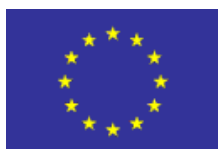


Acoustic toys and risks for impaired hearing

Report to the PROSAFE Project TOYS-JA2014

by Stig Arlinger

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Disclaimer

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1. Introduction

A number of market surveillance authorities involved in the product safety of acoustic toys took part in a joint market surveillance activity called 'TOYS-JA2014'. This project, coordinated by PROSAFE and funded by the European Union, was implemented between 2015 – 2016. In view that the surveillance authorities were mainly going to test the products in line with the latest acoustic requirements as found within the standard EN 71-1:2011+A3:2014, I was asked by this working group to see if some form of guidance could be given in relation to risk assessment of these acoustic toys in line with this revised standard.

One needs to first and foremost explain that this report should only be considered as generic guidance and ultimately one needs to ascertain the final level of risk on a case-by-case basis in line with the guidance given within this report and after fully considering all the aspects associated with that particular toy.

The European Standard EN 71-1:2011+A3:2014 specifies requirements on maximum sound pressure levels from toys that are clearly designed to produce sound. The sounds may be continuous, impulsive or a combination of both in character. Eleven different types of toys are defined in the standard, mainly related to their design and the ways in which children are assumed to play with them.

As yet there exists no scientific evidence that the sensitivity of children with relation to auditory hazard by exposure to loud sounds is significantly different from that of adults. The absolutely dominating scientific knowledge about noise as a hazard to human hearing is based on studies on adult human subjects. Most studies have focused on occupational noise exposure, but also to some extent on exposure to loud sounds in free-time activities such as listening to music. Studies have concerned retrospective analyses after exposures over longer time periods with focus on effects in terms of permanent hearing loss, but also short term effects have been studied, recording temporary changes in auditory function after well-defined exposures.

2. Auditory effects of noise exposure

Three main types of effects after noise exposure are known:

- 1.1 Hearing thresholds shifts. Hearing thresholds, tested using pure tones in the frequency range from 125 to 8.000 Hz, represent the sensitivity of the auditory organ. Physiologically they are mainly determined by the state of the outer hair cells in the human inner ear. Threshold shifts may be temporary in character – **Temporary Threshold Shifts, TTS**. Directly after an exposure a loss of sensitivity can be

recorded at one or several test frequencies, usually most pronounced in the range 3-6 kHz. After a sufficiently long recovery time – from hours to a few weeks – the hearing thresholds return to pre-exposure levels. Daily exposure levels not exceeding 75-80 dB(A) are unlikely to produce significant TTS.

- 1.2 In case of sufficiently long and loud exposure, hearing thresholds may never recover, but a permanent hearing loss is present – **Permanent Threshold Shift, PTS**. This situation is assumed to reflect permanent damage of outer hair cells, but other structures in the inner ear may be damaged as well. When TTS after a single exposure reaches 30-40 dB, the risk for PTS is considered real, i.e. the hearing thresholds will never return to pre-exposure levels.
2. Tinnitus is an auditory perception of sound without the presence of a corresponding external physical signal. The sound may be heard as a tone, a whistling or a buzzing sound. The most likely explanation for tinnitus is some type of damage to the inner ear and/or auditory nerve. Tinnitus may occur also when no measureable hearing loss is present. No clear evidence exists for critical exposure values with regard to noise causing permanent tinnitus. However, indirect evidence makes tinnitus as a consequence of “hidden hearing loss” very likely (Schaette & McAlpine, 2011).
3. “Hidden hearing loss” is a term that has been suggested to represent damage that has occurred to inner hair cells in the inner ear and/or to nerve fibers in the auditory nerve, leading from the inner ear to the brainstem. Animal studies have shown that such damage may occur after noise exposure that gives rise to TTS without leaving any PTS. These studies were performed on mice and guinea-pigs with exposures that gave rise to TTS of around 40 dB measured 24 hours after the exposure (Kujawa & Liberman, 2009; Furman et al, 2013). Prell et al (2012) estimates that a noise exposure resulting in TTS of less than 20 dB represents negligible risk for permanent effects on inner hair cells and/or auditory nerve fibers.

3. The noise at work directive

As explained in section A.25 of the EN 71-1 standard, the limit values of the standard are based on the lower action values found in directive 2003/10/EC (2003), commonly referred to as the “noise at work directive”.

This Directive specifies the following concepts with regard to occupational exposure to noise in Article 3, clause 1:

- (a) *exposure limit values: $L_{EX,8h} = 87 \text{ dB(A)}$ and $p_{peak} = 200 \text{ Pa}$, corresponding to 140 db (C) in relation to 20 uPa, respectively;*
- (b) *upper exposure action values: $L_{EX,8h} = 85 \text{ dB(A)}$ and $p_{peak} = 140 \text{ Pa}$, corresponding to 137 dB (C) in relation to 20 uPa, respectively;*
- (c) *lower exposure action values: $L_{EX,8h} = 80 \text{ dB(A)}$ and $p_{peak} = 112 \text{ Pa}$, corresponding to 135 dB (C) in relation to 20 uPa, respectively.*

These limit values are related to the position(s) normally occupied by the head of the person who is affected by the noise.

Further, in Article 6 on hearing protectors is stated:

- (a) where noise exposure exceeds the lower exposure action values, the employer shall make individual hearing protectors available to workers;
- (b) where noise exposure matches or exceeds the upper exposure action values, individual hearing protectors shall be used;

And in Article 7, Limitation of exposure, is stated:

1. Under no circumstances shall the exposure of the worker as determined in accordance with Article 3(2) exceed the exposure limit values.

4. Exposure to continuous noise

The International Standard ISO 1999 (2013), “Acoustics — Estimation of noise-induced hearing loss” provides data that allows calculation of the statistical risk for permanent noise-induced hearing loss after exposure to noise at various sound pressure levels. Figure 1 below illustrates the degree of permanent hearing loss, PTS, in decibel (dB) after 10 years of daily exposure for the 10 percent of the exposed population most affected by the noise. This figure shows that the lower action level for continuous noise of 80 dB(A) implies a very low risk for PTS at the most vulnerable frequencies 3-4 kHz even after many years of daily exposure.

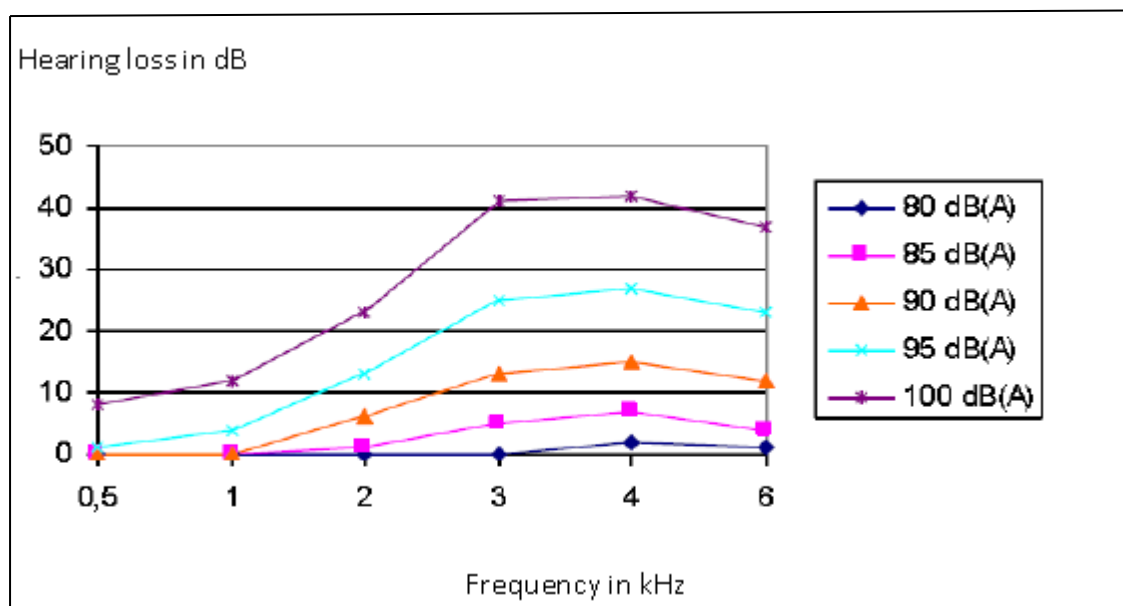


Fig. 1. Noise-induced permanent hearing loss after 10 years in occupational noise in levels between 80 and 100 dB(A) (8h/day) - 10-percentiles according to ISO1999.

With regard to temporary threshold shift, TTS, a number of laboratory studies have been published. Exposures to noise at 105 dB(A) for 10 min was used by one group in several studies, resulting in mean TTS at 3-4 kHz of between 7 and 18 dB with individual cases exceeding 20 dB. This exposure corresponds to approximately 88dB(A) during 8 hours. Based on 8 hours exposure duration, Mills et al (1981) estimated average TTS as a function of noise level. A noise level of 80 dB(A) resulted in a TTS of 6 dB, 85 dB(A) produced

13 dB, and 90 dB(A) gave rise to a TTS of 21 dB. Above approximately 85 dB, TTS increased by 1,7 dB for each dB increase in noise level. Melnick (1991) estimates that a broadband noise of 78 dB(A) may give rise to a TTS of approximately 8 dB. According to Ward et al (1961) noise-induced TTS increases in proportion to the logarithm of time, i.e. average TTS increases by 3 dB when exposure time is doubled.

As explained in section A.25 of EN 71-1:2011+A3:2014 the effective daily playing time for toys with continuous sound generation is assumed to be 2 hours, allowing a maximum emission sound pressure level of 86 dB (rounded to 85 dB), corresponding to 80 dB during 8 hours exposure time. Such an exposure might thus give rise to an average TTS of approximately 5-6 dB. There is no evidence to assume that such an exposure would give rise to any permanent effect on the exposed person.

A noise level of 90 dB(A) for an 8 hour exposure would according to Mills et al (1981) give rise to an average TTS of approximately 20 dB. Exceeding this amount of TTS might involve a risk of permanent effects in terms of damage to inner hair cells or auditory nerve cells, the “hidden hearing loss”. Converted to 2 hours exposure time, this corresponds to 96 dB(A) – conveniently rounded to 95 dB(A). A further increase in noise level by 10 dB is likely to involve a certain risk of permanent effects on hearing thresholds, PTS.

The EN-standard divides toys into three different categories, depending on assumed effective daily operating time of 120 minutes (category 1), less than 40 minutes (category 2), and less than 12 minutes (category 3). Due to the shorter exposure times for the two latter categories, the maximum permitted emission sound pressure levels are 5 and 10 dB higher, respectively.

Concluding this section on exposure to continuous noise from toys the following recommendations for all three categories of toys seem reasonable:

- Emission sound pressure levels fulfilling the requirements of EN 71.1:2011+A3:2014 are safe.
- Exceeding the requirement by 10 dB may introduce a risk for a TTS of 20 dB or more and permanent effects on inner hair cells and auditory nerve cells – “hidden hearing loss”.
- Exceeding the requirement by 20 dB may represent risk for immediate permanent hearing loss, PTS.

5. Exposure to impulse noise

C-weighted peak sound pressure level, independent of impulse duration, is the parameter used in the noise at work directive as well as in EN 71.1:2011+A3:2014. This is what has to be accepted, although several studies have shown that the peak sound pressure level is a rather simplistic measure of impulse noise with regard to risk for hearing impairment.

Ward et al (1961) found that 25 impulses delivered during one minute at 140 dB gave rise to a TTS of approximately 10 dB. Coles et al (1968), assessing earlier experiences from military exposures, proposed a criterion based on a combination of peak sound pressure level and impulse duration. For a 1 msec duration the limit was approximately 160 dB(C) and for 10 msec the limit was 152 dB(C) for 90% of exposed subjects showing a TTS of maximum 20 dB. A detailed NATO-study (2003) reconsidered all available studies with focus on exposure

to military weapons. For rifles a limit of approximately 153 dB (C) peak sound pressure level was assumed to limit TTS 2 minutes after exposure to less than 25 dB in 95% of the exposed population. Pfander et al (1980) identified a maximum peak sound pressure level of 148 dB (C) which would be acceptable also for impulses of very long duration. Their criterion for safe exposure was based on less than 5% of the exposed population to have a measureable TTS 24 hours after the exposure.

Based on the above data and considering the lack of data for impulse noise exposure that is not related to firearms, the following conclusions are drawn:

- Peak sound pressure levels fulfilling the requirements of EN 71.1:2011+A3:2014 are safe.
- Exceeding the requirement by 5 dB, i.e. 140 dB (C) peak sound pressure level, may introduce a risk for permanent effects on inner hair cells and auditory nerve cells – “hidden hearing loss”.
- Exceeding the requirement by 10 dB, i.e. 145 dB (C) peak sound pressure level, may represent risk for immediate permanent hearing loss, PTS.

6. Severity of injury

The RAPEX Guideline defines 4 degrees of severity of injury. With regard to hearing injury the following severity levels are listed (page 63):

1. Temporary pain in ear without need for treatment.
2. Temporary impairment of hearing.
3. Partial loss of hearing. Complete loss of hearing (one ear)
4. Complete loss of hearing (both ears)

Severity level 1, ‘temporary pain in ear’, may occur as a reaction to a very loud sound. Such an experience will invariably give rise to some kind of defense reaction, making the exposure to the particular sound very short in time and unlikely to be repeated.

With reference to section 2 of this document it is obvious that severity level 2 or severity level 3 may occur.

Severity level 2, ‘temporary impairment of hearing’, i.e. TTS, may occur for any exposure that exceeds the requirement for emission sound pressure levels according to EN 71-1:2011+A3:2014.

Severity level 3, ‘partial loss of hearing’, may occur as tinnitus, “hidden hearing loss” or permanent threshold shift, PTS. Tinnitus and “hidden hearing loss” may occur if the requirements for emission sound pressure levels are exceeded by 10 dB or if the requirements for peak sound pressure level are exceeded by 5 dB. Immediate PTS may occur if the requirements for emission sound pressure levels are exceeded by 15 dB or if the requirements for peak sound pressure level are exceeded by 10 dB.

It is not easy to state in general terms that one or the other of these three types of injury is a worse burden for the affected person. Therefore, it is reasonable to state that exceeding the requirements for emission sound pressure level by 10 dB or exceeding the requirements for peak sound pressure level by 5 dB represent the risk of injury of severity level 3.

Severity level 4, 'complete loss of hearing in both ears', is impossible to cause with any type of loud sound from a toy.

7. Probability of damage

The risk for injury is defined as a combination of severity of injury and probability of damage during the lifetime of the product. The standard defines eleven toy types which differ in size and in the way children are assumed to play with them. These aspects affect the probability that a toy may emit its sound close to the ear of a child, be it the child who is handling the toy in question or another child. When the distance between a sound source and a child's ear decreases, the sound level reaching the ear increases. By a first approximation this increase is 6 dB for each halving of the distance. This means that for short distances even small changes in distance may have a large effect on the sound level reaching the ear. Therefore, toys that are intended to be used close to the ear or can easily be moved to such positions represent the highest probability of damage.

Close-to-the-ear toys are by definition intended to be used close to a child's ear. If the child manages to place the toy in such a way as to produce a closed coupling to the ear, this is likely to increase the sound pressure entering the ear. The probability for this is estimated at e 1/10 000.

Table-top or floor toys are typically relatively large and unlikely to be close to a child's ears during play. The probability of damage is estimated to be e 1/1 000 000.

Hand-held toys are sometimes relatively small and therefore easily placed close to an ear. Examples are clicking toys or toy guns that may generate high impulse sounds at short distances. The probability of damage is estimated to be e 1/100 000.

Pull-along or push toys are typically relatively large and unlikely to be close to a child's ears during play. The probability of damage is estimated to be e 1/1 000 000.

Voice toys may in some cases be close to a child's ear when activated by another child. The probability of damage is estimated at e 1/10 000.

Toys using headphones or earphones are by definition placed on the child's ears. Thus, the probability is e 50%.

Rattles may be activated relatively close to a small child's ears but more likely the activation takes place at a longer distance, with the intent to allow the child to see the movements that activate the rattle. The probability for damage is estimated to be e 1/100 000.

Squeeze toys may be activated relatively close to a small child's ears but more likely the activation takes place at a longer distance, with the intent to allow the child to see the

movements that activate the toy. The probability for damage is estimated to be e 1/100 000.

Percussion toys are normally relatively large in size and therefore unlikely to be activated when close to a child's ear. However, for example tambourines, belonging to this group, may be used relatively close to an ear. The probability of damage is estimated to be e 1/100 000.

Wind toys may relatively easily be activated close to another child's ears. The probability of damage is estimated to be e 1/1 000.

Cap-firing toys may easily be fired close to another child's ear. The probability of damage is estimated at e 1/1 000.

8. Risk level

When the requirements according to EN 71-1:2011+A3:2014 are met the risk level for any hearing injury is very low.

When the requirements for emission sound pressure levels are exceeded by less than 10 dB and for peak sound pressure level by less than 5 dB there is a risk of injury of severity level 2 (TTS).

When the requirements for emission sound pressure levels are exceeded by 10 dB or more and the requirements for peak sound pressure level are exceeded by 5 dB or more there is a risk of injury of severity level 3 (permanent effects). Related to the estimated probabilities for damage according to section 7, the following risk levels are estimated as shown in Table 1:

Toy category	Risk level regarding injury level 2	Risk level regarding injury level 3
Close-to-the-ear toy	M	H
Table-top or floor toy	L	L
Hand-held toy	L	M
Pull-along or push toy	L	L
Voice toy	M	H
Toy using headphones or earphones	S	S
Rattle	L	M
Squeeze toy	L	M
Percussion toy	L	M
Wind toy	H	S
Cap-firing toy	H	S

Table 1: Estimated risk levels for injury levels 2 or 3. L=Low, M=Medium, H=High, S=Serious risk

When the requirements for emission sound pressure levels are exceeded by 15 dB or more and/or the requirements for peak sound pressure level are exceeded by 10 dB or more, the probability of damage shall be increased by a factor of 10 and the risk levels adjusted accordingly.

Table 2 below indicates the maximum emission sound pressure levels and peak sound pressure levels for the different toy categories with respect to the estimated risk levels. Where risk of a certain level is not relevant for a specific type of toy, i.e. the risk level in question is assumed to never occur, this is indicated by NR = Not Relevant.

Acoustic Levels as determined by EN71-1:2011+A2:2013

CODE	PRODUCT GROUP	Description as specified within EN71-1	Related Examples from EN71-1	A-weighted time averaged emission sound pressure level LpA									C-weighted peak emission sound pressure level LpCpeak			Comments		
				Test Measurement	Category 1: Toys emitting sound during time periods typically longer than 30 s after each initiation			Category 2: Toys emitting sound during time periods typically shorter than 30 s but longer than 5 s after each initiation			Category 3: Toys emitting sound during time periods typically shorter than 5 s after each initiation							
CE	Close-to-the-ear toys	Toy clearly designed to emit sound, intended to be used within 2.5cm of the ear (Clause 3.10 of EN71-1)	Toy telephones, toy rifles with a loudspeaker in the stock	Measurement at 50cm	Shall not exceed 60dB	Medium Risk	Max Limit: 69 dB	shall not exceed 65dB	Medium Risk	Max Limit: 74 dB	shall not exceed 70dB	Medium Risk	Max Limit: 79 dB	shall not exceed 110dB	Medium Risk	Max Limit: 114 dB	Old Standard: LpA - 80dB / LpCpeak - 115dB	
						High Risk	Min Limit: 70 dB		High Risk	Min Limit: 75 dB		High Risk	Min Limit: 80 dB		High Risk	Min Limit: 115 dB		
						Serious Risk	Min Limit: 75 dB		Serious Risk	Min Limit: 80 dB		Serious Risk	Min Limit: 85 dB		Serious Risk	Min Limit: 120 dB		
TF	Table-top or floor toys	Toy clearly designed to emit sound, intended to be used on a table, floor or another large surface (Clause 3.59 of EN71-1)	Toy cars, mechanical animals, and large and bulky toys	Measurement at 50cm	Shall not exceed 80dB	Medium Risk	Min Limit: 95 dB	shall not exceed 85dB	Medium Risk	Min Limit: 100 dB	shall not exceed 90dB	Medium Risk	Min Limit: 115 dB	shall not exceed 110dB	Medium Risk	Min Limit: 120 dB	Old Standard: LpCpeak - 115dB	
						High Risk	Max Limit: NR		High Risk	Max Limit: NR		High Risk	Max Limit: NR		High Risk	Max Limit: NR		
						Serious Risk	Max Limit: NR		Serious Risk	Max Limit: NR		Serious Risk	Max Limit: NR		Serious Risk	Max Limit: NR		
HH	Hand-held toys	Toy clearly designed to emit sound, intended to be held in the hand but excluding close-to-the-ear toys, rattles, squeeze toys, cap-firing toys, wind toys, voice toys and percussion toys (Clause 3.31 of EN71-1)	Clicking toys, Toy Tools, toy guns	Measurement at 50cm	Shall not exceed 80dB	Medium Risk	Min Limit: 90 dB	shall not exceed 85dB	Medium Risk	Min Limit: 95 dB	shall not exceed 90dB	Medium Risk	Min Limit: 100 dB	shall not exceed 110dB	Medium Risk	Min Limit: 115 dB	Old Standard: LpCpeak - 115dB	
						High Risk	Min Limit: 95 dB		High Risk	Min Limit: 100 dB		High Risk	Min Limit: 105 dB		High Risk	Min Limit: 120 dB		
						Serious Risk	Max Limit: NR		Serious Risk	Max Limit: NR		Serious Risk	Max Limit: NR		Serious Risk	Max Limit: NR		
PA	Pull-along or push-along toys	Toy on which movement is imparted by the user for example by pulling it by a cord or pushing it by means of a rigid extension (Clause 3.48 of EN71-1)		Measurement at 50cm	Shall not exceed 80dB	Medium Risk	Min Limit: 95 dB	shall not exceed 85dB	Medium Risk	Min Limit: 100 dB	shall not exceed 90dB	Medium Risk	Min Limit: 115 dB	shall not exceed 110dB	Medium Risk	Min Limit: 120 dB	Old Standard: LpCpeak - 115dB	
						High Risk	Max Limit: NR		High Risk	Max Limit: NR		High Risk	Max Limit: NR		High Risk	Max Limit: NR		
						Serious Risk	Max Limit: NR		Serious Risk	Max Limit: NR		Serious Risk	Max Limit: NR		Serious Risk	Max Limit: NR		
VT	Voice toys	Toy clearly designed to emit sound by electronically amplifying or distorting the voice and where the output sound level depends on the input sound level of the voice (Clause 3.68 of EN71-1)	Telephones, walkie-talkies, voice recording toys, sing-along microphones and electronic bull horns (toy megaphones)	Measurement at 50cm	Shall not exceed 80dB	Medium Risk	Max Limit: 89 dB	shall not exceed 85dB	Medium Risk	Max Limit: 94 dB	shall not exceed 90dB	Medium Risk	Max Limit: 99 dB	shall not exceed 110dB	Medium Risk	Max Limit: 114 dB	Old Standard: Levels - ??	
						High Risk	Min Limit: 90 dB		High Risk	Min Limit: 95 dB		High Risk	Min Limit: 100 dB		High Risk	Min Limit: 115 dB		
						Serious Risk	Min Limit: 95 dB		Serious Risk	Min Limit: 100 dB		Serious Risk	Min Limit: 105 dB		Serious Risk	Min Limit: 120 dB		
HE	Toys using headphones or earphones			Measurement at a	Shall not exceed 85dB	Medium Risk	Max Limit: NR						shall not exceed 135dB	Medium Risk	Max Limit: NR	Old Standard: LpA - 90dB / LpCpeak - 115dB		
						High Risk	Max Limit: NR							High Risk	Max Limit: NR		High Risk	Max Limit: NR
						Serious Risk	Max Limit: NR							Serious Risk	Max Limit: NR		Serious Risk	Max Limit: NR
RA	Rattles	Toy, intended for children who are too young to sit up unaided, that is clearly designed to emit sound when shaken or activated by the child or another person (Clause 3.49 of EN71-1)		Measurement at 50cm		Shall not exceed 85dB	Medium Risk	Min Limit: 95 dB					shall not exceed 110dB	Medium Risk	Min Limit: 115 dB	Old Standard: LpA - 85dB / LpCpeak - 110dB		
							High Risk	Min Limit: 100 dB						High Risk	Min Limit: 120 dB			
							Serious Risk	Max Limit: NR						Serious Risk	Max Limit: NR			
ST	Squeeze toys	Pliable toy, intended for children who are too young to sit up unaided, incorporating a sound-making feature activated by forcing air through an opening, clearly designed to emit sound when flexed or squeezed by the child or another person. (Clause 3.55 of EN71-1)		Measurement at 50cm		Shall not exceed 85dB	Medium Risk	Min Limit: 95 dB					shall not exceed 110dB	Medium Risk	Min Limit: 115 dB	Old Standard: LpA - 85dB / LpCpeak - 110dB		
							High Risk	Min Limit: 100 dB						High Risk	Min Limit: 120 dB			
							Serious Risk	Max Limit: NR						Serious Risk	Max Limit: NR			
PT	Percussion toys	Toy clearly designed to emit sound when struck with a beater, such as a drumstick, or by the hand (Clause 3.43 of EN71-1)	Drums, xylophones and tambourines	Measurement at 50cm		Shall not exceed 85dB	Medium Risk	Min Limit: 95 dB					shall not exceed 130dB	Medium Risk	Min Limit: 135 dB			
							High Risk	Min Limit: 100 dB						High Risk	Min Limit: 140 dB			
							Serious Risk	Max Limit: NR						Serious Risk	Max Limit: NR			
WT	Wind toys	Toy clearly designed to emit sound when actuated by the blowing action of the child or another person (Clause 3.69 of EN71-1)	Trumpets and toy whistles	Measurement at 50cm		shall not exceed 85dB	Medium Risk	Max Limit: NR			shall not exceed 90dB	Medium Risk	Max Limit: NR	shall not exceed 110dB	Medium Risk	Max Limit: NR		
							High Risk	Max Limit: 94 dB				High Risk	Max Limit: 99 dB		High Risk	Max Limit: 114 dB		
							Serious Risk	Min Limit: 95 dB				Serious Risk	Min Limit: 100 dB		Serious Risk	Min Limit: 115 dB		
CF	Cap-firing toys	Toy clearly designed to emit sound caused by discharge of a percussion cap (Clause 3.7 of EN71-1)	Cap guns	Measurement at 50cm						shall not exceed 90dB	Medium Risk	Max Limit: NR	shall not exceed 125dB	Medium Risk	Max Limit: NR	Old Standard: LpCpeak - 125dB		
											High Risk	Max Limit: 99 dB		High Risk	Max Limit: 129 dB			
											Serious Risk	Min Limit: 100 dB		Serious Risk	Min Limit: 130 dB			

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