SHE WHILE WASHING THE PRODUCT SHE DISCOVERED MOLD ON THE SEAT STRAPS AND BOTTOM. SHE IS FRUSTRATED THAT HER SON HAS BEEN SLEEPING ON MOLD AND SAYS HE HAS HAD BREATHING ISSUES FOR3 NIGHTS.
S S	D THE	mojd m	mold TE	D SE	्छ ER
) Mr.		<u> </u>		
	1				

Page 326

Y12A5761, IPII 10/27/2012 8/1/2012 1537 MATTEL / FIS M# W9443 / NEWBORN ROCK N CA AGE AT THE TIME OF INCIDENT: 0YEAR(S)

3MONTH(S): WEIGHT AT THE TIME OF
INCIDENT GENDER: FEMALE;
DATE OF INCIDENT: 08/01/2012;INJURY FLAG:
NO; EVENT DESCRIPTION: THE CONSUMER
EXPRESSED CONCERNITHAT THE LINER HAD
MOLD ON IT. mold

	****FOR OFFICIAL USE ONLY****	*****				PSA ACTION (FOR PSA COORDINATOR USE ONLY)	OR PSA USE ONLY)
PRODUCT S	PRODUCT SAFETY ASSESSMENT (PSA) TECHNICAL EVALUATION REQUEST	INICAL I	EVALUATIO	N REQU	EST	PSA Number	: 0120.13
1				•		Date Processed	: 11/5/12
Requested by :Theresa	:Theresa Nelson, (301) 504-7509	Org. Code	e :CRC	Field Off	FOER	Date Requested	: 11/20/12
Date Submitted : 11/2/2012	012	Priority	:c	Case #	:CA120159	Due Date:	
Pruested Completion Date	: 11/20/2012						
PRODUCT INFORMATION:	ON:					Assigned to	
Manufacturer :Fishe	:Fisher-Price, Inc.		City :East Aurora	72	State :NY	Organization:	: EP
Product :Fisher-Pi	:Fisher-Price Rock 'N Play Sleeper		NEISS Code	:1549 , 1537, 1558. 1529, 1543	7, 1558,	Technical Off.	••
Brand name, model, etc.	: Fisher-Price					Request Summary:	.:
Sample number :						•	
Sample Disposition:	Return to RequesterStore at Warehouse	se	_Other :			•	
IDI Number :							
EVALUATION REQUES name Rock N' Play Sle	EVALUATION REQUESTED: HA – Conduct a data search for all incidents using the following criteria: Fisher Price, name Rock N' Play Sleeper (any model) entered between 8/9/2012 and 11/2/2012.	ents using th nd 11/2/201	he following crite	ria: Fisher	Price,	Comments:	
Lase refer to PSA# 0	ase refer to PSA# 0873.12 and use same criteria except dates of Time Frame	ime Frame.	Workers of the control of the contro				
EPI ASSESSMENT: Dates:	From 8/9/2012 To :11/2/2012	Sort by Mfg.:	X Yes _No	lo		•	
X IDI X IPI	_NEISS CommentsNEISS Estimates		X Death	NFIRS			
HAZARD : Develop system. / from infa	: Development of mold in plastic liner is harmful to infant's respiratory system. Also incidents of head plagiocephaly and neck torticollis reported from infant's lying on their back in sleeper.	iratory is reported	HAZARD CODE	: 203			
LOCATIONS OF	Samples: SSF	Files:				(MSWordRe	(MSWordRev 2/99 rp/jb/bh)
MOCKETON OF	The same of the sa					_	



FOR OFFICIAL USE ONLY



UNITED STATES **CONSUMER PRODUCT SAFETY COMMISSION** WASHINGTON, DC 20207 DIRECTORATE FOR EPIDEMIOLOGY

.00.

TO: Theresa Nelson, CRC FROM: Angie Qin, EPHA

DATE: 8/17/12

RE: Data Review for PSA #10873.12 G

ase # PI110066

Date due: 8/17/12 (scheduled as fast track)

Priority: c

Request: Data search for all incidents regarding Fisher-Price Rock 'N Play Sleeper

Hazard Pattern: Concern of infant's developing head plagiocephaly and/or neck torticollis from sleeping in product; also development of mold in plastic liner could be harmful to

infants.

Selection Criteria:

Product Code(s): 1549 1537 1558 1529 1543

Manufacturer/Model Text: fisher-price/fisher price/sleeper

Narrative Text:

Time Frame 6/1/09-8/8/12 NFIRS Search Criteria: N/A

Incidents Identified:

Databases	Incident Count* (see notes below)	Death Count*
Incident Investigations (INDP)	6	0
Reported Incidents (IPII)	83	0
Death Certificates (DTHS)	0	0
NEISS reports (count)	N/A	N/A
Fire reports (NFIRS)	N/A	N/A
Total	(89)	0

^{*} For INDP, IPH and DTHS, duplicate reports have been removed, i.e. counted only once, in the database listed first. The reports enumerated in the table have been identified from CPSC databases on the date the search was completed. These should be considered neither a statistical sample nor a complete count of all such incidents, but only a count of those in CPSC databases on the search date.

NOTES:

Search found 89 incidents involving Fisher-Price Rock 'N Play Sleepers (including 8 RNP Sleeper-circles).



FOR OFFICIAL USE ONLY



TO: Theresa Nelson, CRC FROM: Angie Qin, EPHA

DATE: 1/30/12

RE: Data Review for PSA # 0305.12 Case # PI110066

Date due:(2/3/12

Priority: c

Request: Data search for all incidents involving Fisher-Price Rock 'N Play Sleeper

Hazard Pattern: Concern of infant's developing head plagiocephaly and/or neck torticollis from sleeping in product, also development of mold in plastic liner could be harmful to

infants

Selection Criteria:

Product Code(s):

Manufacturer/Model Text: fisher-price/fisher price/sleeper

Narrative Text:

Time Frame (5/1/10)1/24/12

NFIRS Search Criteria: N/A

Incidents Identified:

Databases	Incident Count* (see notes below)	Death Count*
Incident Investigations (INDP)	6	0
Reported Incidents (IPII)	43	0
Death Certificates (DTHS)	N/A	N/A
NEISS reports (count)	N/A	N/A
Fire reports (NFIRS)	N/A	N/A
Total	49,)	0

^{*} For INDP, IPII and DTHS, duplicate reports have been removed, i.e. counted only once, in the database listed first. The reports enumerated in the table have been identified from CPSC databases on the date the search was completed. These should be considered neither a statistical sample nor a complete count of all such incidents, but only a count of those in CPSC databases on the search date.

NOTES:

Search found 49 incidents involving Fisher-Price Rock 'N Play Sleeper. Incidents that could be determined to have duplicate reports are counted only once and noted on the spreadsheets.

		****FO	****FOR OFFICIAL USE ONLY***	- 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1		PSA ACTION (FOR PSA COORDINATOR USE ONLY)	OR PSA USE ONLY)
TIGORG		PRODUCT CAFFTV ASSESSMFNT (PSA)		TECHNICAL EVALUATION REQUEST	N REOUEST	PSA Number	(:0305.12)
CONT						Date Processed	:1725/12
Requested by	:Theresa No	:Theresa Nelson, (301) 504-7509	Org.	Org. Code :CRC	Field Off :FOER	Date Requested	: 2/3/12
Date Submitted :	: 1/25/2012		Priority	ity :c	Case # :PI110066	Due Date:	••
Requested Completion Date	tion Date	: 2/3/2012					
PRODUCT INFORMATION:	RMATIO	7				Assigned to	•
Manufacturer	:Fisher-P	Fisher-Price, Inc.		City :East Aurora	rora State :NY	Organization:	: EP
Product :F	Fisher-Price	Fisher-Price Rock 'N Play Sleeper		NEISS Code	:1549, 1537, 1558	Technical Off.	
Brand name, model, etc.	l, etc.	: Fisher-Price				Request Summary:	<i>y</i> :
Sample number							
Sample Disposition:		Return to Requester	Store at Warehouse	Other :			
IDI Number		•					
EVALUATION R. 1549, 1537,1558	REQUESTI 8 between	EVALUATION REQUESTED HA 2 Conduct a data search for a 1549, 1537,1558 between 6/172009 to 1/25/2012, name Rock	EVALUATION REQUESTED (HA 2 Conduct a data search for all incidents using the following criteria: Fisher Price, PC 1549, 1537,1558 between 6/172009 to 1/25/2012, name Rock N' Play Sleeper (any model).	ig the following cri (any model).	teria: Fisher Price, PC	Comments:	•
EPI ASSESSMENT: Dates:	VT: Dates:	From : 6/1/2009	To : 1/25/2012 Sort by Mfg.:	X Yes	No		
XIDI	X IPI	NEISS Comments	NEISS Estimates	X Death	_NFIRS	Ī	
HAZARD :C	Concern of infant from sleeping in p harmful to infants.	:Concern of infant's developing head plagiocephaly and from sleeping in product. Also development of mold in harmful to infants.	Concern of infant's developing head plagiocephaly and/or neck torticollis from sleeping in product. Also development of mold in plastic liner could be harmful to infants.	HAZARD CODE	: 203		
LOCATIONS OF		Samples: SSF	Files:	:8		(MSWordR	(MSWordRev 2/99 m/jb/bh)

Nelson, Theresa

From:

Nelson, Theresa

Sent:

Friday, September 07, 2012 8:46 AM

To:

Pilarz, Kitty (Kitty.Pilarz@Fisher-Price.com)

Cc:

Moore, Kelly; Rauchschwalbe, Renae; Simmons, Scott; Schoem, Marc

Subject:

PD letter re Rock N Play Sleeper CA120159

Attachments:

PDltr8-6-12.pdf

Kitty

The attached letter explains the Commission staff's decision of a Preliminary Determination that the exposure of "mold growth" on the Rock 'N Play Sleeper presents a substantial product hazard under section 15(a) of the Consumer Product Safety Act and the Federal Substances Act.

This letter is also being sent to you via FedEx (tracking number #8770 5220 2947) and will be delivered today, Friday, September 7, 2012. We look forward to receiving the firm's corrective action plan (CAP) by Friday, September 21, 2012.

Regards, Terri

Terri Nelson

Compliance Officer
Office of Compliance & Field Operations
U.S. Consumer Product Safety Commission
Phone: 301-504-7509 or
1-800-638-8095 ext. 7509

Fax: 301-504-0359 tnelson@cpsc.gov

SIGN UP FOR RECALL NOTICES: http://www.cpsc.gov/cpsclist.aspx

SENCER: COMPLETE THIS SECTION	COMPLETE THIS SECTION ON DELIVERY
Complete items 1, 2, and 3. Also complete item 4 if Restricted Delivery is desired. Print your name and address on the reverse so that we can return the card to you. Attach this card to the back of the mailpiece, or on the front if space permits.	A. Signature X
Partner Goldberg Segalla Ms. Cheryl Possenti, Esq. 665 Main St, Ste 400	3. Sendoe Type Certified Meil
Buffalo NY 14203	☐ Registered ☐ Return Receipt for Merchandise ☐ Insured Mail ☐ C.O.D.
	4. Restricted Delivery? (Extra Fee) ☐ Yes
2. Article Number	



U.S. CONSUMER PRODUCT SAFETY COMMISSION 4330 EAST WEST HIGHWAY BETHESDA, MD 20814

Office of Compliance and Field Operations

Defect Investigations Division Email: tnelson@cpsc.gov

SEP - 6 2012

Theresa Nelson Compliance Officer Tel: 301-504-7509 Fax: 301-504-0060

Via Certified Mail/Email: Kitty.Pilarz@Fisher-Price.com

Ms. Kitty Pilarz
Senior Director,
Product Safety and Regulatory Affairs
Fisher-Price, Inc.
636 Girard Avenue
East Aurora, NY 14052

Re:

CPSC File No. CA120159

Fisher-Price, Inc. Rock 'N Play Sleepers

Model #'s: R6070, V9102, V9196, V9197, W9442, W9443,

X2532, X2897

Dear Ms. Pilarz:

The staff of the Office of Compliance and Field Operations of the U.S. Consumer Product Safety Commission ("Commission") has reviewed the information that you have provided concerning Rock 'N Play Sleepers.

After careful consideration and in accordance with 16 C.F.R. § 1115.12(a), the staff has made a preliminary determination that the exposure of "mold growth" on the Rock 'N Play Sleepers ("Subject Product") presents a substantial product hazard under section 15(a) of the Consumer Product Safety Act* ("CPSA"), 15 U.S.C. § 2064(a) and the Federal Hazardous Substances Act* ("FHSA"). Specifically, infant's exposure to the mold growth on the Subject Product can increase infants' susceptibility to asthma and other respiratory illnesses due to their immature immune and respiratory systems.

*Links provided at the end of letter.

Page 2 CA120159

The staff welcomes and will give full consideration to any comments or additional information from the firm concerning the staff's preliminary determination. The staff will meet with the firm as necessary to discuss its comments or corrective action.

Voluntary Corrective Actions

The Office of Compliance and Field Operations acknowledges and encourages the actions that Fisher-Price, Inc. has already taken to correct this problem in future productions. However, the staff believes that the following additional actions are necessary to assure the maximum notification for subject products previously purchased by consumers.

- Joint press release announcing recall informing consumers to check their model of the Subject Products for "mold growth";
- Direct recall notice to identified purchasers;
- Approved repair/replacement or refund remedy if consumer discovers mold in the Subject Product;
- Recall posters at retail locations;
- Recall notice posted on the firm's Web site;
- Future production:
 - Improved design to prevent mold growth;
 - o Improved cleaning instructions to avoid mold growth.

Please provide the Office of Compliance and Field Operations with a written corrective action plan describing the actions which the firm is taking and plans to take. This written plan should contain the elements listed in 16 C.F.R. § 1115.20(a).

Additionally, rather than the Commission unilaterally issuing a press release, the staff believes it would be appropriate for the firm and the Commission to issue a joint press release announcing the corrective action or recall. The staff will work with the firm to develop and issue a mutually acceptable release.

A voluntary corrective action plan must include an agreement that the Commission may publicize the terms of the plan and inform the public of the nature and the extent of the alleged substantial product hazard. Please see 16 C.F.R. § 1115.20 and Part 1101, Information Disclosure.

When the corrective action program begins, the Office of Compliance and Field Operations will monitor the progress of the program.

Compliance With Reporting Obligations

The staff will also investigate and assess whether it believes the firm has complied with the reporting requirements of section 15(b) of the Consumer Product Safety Act ("CPSA"), 15 U.S.C. § 2064(b). That section requires every manufacturer, importer, distributor, and retailer of a consumer product, or of any other product or substance over which the Commission has

Page 3 CA120159

jurisdiction under any other statute enforced by the Commission, who obtains information which reasonably supports the conclusion that the product (1) contains a defect which could create a substantial product hazard, (2) creates an unreasonable risk of serious injury or death, (3) fails to comply with an applicable consumer product safety rule or with a voluntary consumer product safety standard upon which the Commission has relied under section 9 of the CPSA, 15 U.S.C. § 2058, or (4) fails to comply with any other rule, regulation, standard, or ban under the CPSA or any other statute enforced by the Commission, to immediately inform the Commission of the defect, risk, or failure to comply, unless the firm has actual knowledge that the Commission has been adequately informed of the defect, risk, or failure to comply. See 16 C.F.R. Part 1115. The CPSA makes it a prohibited act to violate the reporting requirements. Firms may be liable for a civil penalty of \$100,000 for each violation involved up to a maximum of \$15,000,000 for any related series of violations. The maximum penalty increases to \$15.15 million after January 1, 2012. Sections 15(b), 19(a)(4), 20, and 21 of the CPSA, 15 U.S.C. §§ 2064(b), 2068(a)(4), 2069, and 2070, describe the duties of manufacturers, importers, distributors, and retailers to furnish information to the Commission and the penalties for failing to furnish such information.

Continuing Obligations

The staff requests that the firm continue to implement its corrective action plan until as many Subject Products as possible have been removed from the marketplace. Please continue to maintain your toll-free recall number as a means for consumers to reach you about your recall. Should the firm decide to change or discontinue the toll-free number, you must notify the Office of Compliance and Field Operations and provide a new recall contact number for the firm. This information will be maintained by the Commission staff and provided to consumers and others seeking information on your recall.

If the firm receives or learns of any information concerning complaints, claims, incidents, or injuries that the firm did not report, or other information affecting the scope, prevalence, or seriousness of the reported problem, issue, or potential defect or hazard, the firm must immediately report that information to the Office of Compliance and Field Operations. Additionally, if the firm receives information that might indicate that its corrective actions are not satisfactory in eliminating the risk of injury or the potential defect or hazard, or that the effectiveness of the corrective action plan was less than what had been reported, it must immediately report that information to the Office of Compliance and Field Operations. In addition, under section 19(a)(2)(B) of the CPSA, 15 U.S.C. § 2068(a)(2)(B), it is unlawful to sell, offer for sale, manufacture for sale, distribute in commerce, or import into the United States a product that it is covered by a manufacturer's corrective action plan created in consultation with, and publicized by, the Commission.

Until this matter and any related matters are resolved, there will remain the possibility of further enforcement action, including reasonably anticipated litigation. Therefore, the firm must abide by the continuing legal obligation to preserve all information, documents, records, and samples, now in existence or created hereafter, related to the Subject Product.

Page 4 CA120159

Due Date and Contact Information

The staff requests that the firm respond in writing and in full by providing all requested documents, records, and information within 10 working days from receipt of this letter.

Please also send an electronic copy of all documents you are providing to the email address listed on the letterhead of this letter. Please reference the file number CA120159 in your response.

The staff will make every effort to work closely and cooperatively with the firm to assure a successful corrective action plan which will protect the public while at the same time create a minimum of burden and inconvenience for the firm. If you have any questions or desire assistance in responding to this letter, you may contact me at 301-504-7509. Please address your correspondence to the following: Office of Compliance and Field Operations, U.S. Consumer Product Safety Commission, Room 613, 4330 East West Highway, Bethesda, MD 20814-4408. The Office of Compliance and Field Operations telefax number is (301) 504-0359.

Thank you for your cooperation.

Sincerely,

Theresa Nelson Compliance Officer

Defect Investigations Division

Enclosed:

Consumer Product Safety Act - http://www.cpsc.gov/about/cpsia/legislation.html 16 C.F.R. Part 1101, Information Disclosure –

http://www.cpsc.gov/ABOUT/guide.html Part 1115, Substantial Product Hazard Reports -- http://www.cpsc.gov/BUSINFO/frnotices/fr06/E611758.pdf

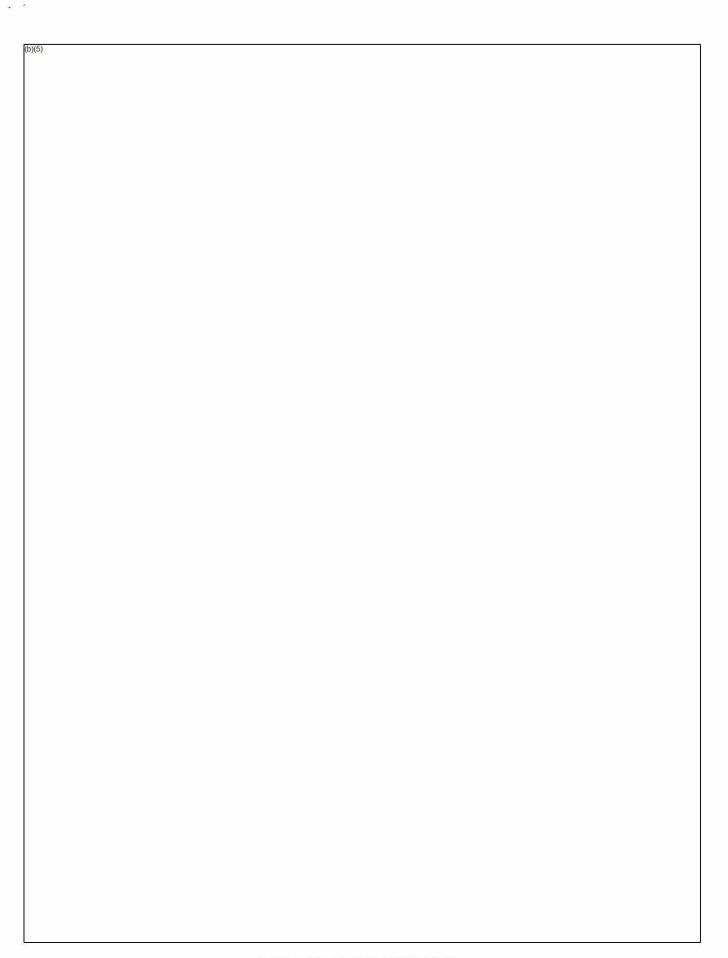
Part 1116, Section 37 Reports - http://www.cpsc.gov/BUSINFO/cpsa37.pdf
Federal Hazardous Substances Act - http://www.cpsc.gov/businfo/fhsa.pdf
Recall Handbook - http://www.cpsc.gov/businfo/fecallcheck
Recall Checklist - http://www.cpsc.gov/businfo/fecallcheck

U.S. CONSUMER PRODUCT SAFETY COMMISSION Office of Compliance and Field Operations

PRELIMIN	ARY STAFF DETERM	INATION	
(b)(5)			

(b)(5)	

OFFICIAL USE ONLY



(b)(5)			
	100	15 YO 6GP 50 6GP 1807	
Date of Prelimina	ary Determination Pan	el Meeting: 8/21/2012	
PDP Attendees (recented).	
	(Name and Office Rep	resemed).	
	(Name and Office Rep	resented).	
,	(Name and Office Rep	resemed).	
Name	(Name and Office Rep Office	Name Office	



Sample Tracking System



Version 2.11 - 04/15/2011 Production Environment - DBDBNew Logged in as: TNelson

Sample Collection Data

Go Back View	w Sample History		
1. Sample Flag:	2. Date Collected: 04/27/2011	3. Sample No 6684 Physical	Imber and Type: 11-810-
4a. Product Name: NEWBORN ROCK N PLAY SLEEP	4b. Model: R6070	4c. NEISS: 1549 4d. UPC Code:	5. Assignment Number: 110425ERC2472
 For Import Samples Port of Entry: Country of Origin: Entry No. and Date: Customs Contact: 			
7. MIS: 32202	8. Hours - Activity: 2 Travel: 0,5	9a. Home RO: CFIE	9b. Collecting RO: ISU
10. Sample Cost: \$55.19	11. Invoice Value of Lot: \$55.19	12. Size of Lot: 1	Units: unt
13. Manufacturer/Imprisher PRICE, INC. 636 GIRARD AVE. EAST			
14. Shipper/Foreign NUPS	lanufacturer:		
15. Dealer/Importer I AMAZON.COM LLC 172 TRADE STREETLEXI			
16. Supporting docum	ents attached:		
Invoice No. and Date Shipping Record and Affidavit Signer's Nan	Date:		

17. Product Identification:

The product is a Fisher Price Newborn Rock 'n Play Sleeper. The product requires assembly, comes with metal assembly base, sling and pad cover. The product is packaged in a box with

labeling which states in part, "***Nighttime Sleeper and playtime seat all in one***Maximum weight birth to 25 lbs.***All new material Made in China***Reg. No. PA-27960(CO)***Fisher Price Inc. a subsidiary of Mattel Inc. East Aurora, NY 14052 U.S.A.***" Model number R6070. A bar code on the box reads, 027084834185.
18. Reason Collection Analysis Needed: ☐ FHSA ☐ CPSA ☐ FFA ☐ PPPA ☐ RSA ☐ VGBA ☐ CGBP collected under ISU team in support of open case PI110066
19. Summary of Field Screening: none
20. Sample size/Method of Collection: The product was ordered through online retailer amazon.com, shipped to this investigator's local UPS box store, and was collected at the UPS store on 04/27/2011 and transported by this investigator's vehicle to the Miami Resident Post where it was identified as in Box #21 and officially sealed as in Box #22. Sample remained under lock & key, or in investigator's possession from the time of collection until submission through UPS to T. Nelson through the SSF.
21. Identification on Sample: 11-810-6684 SUB 1 RXM 04/27/2011 22. Identification on Seal and Date: 11-810-6684 Renee Y. Morelli 05/02/2011 23. Sample Delivered To: UPS 33175 23b. Date: 05/02/2011 24. Report/Record Sent To: CFIE
25. Laboratory/Office: LSE LSM CRC SIU LSC LS CLD SSF Other SSF TO T. NELSO
26. Remarks: Attach#1: photos, online purchase invoice, packing list
27. Related Samples: 28a. Collector's Name/Title/Date: Renee Y. Morelli - Acting Supervisor - 05/02/2011 29a. Reviewer's Name/Title/Date: Michelle A. Mach - Supervisor - 05/02/2011

ind meeting Notice to

Nelson, Theresa

From:

Cheryl Possenti [cpossenti@goldbergsegalla.com]

Sent:

Monday, July 23, 2012 10:26 AM

To:

Nelson, Theresa; Moore, Kelly; Thomas, Treye

Cc:

Pilarz, Kitty; Dzialga, Dan; Schoem, Marc

Subject:

RE: Fisher-Price Rock 'n Play Sleeper PI11066 CONFIDENTIAL

Hi Terry,

Thank you very much. We would be able to meet at 1:30 p.m. on Tuesday, August 14, 2012, if that is convenient for you and the other staff members.

(b)(4); (b)(3):CPSA Section 6(a); (b)(3):CPSA Section 6(b)

We look forward to meeting with you and other members of the staff to share this information and to discuss these issues.

Best regards,

Cheryl



New York London Philadelphia Princeton Hartford Buffalo Rochester Syracuse Albany White Plains Garden City

Cheryl A. Possenti, Esq.
Partner
665 Main Street / Suite 400
Buffalo, NY 14203
716.566.5444/FAX 716.566.5401
cpossenti@goldbergsegalla.com
http://www.goldbergsegalla.com

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Privileged Attorney-Client Communication / Attorney's Work Product

From: Nelson, Theresa [mailto:TNelson@cpsc.gov]

Sent: Wednesday, July 18, 2012 11:07 AM
To: Cheryl Possenti; Moore, Kelly; Thomas, Treye
Cc: Pilarz, Kitty; Dzialga, Dan; Schoem, Marc

Subject: RE: Fisher-Price Rock 'n Play Sleeper PI11066 CONFIDENTIAL

Cheryl



February 28, 2012

Via Overnight Mail

Theresa Nelson Compliance Officer Office of Compliance & Field Operations U.S. Consumer Product Safety Commission 4330 East West Highway Bethesda, MD 20814

Treye A. Thomas, Ph.D.
Office of Hazard Identification & Reduction
U.S. Consumer Product Safety Commission
4330 East West Highway
Bethesda, MD 20814

Re: CPSC File No. PI110066
Fisher-Price Rock 'n Play SleeperTM

Dear Ms. Nelson and Dr. Thomas:

Enclosed herewith is a courtesy copy of the supplemental submission we forwarded on February 24, 2012.

Very truly yours,

Cheryl A. Possenti

CAP/tb Enclosure

cc: Kitty Pilarz

Senior Director, Mattel Product Safety

Fisher-Price, Inc.

Daniel Dzialga, Esq. Senior Counsel Fisher-Price, Inc.

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Page 345
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(b)(4); (b)(3):CPSA Section 6(a); (b)(3):CPSA Section 6(b)
of the Freedom of Information Act

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of the Freedom of Information Act

Page 354 Withheld pursuant to exemption

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of the Freedom of Information Act

Nelson, Theresa

Rock Play

AM DR. Gots/molD

From: Sent:

To:

Page 355

Moore, Kelly

Monday, February 27, 2012 8:08 AM Nelson, Theresa; Thomas, Treye

FP Rock N Play Sleeper

Subject: Attachments:

DOC.PDF

(b)(4); (b)(3):CPSA Section 6(a); (b)(3):CPSA Section 6(b)

Please

This just in from FP's lawyer. review, and let's plan to circle up a few minutes before our call with the firm this afternoon.



Buffalo: 665 Main Street / Suite 400, Buffalo, New York 14203-1425 716.566.5400 / FAX 716.566.5401

To:

Kelly M. Moore, Esq.

Office of the General Counsel Division of Compliance

U.S. Consumer Product Safety Commission

Fax No.:

301-504-0121

Telephone No.:

From:

Cheryl A. Possenti, Esq.

Date:

February 24, 2012

Comments: Enclosures to follow via overnight mail

Matter:

CPSC File No. PI110066

Fisher Price Rock 'n Play Sleeper TM

Number of Pages (including fax cover):

Please call 716.566.5400

if there are any problems with this transmission.

This document contains privileged and confidential information. This document is intended for the addressee. If you received this document in error, please notify this office and we will instruct you on its proper handling. Thank you.

Philadelphia	New York	Buffalo	Princeton	Hartford
267.519.6800	646.253.5400	716.566.5400	609.986.1300	860.760.3300
FAX 267.519.6801	FAX 646.253.5500	FAX 716.566.5401	FAX 609.986.1301	FAX 860.760.3301
Rochester	Syracuse	Albany	White Plains	Long Island
585.295.5400	315.413.5400	518.463.5400	914.798.5400	516.281.9800
FAX 585.295.8300	FAX 315.413.5401	PAX 518.463.5420	FAX 914.798.5401	FAX 516.281.9801

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of the Freedom of Information Act

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of the Freedom of Information Act

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of the Freedom of Information Act

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of the Freedom of Information Act

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of the Freedom of Information Act

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of the Freedom of Information Act

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of the Freedom of Information Act

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of the Freedom of Information Act

Monthly Progress Reports FISHER-PRICE - "Rock 'N Play Sleeper" -recall to inspect for Mold January 8, 2013	PRICE - "Rock 'N Pla	y Sleeper" -re	call to ir	spect fo	r Mold	anuary 8,	2013
(703,167 produc	(703,167 products sent to retailers between September 2009 - August 2012)	oetween Septe	mber 2	009 - Au	gust 201	2)	
REMEDY:	JAN18-March 31, 2013 April 1-30, 2013 May	April 1-30, 2013	May	June	July	August	TOTALS
Accept Cleaning Instructions						<u> </u>	6(a) 6(b)
Returned Product for Replacement							; (b)(:
Returned Product for Refund							3):CF
Returned Product for Voucher							SA
Replacement Pad Sent							Secti
Resolution Pending*							ion
					I		
100		Store					
	The second of th	5. 8		3			
		CERRO	20 544	0.00		E 100 100 100 100 100 100 100 100 100 10	
	10 Aug 2015 00 100 1						
		10000					
*Indicates firm is working through a remedy with consumer, consumer may be calling							updated
back, returning product to retail, etc.							5/14/2013
			26,000		100		

Page 377

- April 1- April 30,2013

Monthly Progress Report for Corrective Action Plan & Incident Update

CASE #: CA120159

Company Name: Fisher-Price, Inc.

Reporting Dates, From: 4/1/2013 To: 4/30/2013

Compliance Officer: Theresa Nelson Product: Newborn Rock 'n Play Sleeper Total# of Affected Products: 800,000

I) PRODUCTS CORRECTED/CAPTURED BY YOUR FIRM

Remedy Options	
Accepted Cleaning Instructions Returned Product for Replacement Product Returned Product for Refund	(b)(4), (b)(3):CPSA Section 6(a), (b)(3):CPSA Section 6(b)
Returned Product for Voucher Replacement Pad Sent Resolution Pending*	
TOTALS:	
* Indicates the Firm is working through a remedy with consumer,	consumer may be calling back, returning product to retail, etc.

Reports

t HIS I	reriod
	(b)(4); (b)(3):CPSA Section 6(a); (b)(3):CPSA Section 6(b)

III) NOTIFICATION MEASURES:

(Using the categories listed below, record the number of notifications attempted by your firm during this reporting period, and record the

	Number for this Reporting	
Direct Mail Letter to Known Owners	Period	Total
Direct email to Known Owners	(b)(4); (b)(3):C	(b)(4); (b)(3):CPSA Section 6(a);
Email to All Members of "Fisher-Price Family"	PSA Section	(b)(3):CPSA Section 6(b)
Social Media (Facebook) Posting (po. of followers)	(b)(3):C	(
Note: Retail posters were not necessary with this action as products:	PSA Section Street	
25 SC2000	And the second s	

IV) Consumer Correspondence

188 B	
Phone Contacts	# From Customers This Reporting Period
E-mail Contacts	(b)(3),CPSA
"Live Chats"	Section 6(a); (b)(3):CPSA
Web Site "Hits"	Section 6(b)
Written Inquiries	· · · · · · · · · · · · · · · · · · ·
property is the second of the	(-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1

NOTE: Submit completed by the FIRST of EACH MONTH to Judy Smith, Recall Coordinator at: United States Consumer Product Safety Commission, Office of Compliance 4330 East West Highway, Room 613 Bethesda, MD 20814 OR, fax report to (301) 504-0359 or email to jsmith@cpsc.gov. Address any questions to Ms. Smith at 301-504-7525

II) Reports of Mold

From:

Crosby, Deb < Deb.Crosby@Fisher-Price.com>

Sent:

Wednesday, May 01, 2013 4:17 PM

To:

Nelson, Theresa; Moore, Kelly; Smith, Judy

Subject:

Monthly Progress Report - Fisher-Price, Inc. - Newborn Rock 'n Play Sleeper - CA120159

Attachments:

RocknPlay Sleeper-MPR-April 2013.pdf

Attached is our Monthly Progress Report for the above mentioned product for the period 4/1/2013 to 4/30/2013.

Thanks,

Deb Crosby Sr. Safety Data Coordinator Product Integrity

Fisher-Price, Inc. 636 Girard Avenue East Aurora, NY 14052 716-687-3970 / Fax-3599 Deb.Crosby@Fisher-Price.com

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Page 379 Jan 1- March 31,2013

Monthly Progress Report for Corrective Action Plan & Incident Update

CASE #: CA 120159

Company Name: Fisher-Price, Inc.

Reporting Dates, From: 1/8/2013 To: 3/31/2013

Compliance Officer: Theresa Nelson Product: Newborn Rock 'n Play Sleeper Total# of Affected Products: 800,000

I) PRODUCTS CORRECTED/CAPTURED BY YOUR FIRM

Menter's Options	Corrections this Period
Accepted Cleaning Instructions	(b)(4); (b)(3):CPSA
Returned Product for Replacement Product	Section 6(a); (b)(3):CPSA
Returned Product for Refund	Section 6(b)
Returned Product for Voucher	···
Replacement Pad Sent	
Resolution Pending*	
TOTALS:	
4 Indiantos the Man Is and the state of the	

II) Reports of Mold

Damadu Ontiona

This Period

Reports

III) NOTIFICATION MEASURES:

(Using the categories listed below, record the number of notifications attempted by your firm during this reporting period, and record the total number of notifications to date.)

	Number for this Reporting Period	Total
Direct Mail Letter to Known Owners	(b)(4); (b)(3):CPSA	(b)(4); (b)(3):CPSA Section
Direct email to Known Owners	Section 6(a); (b)(3):CPSA Section	6(a); (b)(3):CPSA Section 6(b)
Email to All Members of "Fisher-Price Family"	6(b)	
Social Media (Facebook) Posting (no. of followers)		
Note: Retail posters were not necessary with this action as products	at retail were unaffected	5 - 455 - E

IV) Consumer Correspondence

From Customers This Reporting Period **Phone Contacts** (b)(4); (b)(3):CPSA Section 6(a); E-mail Contacts (b)(3):CPSA Section "Live Chats" Web Site "Hits" Written Inquiries

NOTE: Submit completed by the FIRST of EACH MONTH to Judy Smith, Recall Coordinator at: United States Consumer Product Safety Commission, Office of Compliance

4330 East West Highway, Room 613 Bethesda, MD 20814

OR, fax report to (301) 504-0359 or email to jsmith@cpsc.gov. Address any questions to Ms. Smith at 301-504-7525

the Firm is working through a remedy with consumer, consumer may be calling back, returning product to retail, etc.

From:

Crosby, Deb < Deb.Crosby@Fisher-Price.com>

Sent:

Thursday, April 04, 2013 9:54 AM

To:

Page 380

Smith, Judy

Cc:

Nelson, Theresa; Moore, Kelly

Subject:

Monthly Progress Report - Newborn Rock 'n Play Sleeper - Fisher-Price - 1/8/13 to

3/31/13

Attachments:

DOC.PDF

Follow Up Flag:

Follow up

Flag Status:

Flagged

Any questions can be directed to (b)(4); (b)(3):CPSA Section 6(a); (b)(3):CPSA Section 6(b) class.

This was also faxed to Ms. Smith on 4/3 and mailed first

Thanks,

Deb Crosby Sr. Safety Data Coordinator **Product Integrity**

Fisher-Price, Inc. 636 Girard Avenue East Aurora, NY 14052 E 716-687-3970 / Fax-3599 Deb.Crosby@Fisher-Price.com

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From:

Crosby, Deb < Deb.Crosby@Fisher-Price.com>

Sent:

Thursday, April 04, 2013 9:54 AM

To:

Smith, Judy

Cc:

Nelson, Theresa; Moore, Kelly

Subject:

Monthly Progress Report - Newborn Rock 'n Play Sleeper - Fisher-Price - 1/8/13 to

3/31/13

Attachments:

DOC.PDF

Follow Up Flag:

Follow up

Flag Status:

Flagged

Any questions can be directed to Don Fest (716-687-3653). This was also faxed to Ms. Smith on 4/3 and mailed first class.

Thanks,

Deb Crosby Sr. Safety Data Coordinator Product Integrity

Fisher-Price, Inc.
636 Girard Avenue
East Aurora, NY 14052
E 716-687-3970 / Fax-3599
Deb.Crosby@Fisher-Price.com

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From:

Fest, Don < Don.Fest@Fisher-Price.com>

Sent:

Thursday, March 21, 2013 3:55 PM

To:

Nelson, Theresa

Cc:

Pilarz, Kitty; Moore, Kelly

Subject:

RE: Rock n' Play Sleeper Monthly Progress Report

Hi Terry,

So glad you like the report.

I'll eliminate the cumulative data as you requested and submit the first report on (or shortly after) April 1.

Thanks,

Don Fest Regulatory Project Manager Product Integrity

Fisher-Price, Inc. 636 Girard Ave. East Aurora, NY 14052 716.687.3653

From: Nelson, Theresa [mailto:TNelson@cpsc.gov]

Sent: Sunday, March 17, 2013 9:56 PM

To: Fest, Don

Cc: Pilarz, Kitty; Moore, Kelly

Subject: FW: Rock n' Play Sleeper Monthly Progress Report

Don – I apologize for not getting back to you sooner and yes, I'm sorry we missed meeting at ICPHSO as well. Yes, this proposed monthly report is much better and more accurate for reporting the returns since the recall. Instead of adding and sending a cumulative report each month added to the previous month, could you please send the numbers for the month that you are reporting? Other than that, this method would be great.

I will be out of the office this week. Feel free to email me if you have any questions.

Thanks, Terri

Terri Nelson

Compliance Officer
Office of Compliance & Field Operations
U.S. Consumer Product Safety Commission
Phone: 301-504-7509 or

1-800-638-8095 ext. 7509

Fax: 301-504-0359 tnelson@cpsc.gov

SIGN UP FOR RECALL NOTICES: http://www.cpsc.gov/cpsclist.aspx

From: Fest, Don [mailto:Don.Fest@Fisher-Price.com]

Sent: Monday, March 11, 2013 11:56 AM

To: Nelson, Theresa **Cc:** Pilarz, Kitty

Subject: RE: Rock n' Play Sleeper Monthly Progress Report

Hello again Terri,

It was a pleasure speaking with you last week. Sorry I missed you at the ICPHSO conference. Regarding the Rock 'n Play, I spoke with our team regarding your thought that the current format of the Monthly Progress Report form will not work with the variety of "remedies" we offered. I have attached a proposed alternate form we could use for monthly reporting and we have entered data into it as of March 7, 2013 as an example. We have replaced the "incident" and "injury" categories with "Reports of Mold".

Thanks for your consideration. Please don't hesitate to contact me if you have any questions. Unless we hear anything to the contrary from you, we'll use this form to submit our first monthly progress report on April 1, 2013.

Don Fest Regulatory Project Manager Product Integrity Eigher-Price Inc.

Fisher-Price, Inc. 636 Girard Ave. East Aurora, NY 14052 716.687.3653

From: Nelson, Theresa [mailto:TNelson@cpsc.gov]

Sent: Sunday, March 10, 2013 8:21 PM

To: Fest, Don **Cc:** Pilarz, Kitty

Subject: RE: Rock n' Play Sleeper Monthly Progress Report

Don – Thanks for the update. I need to be out of the office on Monday, but will check mail for your response.

Thanks, Terri

Terri Nelson

Compliance Officer
Office of Compliance & Field Operations
U.S. Consumer Product Safety Commission
Phone: 301-504-7509 or

1-800-638-8095 ext. 7509

Fax: 301-504-0359 tnelson@cpsc.gov

SIGN UP FOR RECALL NOTICES: http://www.cpsc.gov/cpsclist.aspx

From: Fest, Don [mailto:Don.Fest@Fisher-Price.com]

Sent: Friday, March 08, 2013 12:31 PM

To: Nelson, Theresa **Cc:** Pilarz, Kitty

Subject: Rock n' Play Sleeper Monthly Progress Report

Hi Terri,

I just wanted to let you know that our team has been working on this and we're still finishing up.

I should have something for you on Monday.

Sorry for the delay.

Hope you have a great weekend.

From: Nelson, Theresa

Sent: Monday, April 29, 2013 5:06 PM

To: Cheryl Possenti (cpossenti@goldbergsegalla.com)

Cc: Fest, Don (Don.Fest@Fisher-Price.com); Pilarz, Kitty (Kitty.Pilarz@Fisher-Price.com);

Moore, Kelly

Subject: CAP letter & reporting
Attachments: CAPacceptLtr.pdf

Cheryl – Attached is the Corrective Action Plan (CAP) accept letter with reporting obligations. I have worked with Don Fest since he has reported the firm's feedback from consumers since the recall on January 8th. Don submitted the Monthly Report on April 4th as included in the last page of the attached letter and will continue the monthly reporting obligation.

Please let me know if you have any questions.

Terri

Terri Nelson

Compliance Officer
Office of Compliance & Field Operations
U.S. Consumer Product Safety Commission

Phone: 301-504-7509 or 1-800-638-8095 ext. 7509

Fax: 301-504-0359 tnelson@cpsc.gov

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U.S. CONSUMER PRODUCT SAFETY COMMISSION 4330 EAST WEST HIGHWAY BETHESDA, MD 20814

Office of Compliance and Field Operations Defect Investigations Division Email: tnelson@cpsc.gov

APR 2 9 2013

Theresa Nelson Compliance Officer Tel: 301-504-7509 Fax: 301-504-0060

Certified Mail/Email: cpossenti@goldbergsegalla.com Don.Fest@Fisher-Price.com Kitty.Pilarz@Fisher-Price.com

Ms. Cheryl Possenti, Esq. Partner, Goldberg Segalla 665 Main Street, Suite 400 Buffalo NY 14203

Re:

CPSC File No. CA120159 Fisher-Price, Inc.

Rock 'N Play Sleepers

Dear Ms. Possenti.

The staff of the Office of Compliance and Field Operations of the U.S. Consumer Product Safety Commission ("CPSC" or "Commission") has reviewed the corrective actions by Fisher-Price, Inc. ("the Firm") concerning Rock 'N Play Sleepers for the recall on January 8, 2013: http://www.cpsc.gov/en/Recalls/2013/Fisher-Price-Recalls-to-Inspect-Rock-N-Play-Infant-Sleepers-Due-to-Risk-of-Exposure-to-Mold/

Acting under delegation from the Commission, the staff has accepted the corrective action plan ("CAP") as adequate. The CAP accepted by the staff includes the following actions:

- Joint press release issued on January 8, 2013;
- Letter to Retailers informing of "recall to inspect" (January 7, 2013);
- Recall notice http://service.mattel.com/us/recall/rock_sleepernew.asp) posted on Firm's website and social media platforms such as Facebook, Twitter;
- Inspect/replacement/refund;

Page 2 #CA120159

- Renegotiate the CAP should the Commission staff determine its effectiveness to be less than adequate;
- Submit modified Monthly Progress Reports in the format agreed upon with Compliance staff (see specific instructions below).

Please continue the corrective actions implemented and initiate any others contained in the CAP. The Office of Compliance and Field Operations will be monitoring the CAP.

Monthly Progress Report Submission

An alternate Monthly Progress Report has been agreed upon with Don Fest, the Firm's Regulatory Project Manager, due to the nature of this recall since consumers are not returning all of the Subject Products. A copy of the first Monthly Progress Report submitted on April 4th, 2013, is included with this letter. The "incident" and "injury" categories have been replaced with "Reports of Mold." Incidents and injuries will continue be reported to CPSC on this product through the retail reporting system already in place.

Deb Crosby, the Firm's Sr. Safety Data Coordinator, will continue to submit the monthly reports for Case #CA121059 to Judy Smith, CPSC's Recall Coordinator at jsmith@cpsc.gov and cc'd to me at jsmith@cpsc.gov.

CPSC Staff Monitoring of Corrective Action Plan

In addition to reviewing the Firm's monthly progress reports, field investigators and/or state investigators may be contacting retailers and consumers who may have received the Subject Products to confirm their receipt of the approved notification material and the Firm's compliance with the associated instructions pursuant to the CAP.

When the Firm determines that the CAP has been implemented to the best of the Firm's ability and as many products as possible have been removed from the marketplace, it may submit a final progress report, referencing the file number, and request that the file be closed. At that time, the staff will review the CAP's progress and decide whether the file should be closed. The Office of Compliance and Field Operations will evaluate the effectiveness of the CAP. The staff could seek broader corrective action if the CAP does not prove effective. When the staff closes its file on a CAP, it asks that the Firm continue the CAP until as many of the Subject Products as possible have been removed from the marketplace. Please continue to maintain the Firm's toll-free recall number as a means for consumers to reach the Firm about the recall. Should the Firm decide to change or discontinue its toll-free recall number, the Firm must immediately notify the Office of Compliance and Field Operations and provide a new recall contact number for the Firm. If the Firm wishes to change the terms of the CAP, it must also discuss any proposal with us before it makes any change. This information will be maintained by the Commission and provided to consumers and others seeking information on the recall or CAP.

Compliance with Reporting Obligations

The staff will also investigate and assess whether it believes the Firm has complied with

Page 3 #CA120159

the reporting requirements of section 15(b) of the CPSA, 15 U.S.C. § 2064(b). That section requires every manufacturer, importer, distributor, and retailer of a consumer product, or of any other product or substance over which the CPSC has jurisdiction under any other statute enforced by the CPSC, who obtains information which reasonably supports the conclusion that the product (1) contains a defect which could create a substantial product hazard, (2) creates an unreasonable risk of serious injury or death, (3) fails to comply with an applicable consumer product safety rule or with a voluntary consumer product safety standard upon which the CPSC has relied under section 9 of the CPSA, 15 U.S.C. § 2058, or (4) fails to comply with any other rule, regulation, standard, or ban under the CPSA or any other statute enforced by the CPSC, to immediately inform the CPSC of the defect, risk, or failure to comply, unless the firm has actual knowledge that the CPSC has been adequately informed of the defect, risk, or failure to comply. See 16 C.F.R. Part 1115.

Failure to comply with the CPSC's reporting requirements is a prohibited act under Sections 19(a)(3) and (4) of the CPSA, 15 U.S.C. §§ 2068(a)(3) and (4). Pursuant to section 20 of the CPSA, 15 U.S.C. § 2069, such violations could subject you and the Firm to civil penalties of up to \$100,000 per violation up to a maximum of \$15.15 million for any related series of violations. In addition, pursuant to section 21 of the CPSA, 15 U.S.C. § 2070, such violations could subject you and the Firm to criminal penalties including a fine, imprisonment for not more than five (5) years and forfeiture of assets associated with the violation(s).

Continuing Obligations and Duty to Preserve

If the Firm receives or learns of any information concerning complaints, claims, incidents, or injuries that the Firm did not report, or other information affecting the scope, prevalence, or seriousness of the reported problem, issue, or potential defect or hazard, the Firm must immediately report that information to the Office of Compliance and Field Operations. Additionally, if the Firm receives information that might indicate that its corrective actions are not satisfactory in eliminating the problem, risk of injury, or potential defect or hazard, or that the effectiveness of the CAP is less than had been anticipated, it must immediately report that information to the Office of Compliance and Field Operations. In addition, under section 19(a)(2)(B) of the Consumer Product Safety Act ("CPSA"), 15 U.S.C. § 2068(a)(2)(B), it is unlawful to sell, offer for sale, manufacture for sale, distribute in commerce, or import into the United States a product that is covered by a manufacturer's corrective action plan created in consultation with, and publicized by, the Commission.

Until this matter and any related matters are resolved, there will remain the possibility of further enforcement action, including reasonably anticipated litigation. Therefore, the Firm must abide by the continuing legal obligation to preserve all information, documents, electronically-stored data, and samples, now in existence or created hereafter, related to the Subject Product.

Information Disclosure

Section 6(b)(1) of the CPSA, 15 U.S.C. § 2055(b)(1), requires the Commission to provide manufacturers and private labelers with advance notice and opportunity to comment on information the Commission intends to disclose, if the public can readily ascertain the identity of

Page 4 #CA120159

the Firm from the information the Commission intends to disclose. See 16 C.F.R. Part 1101. The staff is enclosing a summary of the CAP which the Commission intends to disclose to the public. For full consideration, your written comments must be received within 10 calendar days of the date of this letter. Please include with any comments specific information and documents, where available, to support any claim that the information is inaccurate. If you have no comments or objections, you are not obligated to respond. If the Commission decides to disclose the information, over any accuracy objections, it will give the Firm five (5) days' notice, as required by section 6(b)(2) of the CPSA, 15 U.S.C. § 2055(b)(2), unless the Commission publishes a finding that the public health and safety require less notice.

Contact Information

Thank you for your continued cooperation in this matter. If you have any questions, please contact me at 301-504-7509 or tmelson@cpsc.gov. Written correspondence may be addressed to: Office of Compliance and Field Operations, U.S. Consumer Product Safety Commission, Room 613-28, 4330 East West Highway, Bethesda, MD 20814-4408.

Sincerely,

Theresa Nelson Compliance Officer

Defect Investigations Division

Steri Nelson

Enclosures/Links:

- Corrective Action Plan Summary see below
- Monthly Progress Report Form attached electronically

cc: Kitty Pilarz Kelly Moore Judy Smith Page 5 #CA120159

Voluntary Corrective Action Plans Under Section 15 of the Consumer Product Safety Act and Section 15 of the Federal Hazardous Substances Act

The following is a list of voluntary corrective action plans recently accepted by the Commission (or the staff acting under authority delegated by the Commission). A firm's taking corrective action does not constitute an admission by the firm that a substantial product hazard exists.

Space does not permit the staff to give a complete list of the specific model numbers of the products involved in each of these corrective actions. Consumers who believe that they have a product affected by one of these actions should follow the instructions given in this list or contact either the manufacturer or the Commission to determine if their product is one of those affected.

Corrective Action Plan Summary

DATE	FIRM AND PRODUCT	ALLEGED HAZARD	CORRECTIVE NARRATIVE
4/17/2013	Fisher-Price, Inc. 636 Girard Ave. East Aurora, NY 14052 Rock 'N Play Sleeper	Infants in product containing mold may be more susceptible to respiratory illness or may experience the exacerbation of respiratory illnesses.	Recall to Inspect Rock 'N Play Infant Sleepers due to risk of exposure to mold. Firm agreed to Replace or Refund if mold could not be eradicated with cleaning.

Monthly Progress Report for Corrective Action Plan & Incident Update

CASE #: CA 120159

Page 391

Company Name: Fisher-Price, Inc.

Reporting Dates, From: 1/8/2013 To: 3/31/2013

Compliance Officer: Theresa Nelson Product: Newborn Rock 'n Play Sleeper Total# of Affected Products: 800,000

I) PRODUCTS CORRECTED/CAPTURED BY YOUR FIRM

Remedy Options	Corrections this Period	
Accepted Cleaning Instructions	(b)(4); (b)(3):CPSA	
Returned Product for Replacement Product	Section 6(a); (b)(3):CPSA Section	
Returned Product for Refund	6(b)	
Returned Product for Voucher		
Replacement Pad Sent	-	
Resolution Pending*		
TOTALS:		
* Indicates the Firm is working through a remedy with con	sumer, consumer may be calling back, returning avaduet to small	_

II) Reports of Mold

This Period

Reports (b)(4); (b)(3):CPSA Section 6(4)

III) NOTIFICATION MEASURES:

(Using the categories listed below, record the number of notifications attempted by your firm during this reporting period, and record the total number of notifications to date.)

	Number for this Reporting	945// et 25
Direct Mail Letter to Known Owners	Period (b)(4): (b)(3):CPSA	Total
Direct email to Known Owners	Section 6(a); (b)(3):CPSA Section	(b)(4); (b)(3):CPSA Section 6(a); (b)(3):CPSA Section
Email to All Members of "Fisher-Price Family"		(b)(3).CPSA Section 6(b)
Social Media (Facebook) Posting (no. of followers)		
Note: Retail posters were not necessary with this action as products	at retail were unaffected	

IV) Consumer Correspondence

NOTE: Submit completed by the FIRST of EACH MONTH to Judy Smith, Recall Coordinator at: United States Consumer Product Safety Commission, Office of Compliance 4330 East West Highway, Room 613 Bethesda, MD 20814 OR, fax report to (301) 504-0359 or email to jsmith@cpsc.gov. Address any questions to Ms. Smith at 301-504-7525

U.S. CONSUMER PRODUCT SAFETY COMMISSION Office of Compliance and Field Operations

Firm Name: Fisher-Price, Inc.

File Number: CA120159

Product Brand: Fisher-Price Product Model: All models

Product Name: Rock N Play Sleeper

Hazard Priority: c

CORRECTIVE ACTION PLAN:

A. Notice (to Consumers):

ent:	Date:
	Date.
all alert	January 8, 2013
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be)	
	January 8, 2013
ebook, Twitter, etc.)	January 8, 2013
е	
É	ebook, Twitter, etc.)

B. Repair, replacement, refund:

X	repair approved by technical support
	replacement with product approved by technical support
X	Refund
	other (describe):

C. Procedures:

	1 100cduics.	CONTRACTOR				
	Distribution chain recall					
	manufacturer/importer l	evel				
	wholesaler/distributor level					
	retailer level		1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1			
	consumer level					
X	X Mail in to firm					
x	Return to retailer					
X	repair or replace					
	Home visit	At dealer	X At Retailer			
X	Home repair by consumer		neren erre villerennelle de errer des Addesses geste errer errer errer errer errer errer errer errer errer err			
X	Toll-free line					
x	Website registration					
	Other (describe):					

Firm Name: Fisher-Price, Inc.

File Number: CA120159

D. Effectiveness:

	Total Products	Involved:	Total Products Corrected:
At Manufacturer:			
At Distributors:			
At Retailers:		***************************************	
With Consumers:		800,000	
Totals:		800,000	

E. Decision on corrective action:

X Accept CAP and Monitor		
Fast Track Product Recall Case		
Accept CAP and Close File (provide rationale)		
Pursue further remedial action (provide rationale)		
Refer to Legal Division		
Refer to Commission with recommendation to accept CAP [Class A case]		

F. Data Quality (Performance Goal):

X	All appropriate firm and mail firm data entered and verified
X	Hazard code verified and country of origin verified
X	Products involved and corrected identical to database numbers
X	All associated IDI's linked in Case Management System
X	All associated samples linked in Case Management System
X	All sample collection reports reviewed for accuracy and MIS #
X	All samples have accurate SEND and RECEIVE location info in Sample Tracking
	All incident data submitted to EPI

CAP APPROVALS:

Compliance Officer	Theresa Nelson 4/18/2013	T WAS THE S
Attorney	122 - 4/24/2013	
Compliance Lead	M18113	
Director – CRE/CDI	4/22/13	

PUT CPSC RECALLS
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NEWS from CPSC

SHARE # 12 15 ...

U.S. Consumer Product Safety Commission

Office of Communications

Washington, D.C.

FOR IMMEDIATE RELEASE January 8, 2013 Release #13-087 Firm's Recall Hotline: (800) 432-5437 CPSC Recall Hotline: (800) 638-2772 CPSC Media Contact: (301) 504-7908

Fisher-Price Recalls to Inspect Rock 'N Play Infant Sleepers Due to Risk of Exposure to Mold

WASHINGTON, D.C. - The U.S. Consumer Product Safety Commission, in cooperation with the firm named below, today announced a voluntary recall of the following consumer product. Consumers should immediately inspect this product and stop using it if mold is found. Units currently in retail stores are not included in this recall to inspect.

Name of Product: Newborn Rock 'n Play Sleeper™

Units: About 800,000 units

Importer: Fisher-Price Inc., of East Aurora, N.Y

Hazard: Mold can develop between the removable seat cushion and the hard plastic frame of the sleeper when it remains wet/moist or is infrequently cleaned, posing a risk of exposure to mold to infants sleeping in the product. The CPSC advises that mold has been associated with respiratory illnesses and other infections. Although mold is not present at the time of purchase, mold growth can occur after use of the product.

Incidents/Injuries: Fisher-Price has received 600 reports of mold on the product. Sixteen consumers have reported that their infants have been treated for respiratory issues, coughs and hives after sleeping in the product.

Description: This recall to inspect includes all Fisher-Price Rock N' Play infant recliner seats called sleepers. The sleeper is designed for babies up to 25 pounds and is composed of a soft plastic seat held by a metal rocking frame. The product has a removable, fabric cover that is sold in 14 patterns and color palettes.

Sold at: Mass merchandise stores nationwide and online since September 2009 for between \$50 and \$85. Units currently in retail stores are not affected by this recall to inspect. Only products that show signs of mold after use by consumers are included in this announcement.

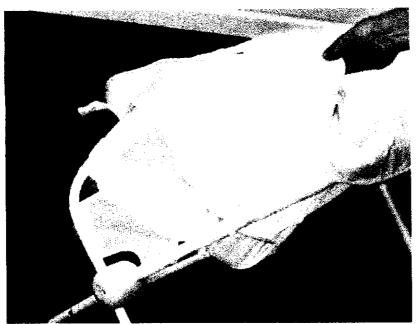
Manufactured in: China

Remedy: Consumers should immediately check for mold under the removable seat cushion. Dark brown, gray or black spots can indicate the presence of mold. If mold is found, consumers should immediately stop using the product. Consumers can contact Fisher-Price for cleaning instructions or further assistance. Cleaning and care instructions can also be found at www.service.mattel.com or by contacting the firm.

Consumer Contact: Fisher-Price; at (800) 432-5437, from 9 a.m. to 6 p.m. ET Monday through Friday, or online at www.service.mattel.com for more information.



Fisher-Price Rock 'N Play Infant Sleeper



Fisher-Price Infant Sleeper Removable Seat Cushion

The U.S. Consumer Product Safety Commission (CPSC) is still interested in receiving incident or injury reports that are either directly related to this product recall or involve a different hazard with the same product. Please tell us about your experience with the product on SaferProducts.gov

CPSC is charged with protecting the public from unreasonable risks of injury or death associated with the use of the thousands of consumer products under the agency's jurisdiction. Deaths, injuries and property damage from consumer product incidents cost the nation more than \$900 billion annually. CPSC is committed to protecting consumers and families from products that pose a fire, electrical, chemical or mechanical hazard. CPSC's work to ensure the safety of consumer products - such as toys, cribs, power tools, cigarette lighters and household chemicals - contributed to a significant decline in the rate of deaths and injuries associated with consumer products over the past 30 years.

To report a dangerous product or a product-related injury go online to www.SaferProducts.gov or call CPSC's Hotline at (800) 638-2772 or teletypewriter at (800) 638-8270 for the hearing impaired. Consumers can obtain news release and recall information at www.cpsc.gov, on Twitter @OnSafety or by subscribing to CPSC's free e-mail newsletters.



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Recall Information

Recall to Inspect

Fisher-Price®, in cooperation with the United States Consumer Product Safety Commission, is voluntarily announcing a recall to inspect Fisher-Price Newborn Rock 'n Play Sleepers™. Mold can develop between the removable seat cushion and the hard plastic frame of the sleeper when it remains wet/moist or is infrequently cleaned.



Mold is not present at the time of purchase, but mold can grow after use of the product. Newborn Rock 'n Play™ Sleepers currently in retail stores are not affected by this recall to inspect.

The Newborn Rock 'n Play Sleeper™ is designed for babies up to 25 pounds and is composed of a metal rocking frame and removable, washable fabric cover. The product is sold in various patterns and color palettes.

Please examine under the removable fabric seat cover and fabric liner for dark brown, gray or black spots indicating mold.



If mold growth is discovered, you can click here for cleaning instructions.

You can also contact Fisher-Price at 1-800-432-5437 Monday through Friday between the hours of 9 AM and 6 PM Eastern Time.

You can click here for the press release.

Fisher-Price

Mattel

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U.S. Consumer Product Safety Commission - Recall

Recall Date: January 8, 2013 Recall Number: 13-087

Fisher-Price Recalls to Inspect Rock 'N Play Infant Sleepers Due to Risk of Exposure to Mold

WASHINGTON, D.C. - Consumers should immediately inspect this product and stop using it if mold is found. Units currently in retail stores are not included in this recall to inspect.

Recall Summary

Name of product: Newborn Rock 'n Play SleeperTM

Hazard: Mold can develop between the removable seat cushion and the hard plastic frame of the sleeper when it remains wet/moist or is infrequently cleaned, posing a risk of exposure to mold to infants sleeping in the product. The CPSC advises that mold has been associated with respiratory illnesses and other infections. Although mold is not present at the time of purchase, mold growth can occur after use of the product.

Remedy: New Instructions, Repair

Consumer Contact: Fisher-Price; at (800) 432-5437, from 9 a.m. to 6 p.m. ET Monday through Friday, or online at www.service.mattel.com for more information.

Recall Details

Units: About 800,000 units

Description: This recall to inspect includes all Fisher-Price Rock N' Play infant recliner seats called sleepers. The sleeper is designed for babies up to 25 pounds and is composed of a soft plastic seat held by a metal rocking frame. The product has a removable, fabric cover that is sold in 14 patterns and color palettes.

Incidents/Injuries: Fisher-Price has received 600 reports of mold on the product. Sixteen consumers have reported that their infants have been treated for respiratory issues, coughs and hives after sleeping in the product.

Remedy: Consumers should immediately check for mold under the removable seat cushion. Dark brown, gray or black spots can indicate the presence of mold. If mold is found, consumers should immediately stop using the product. Consumers can contact Fisher-Price for cleaning instructions or further assistance. Cleaning and care instructions can also be found at www.service.mattel.com or by contacting the firm.

Sold at: Mass merchandise stores nationwide and online since September 2009 for between \$50 and \$85. Units currently in retail stores are not affected by this recall to inspect. Only products that show signs of mold after use by consumers are included in this announcement.

Importer: Fisher-Price Inc., of East Aurora, N.Y.

Manufactured in: China

The U.S. Consumer Product Safety Commission (CPSC) is still interested in receiving incident or injury reports that are either directly related to this product recall or involve a different hazard with the same product. Please tell us about your experience with the product on SaferProducts.gov.

CPSC is charged with protecting the public from unreasonable risks of injury or death associated with the use of the thousands of consumer products under the agency's jurisdiction. Deaths, injuries, and property damage from consumer product incidents cost the nation more than \$900 billion annually. CPSC is committed to protecting consumers and families from products that pose a fire, electrical, chemical, or mechanical hazard. CPSC's work to ensure the safety of consumer products—such as toys, cribs, power tools, cigarette lighters, and household chemicals—contributed to a decline in the rate of deaths and injuries associated with consumer products over the past 30 years.

To report a dangerous product or a product-related injury, go online to: <u>SaferProducts.gov</u>, call CPSC's Hotline at (800) 638-2772 or teletypewriter at (301) 595-7054 for the hearing and speech impaired. Consumers can obtain this news release and product safety information at <u>www.cpsc.gov</u>. To join a free e-mail subscription list, please go to <u>www.cpsc.gov/cpsclist.aspx</u>.

Photos will display in a slideshow at the top right of the recall.

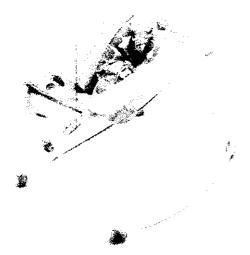


Photo 1 Caption: Fisher-Price Rock 'N Play Infant Sleeper



Photo2 Caption: Fisher-Price Infant Sleeper Removable Seat Cushion

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Nelson, Theresa

From:

Pilarz, Kitty < Kitty.Pilarz@Fisher-Price.com>

Sent:

Wednesday, January 09, 2013 9:33 PM

To:

Nelson, Theresa

Cc:

Schoem, Marc

Subject:

FW: Rock and Play Sleeper - letter to retailers

Attachments:

LetterToRetailers.PDF

Hi Terri,

(b)(4); (b)(3):CPSA Section 6(a); (b)(3):CPSA Section 6(b)

Best regards, Kitty

Confidential treatment requested

Submitted under section 15b

Kitty Pilarz Senior Director, Mattel Product Safety Fisher-Price 636 Girard Avenue East Aurora, New York 14052 716-687-3343

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From:	Pilarz, Kitty <kitty.pilarz@fisher-price.com></kitty.pilarz@fisher-price.com>	
Sent:	Friday, October 12, 2012 9:43 AM	
То:	Moore, Kelly; Nelson, Theresa	
Cc:	Schoem, Marc; Murphy, Mary	
Subject:	FW: Rock and Play Sleeper	
Attachments:	RNPSMessage_10.11.12.doc; Keep This Product Clean and DryFINALdocx.docx	
Actucinities.	NAT SINESSAGE_TO.TT.TZ.GOC, REED THIS Froduct Clean and DigitivaLadex.Gocx	
Dear Kelly and Terri,		
Dear Relly and Terri,		
Hara is our communic	nation plan	
Here is our communic	zation plan.	
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(b)(4); (b)(3):CPSA Section 6(a); (b)(3):CPSA Section 6(b)	
Best regards, Kitty	
Confidential treatment requested	
Submitted under section 15b	
Kitty Pilarz Senior Director, Mattel Product Safety Fisher-Price 636 Girard Avenue East Aurora, New York 14052 716-687-3343	
From: Moore, Kelly [mailto:KMoore@cpsc.gov] Sent: Wednesday, October 10, 2012 4:15 PM To: Pilarz, Kitty Cc: Schoem, Marc; Nelson, Theresa; Murphy, Mary Subject: RE: Rock and Play Sleeper	
Kitty,	
Thank you for your response. At the outset, we all agree that we need to consumers and, to that end, we support your use of the forms of med previously, we will work with you to ensure that the wording of the mes alarm." However, because mold exposure can be harmful to infants, the the general public. (b)(3) CPSA Section 6(b)	dia you identified. As we have told you sage does not cause, as you put it, "undue
(b)(4), (b)(3):CPSA Section 6(a), (b)(3):CPSA Section 6(b)	
We look forward to reviewing your communications plan. When it will be	pe available?
Thanks, Kelly	
From: Pilarz, Kitty [mailto:Kitty.Pilarz@Fisher-Price.com] Sent: Tuesday, October 09, 2012 10:51 AM To: Nelson, Theresa Cc: Schoem, Marc; Moore, Kelly Subject: Rock and Play Sleeper	
Dear Terri,	
(b)(4); (b)(3):CPSA Section 6(a); (b)(3):CPSA Section 6(b)	

1.	(b)(4); (b)(3):CPSA Section 6(a); (b)(3):CPSA Section 6(b)
2.	
3.	
4.	

Confidential treatment requested
Submitted under section 15b
Kitty Pilarz
Senior Director, Mattel Product Safety
Fisher-Price
636 Girard Avenue
East Aurora, New York 14052

716-687-3343

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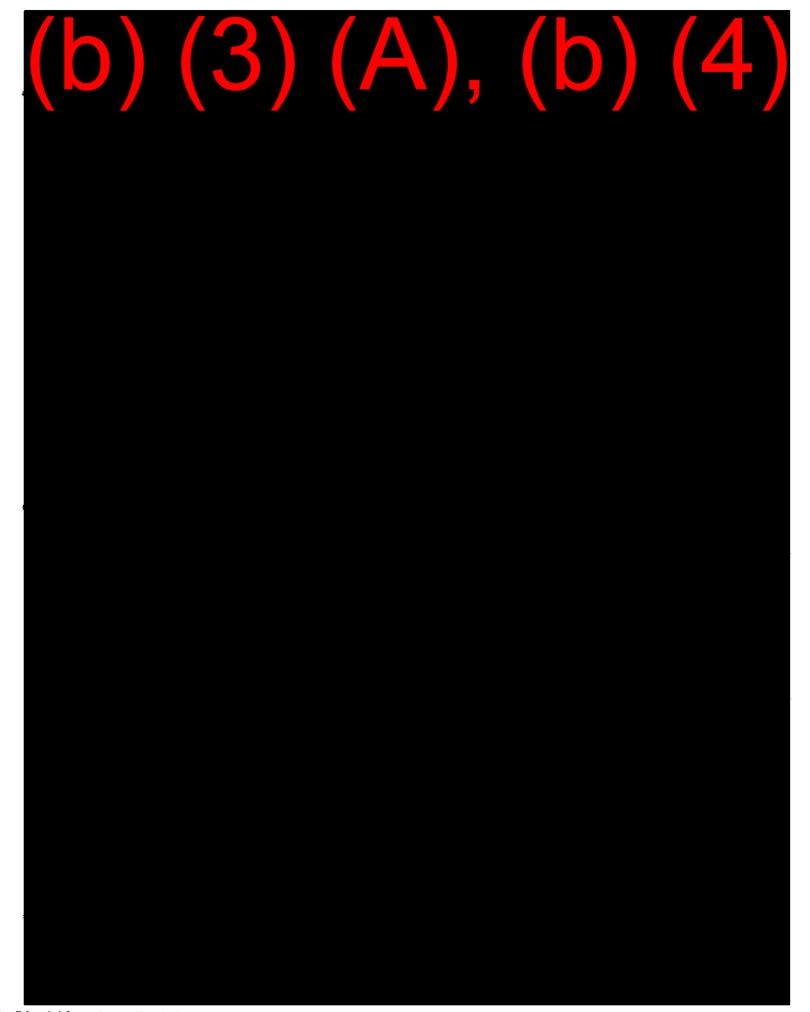
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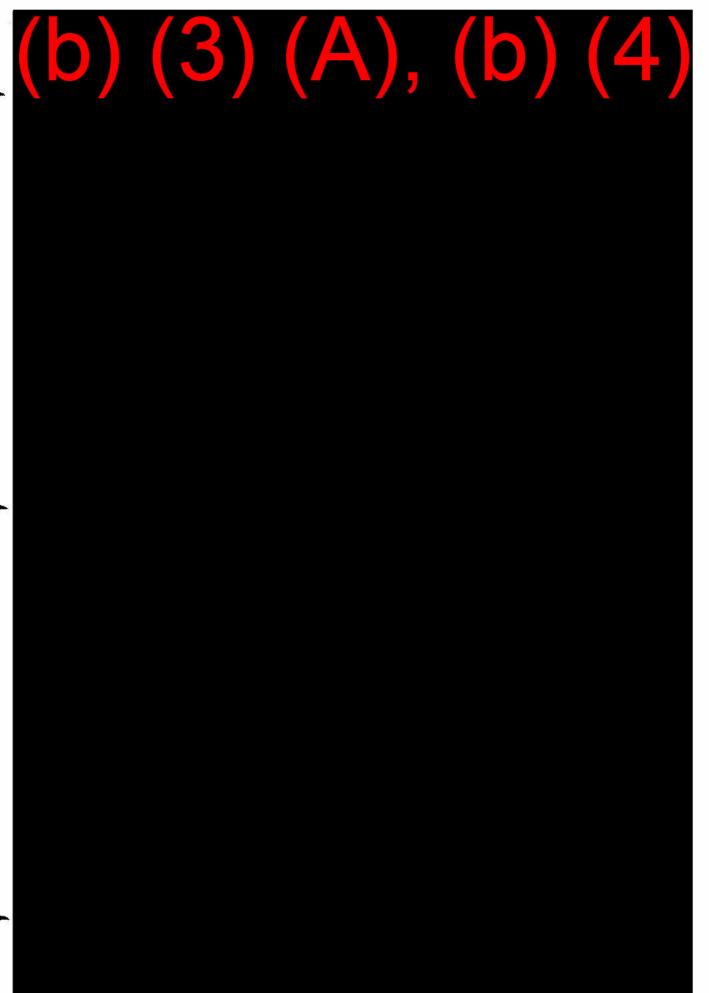
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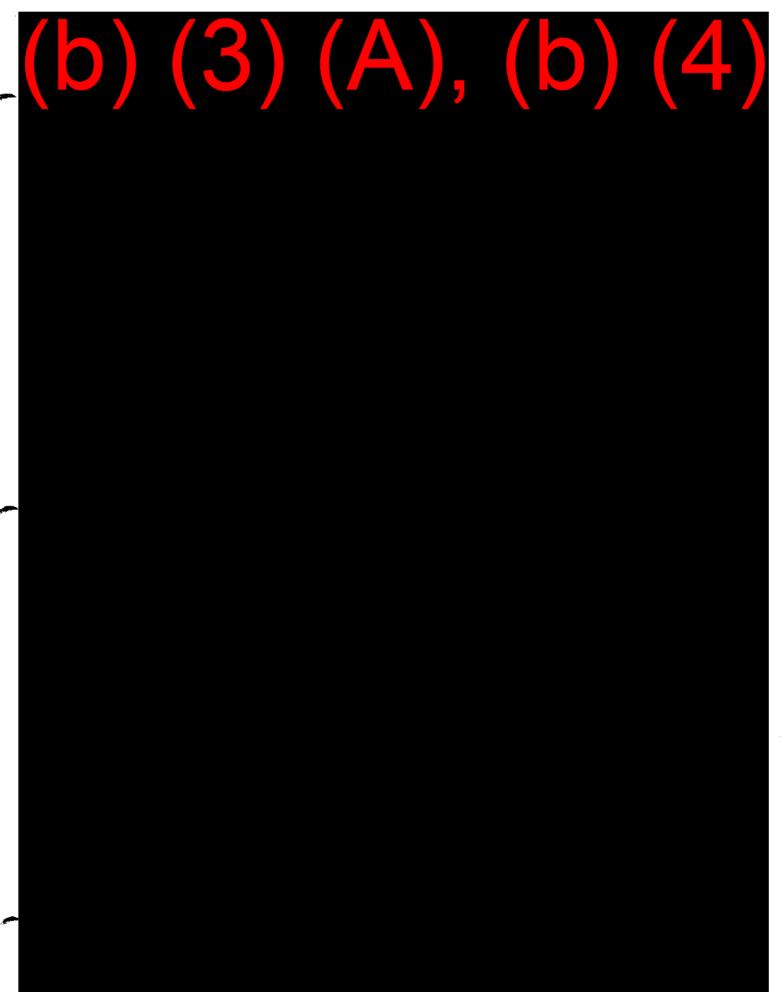
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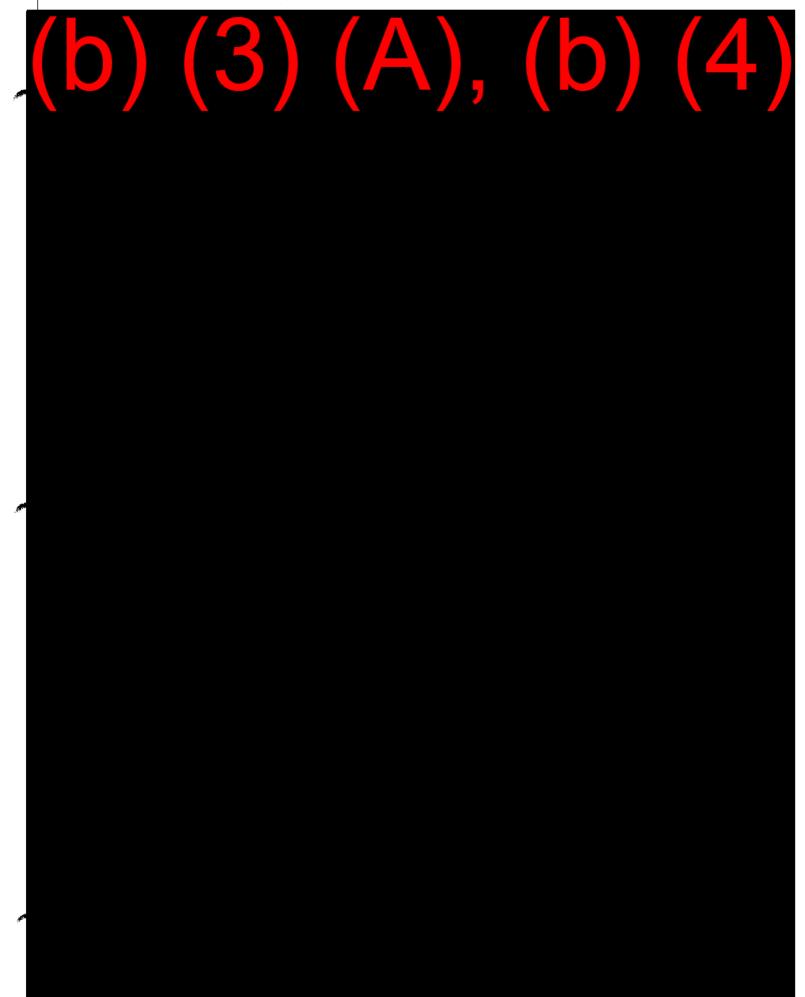


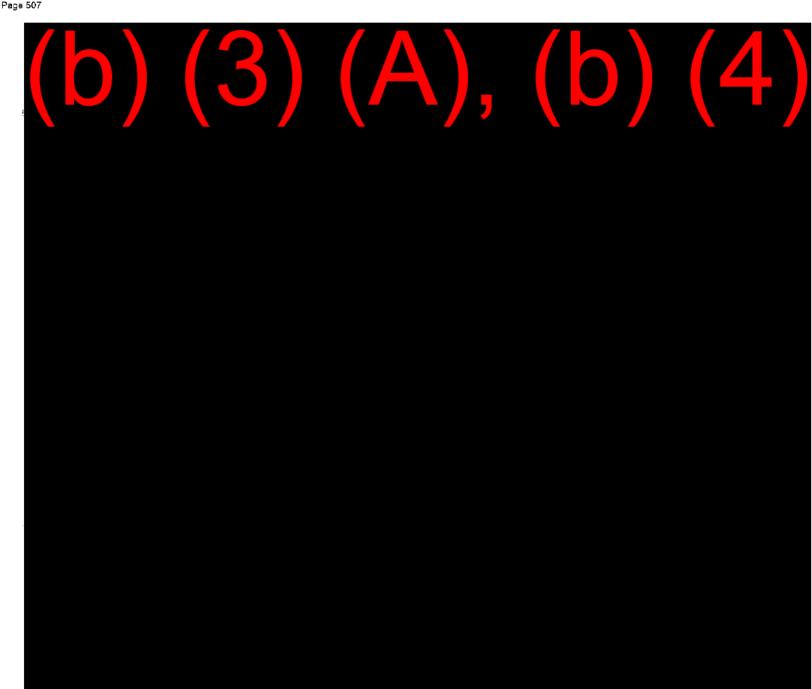
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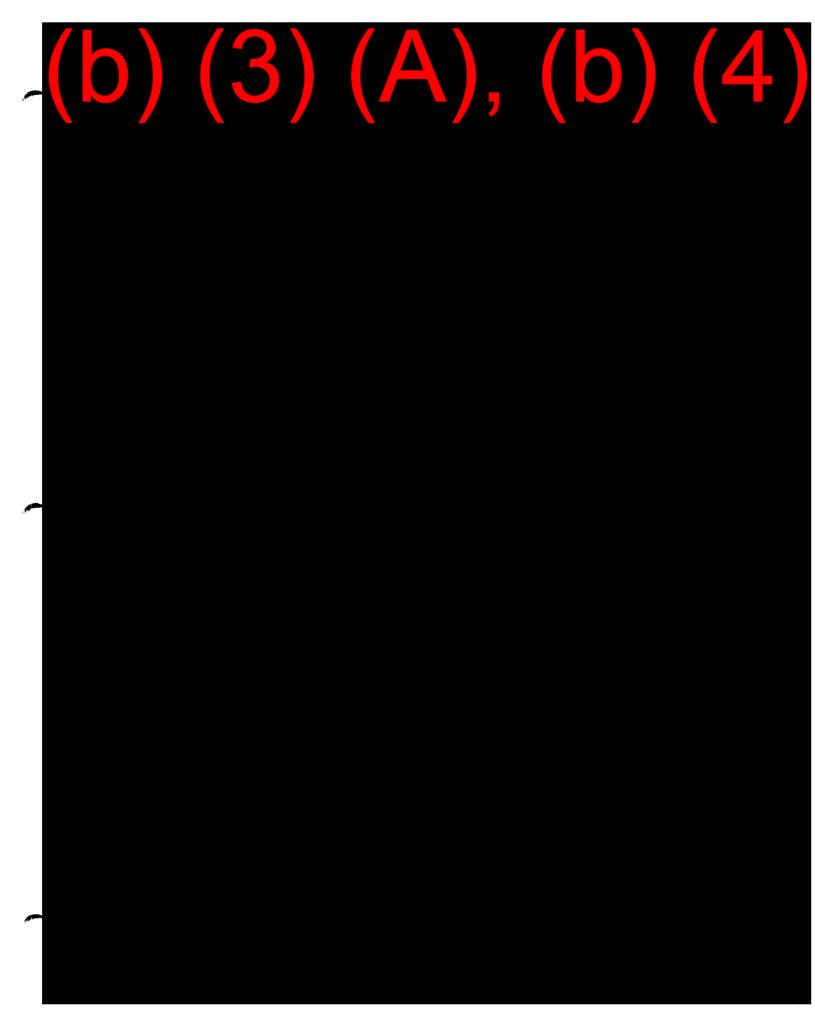


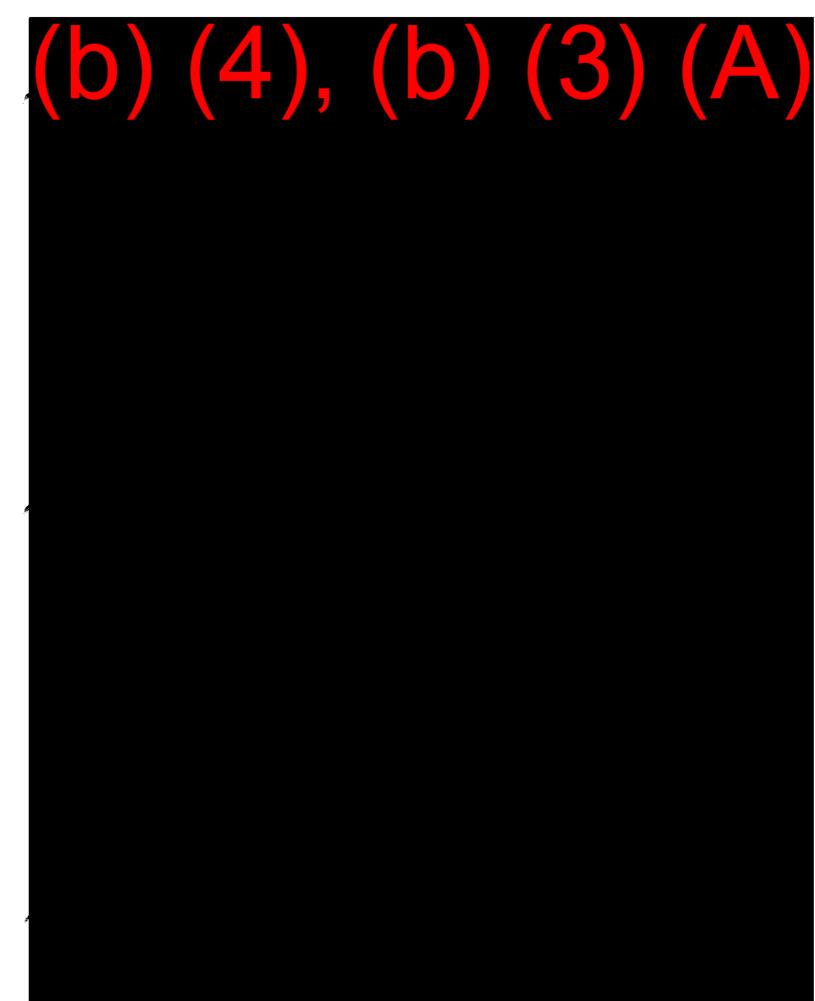














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