



Nederlandse Voedsel- en
Warenautoriteit
*Ministerie van Landbouw,
Natuur en Voedselkwaliteit*

Balloons 2018

Safety requirements investigation

Release of nitrosamines and nitrosatable substances and labelling control

Balloons must meet the European safety requirements for toys. The Netherlands Food and Consumer Product Safety Authority (NVWA) is conducting an investigation to establish whether balloons meet the requirements for the maximum release of nitrosamines and nitrosatable substances

and the obligatory warnings on labels. This fact sheet contains the results of the 2018 market surveillance.

Background

The market surveillances conducted by the NVWA from 2002 to 2010 revealed that 80% of balloons did not meet safety requirements. At that time, the legislation applied was the Dutch Policy rule¹. Balloons are manufactured outside the Netherlands; the supervision conducted in the Netherlands had no impact on the countries of production. As a result, efforts have been devoted to drawing up European requirements for balloons.

Comparable standards have been applicable to balloons throughout Europe (Directive 2009/48/EC) since July 2013. A European standard for the method of analysis has been designated as well (EN71-12).

As this legislation has been in force for a number of years now, it prompted the NVWA to re-investigate balloons in 2018.

Risks

Balloons are made of natural rubber (latex). Nitrosamines and nitrosatable substances can be generated during the latex production process if certain compounds (carbmates) are added to accelerate the process. Because nitrosamines are carcinogenic substances, they pose a health risk². Alternative accelerators are available, making this risk an avoidable one.

Children can ingest these substances by sucking balloons or through hand-to-mouth contact. Some people are allergic to latex. To this end, parents or carers must be warned that balloons are made of latex. Balloons should also have a warning on them to ensure their safe use.

1. Beleidsregel inzake normen t.a.v. veiligheid van ballonnen, Staatscourant 28 maart 2006, nr. 62.
2. Opinion on NDELA in Cosmetic Products and Nitrosamines in Balloons. Scientific Committee on Consumer Safety, June 2012.

Met opmaak: Nederlands (standaard)

Approach

Products

The NVWA sampled 58 types of balloon in total during the period from December 2017 to January 2018. Samples were taken from 35 different brands. They are the brands the most commonly available to the Dutch consumer online and offline (in outlets such as department stores, clothes shops, drug stores and toy shops). Samples were collected from shops, manufacturers, importers and distributors. Balloons were also ordered online from Chinese and Dutch web shops.

The items to be examined and the methods of analysis used were presented to the toy sector in advance. These documents are available on the NVWA website: www.nvwa.nl (search term: ballonnen [balloons]).

Research

The NVWA laboratory tested the balloons for the release of nitrosamines and nitrosatable substances in accordance with European standard EN71-12. This standard requires the release level to be determined in a saliva simulant for one hour at 40 °C, which simulates a child's sucking action. EN17-12 includes a list of the different nitrosamines that can occur in balloons.

If there were balloons of several different colours in one bag, one colour was selected at random for testing.

Assessments were also made to establish whether the labels state the required warnings, the name and address details of the importer or manufacturer, and CE marking.



Legal requirements

The Toy Safety Directive 2009/48/EC sets requirements for the release of nitrosamines and nitrosatable substances from latex toys. For nitrosamines, the requirement is that the total amount released must not exceed 0.05 mg/kg; for nitrosatable substances, the amount released must not exceed 1.0 mg/kg.

EN71-1 prescribes two specific warning phrases for balloons:

- "Warning. Children under eight years can choke or suffocate on uninflated or broken balloons. Adult supervision required. Keep uninflated balloons from children. Discard broken balloons at once."
- "Made of natural rubber latex"

Results

Twenty-five (43%) of the fifty-eight balloons tested do not meet the safety requirements. The results for each product are described in Appendix 1.

Nitrosamines and nitrosatable substances

Sixteen of the fifty-eight (27%) balloons release an excessive level of nitrosamines and nitrosatable substances.

In the case of one balloon, the release level is so high that it poses a serious risk. As this balloon was purchased through a Chinese web shop, the NVWA is unable to take any action against it. The details of the balloon in question may be found in the appendix; do not use this balloon.

Selling balloons with an excessive release of nitrosamines and nitrosatable substances is forbidden. The NVWA informed the European Commission of the products that do not meet the requirements in a RAPEX notification.

In the case of seventeen balloons, there is no detectable release of nitrosamines and nitrosatable substances. Twenty-five balloons did release those substances, but the release level was lower than the legal limit. NDELA, NDMA and NDEA were identified in particular.

Label

Part or all of the label was missing from sixteen of the fifty-eight (27%) balloons, or the label present was not in the Dutch language.

Balloons without warnings on them may be sold only after the label has been amended.

Comparison with previous market studies

Table 1 shows the comparison with the results of previous market studies. They have been assessed against current chemical requirements. The previous market studies applied requirements for nitrosamines and nitrosatable substances of 0.01 mg/kg and 1 mg/kg, respectively. The present requirement for nitrosamines is higher by a factor of five (0.05 mg/kg).

Table 1: Comparison with previous NVWA tests for the release of nitrosamines and nitrosatable substances

year	number tested balloons	nitrosamine ≤ 0.05 mg/kg	nitrosatable ≤ 1 mg/kg
2002	56	39%	29%
2004	58	59%	71%
2006	66	36%	62%
2009	80	43%	41%
2010	35	63%	66%
2018	58	76%	79%

There is a visible improvement in 2018 compared with previous years.

Conclusion

Twenty-five of the fifty-eight balloons (43%) do not meet the safety requirements investigated.

In the case of sixteen balloons (27%), the level of nitrosamines and nitrosatable substances released is higher than the legal limit. The sale of these balloons is forbidden. In the case of one balloon, the release level is so high that use of the balloon is not recommended.

Since the introduction of European legislation in 2013, a considerable improvement in the release of nitrosamines and nitrosatable substances has been noted.

In the case of sixteen balloons, part or all of the required label is missing. As a result, consumers are not properly informed of the risks posed by the balloon in question. The sale of these balloons is forbidden until their labels have been amended.

Appendix 1: Results for each balloon

Table 2: Results for nitrosamines, nitrosatable substances and the labelling of balloons

make, type and identification	colour tested	nitrosamines in mg/kg (requirement $\leq 0.05^1$)	nitrosatable in mg/kg (requirement $\leq 1.0^1$)	label non-compliance ²	assessment and action ³
Globos Metallic silver 30 cm, 21440	Silver	0	0.07	None	No safety risk
Globos No12 Orange 30 cm, 2138	Orange	0	0	None	No safety risk
AH balloons assorted colours, 26 cm 50 pcs, batch No 170125	Red	0	0	None	No safety risk
Party balloons 8 pcs, art. No 1542745	Green	0.68	0.49	None	Safety risk. Sales are forbidden.
Blokker balloons 25 cm 20 pcs, 3387386, batch Yellow 1943	Yellow	0	0	None	No safety risk
Belbal B85 Pastel Royal blue 022, 17/279	Blue	0.02	0.51	None	No safety risk
Belbal B105 038 crystal clear, 17/251	Transparent	0	0.76	None	No safety risk
Pegaso International flag colours, PB 100/84 GHL	Red	0	0.53	None	No safety risk
Pegas 20 balloons round, large, PB 100/01	Green	0	0.50	None	No safety risk
Spiderman – Marvel, art. No 999241	Red	0	0	None	No safety risk
Paw Patrol – Nickelodeon, art. No 999141	Blue	0	0.06	None	No safety risk
Zeeman 20 balloons, C29748 A22136 051700	Orange	0	0.04	None	No safety risk
Xenos 20 balloons, art. No 272.289	Green	0	0.05	None	No safety risk
Haza balloons 100 pcs 30 cm purple, art. 446731	Purple	0.36	0.24	None	Safety risk. Sales are forbidden.
Party factory 10 pcs 30 cm, art. No 442319	Pink	0	0	None	No safety risk

1. Requirement in accordance with Annex II, Part III Chemical Properties, Paragraph 8 of Directive 2009/48/EC.

2. Requirement in accordance with EN71-1 and Directive 2009/48/EC.

3. Assessment based on the safety requirements assessed.

Table 2: Results for nitrosamines, nitrosatable substances and the labelling of balloons (continuation of page 1)

make, type and identification	colour tested	nitrosamines in mg/kg (requirement 0.05 ¹)	nitrosatable in mg/kg (requirement 1.0 ¹)	label non-compliance ²	assessment and action ³
Folatex Balloons orange 10 pcs 30 cm, art. 08172 batch 170145	Orange	0.16	0.14	None	Safety risk. Sales are forbidden.
Balloonía 100 balloons Red P25, art. 90212	Red	0.11	0.13	None	Safety risk. Sales are forbidden.
Everts Polen balloons yellow, art. No EV30	Yellow	0	0	Unwrapped	No safety risk
Balloons blue 500 pieces, G90/09 batch 06/03/17	Blue	0	0	None	No safety risk
Folatex Balloons white 100 pcs 30 cm, 8104	White	0	0	None	No safety risk
Folat basics 100x balloons, 84800, batch No 170012	Orange	0.05	0.06	None	No safety risk
Altijd Handig 12 balloons with stickers, art. No 459729	Orange	0	0.08	Natural rubber latex warning missing	Safety risk. Sales are forbidden without a correct label.
Gemar Party balloons 25 pcs assorted, art. 300116, batch 1875/05/17	Green	0	0	None	No safety risk
Hema 50 balloons, art. No 14.20.0128	Blue	0	0.05	None	No safety risk
Party Balloons 25 pcs, art. 315134, batch 2442/06/17	Red	0	0	None	No safety risk
KÖLN Balloon Funny Fashion	Red	0	1.23 ⁴	None	No safety risk
Balloon 100 pcs 23 cm, KA02109	Green	0	0.52	Natural rubber latex warning missing	Safety risk. Sales are forbidden without a correct label.
Belbal 27 cm pastel mandarin orange, SB12P-005	Orange	0	0.54	None	No safety risk

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2. Requirement in accordance with EN71-1 and Directive 2009/48/EC.

3. Assessment based on the safety requirements assessed.

4. Adjusted for measurement uncertainty, the result is below the limit.

Table 2: Results for nitrosamines, nitrosatable substances and the labelling of balloons (continuation of page 2)

make, type and identification	colour tested	nitrosamines in mg/kg (requirement 0.05 ¹)	nitrosatable in mg/kg (requirement 1.0 ¹)	label non-compliance ²	assessment and action ³
Belbal B85 Pastel 100 balloons, 022 Royal Blue 16/260	Blue	0.05	0	None	No safety risk
Folatex Balloons Orange 10 x 30 cm, art. No 08172, batch 160884	Orange	0	0.11	None	No safety risk
Gemar Balloons 100 pcs, C90/80, art. 09801, batch 27/02/2017	Purple	0	0	None	No safety risk
Balloons 8 pcs copper 12 1/2 years, art. No 90114	Brown	0.39	0.24	None	Safety risk. Sales are forbidden.
Balloonía 50 balloons red, art. No 90194	Red	0.13	0.08	None	Safety risk. Sales are forbidden.
Goodmark emoji balloons 6 pcs, art. No 90160	Yellow	0	0.90	None	No safety risk
W Happy New Year balloons 12 pcs, batch No B20170612-2	Black	0.14	3.22	None	Safety risk. Sales are forbidden.
Boland Peace 6 pcs, 1643	Yellow	0.18	0.06	None	Safety risk. Sales are forbidden.
Sempertex 12 balloons standard/fashion	Blue	0	0	None	No safety risk
Karaloon 20 coloured heart-shaped balloons 10036220	Blue	0	0	None	No safety risk
Shoppartners coloured balloons 50 x, 10046655	Blue	0	0.09	Natural rubber latex warning; warning >8 years; CE marking missing	Safety risk. Sales are forbidden without a correct label.
Comedia 10 balloons light-blue, No 72.008	Blue	0	0	None	No safety risk

1. Requirement in accordance with Annex II, Part III Chemical Properties, Paragraph 8 of Directive 2009/48/EC.

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3. Assessment based on the safety requirements assessed.

Table 2: Results for nitrosamines, nitrosatable substances and the labelling of balloons (continuation of page 3)

make, type and identification	colour tested	nitrosamines in mg/kg (requirement 0.05 ¹)	nitrosatable in mg/kg (requirement 1.0 ¹)	label non-compliance ²	assessment and action ³
Shen Hua 10 pcs orange, art. No 3-385	Orange	0.22	3.36	Not in the Dutch language	Safety risk. Sales are forbidden.
Shen Hua birthday balloons 1 year	Blue	0	3.38	Not in the Dutch language	Safety risk. Sales are forbidden.
Ginger ray hen party balloons, TB-604	White	0	1.12 ⁴	Not in the Dutch language	Safety risk. Sales are forbidden without a correct label.
Cattex balloons red 50 pcs, PT/120.04	Red	0	0	None	No safety risk
Balloonia 6 balloons heart-shaped red, art. 90125	Red	0.15	0.10	None	Safety risk. Sales are forbidden.
Balloon blue	Blue	0	1.14 ⁴	Natural rubber latex warning; warning >8 years; CE marking; name and address details missing	Safety risk. Sales are forbidden without a correct label.
Globos Decorativos happy balloons 100 pcs	Red	14.1	11.6	Natural rubber latex warning; warning >8 years; CE marking; name and address details missing	Serious safety risk. Sales are forbidden. Do not use the product

1. Requirement in accordance with Annex II, Part III Chemical Properties, Paragraph 8 of Directive 2009/48/EC.

2. Requirement in accordance with EN71-1 and Directive 2009/48/EC.

3. Assessment based on the safety requirements assessed.

4. Adjusted for measurement uncertainty, the result is below the limit.

Table 2: Results for nitrosamines, nitrosatable substances and the labelling of balloons (continuation of page 4)

make, type and identification	colour tested	nitrosamines in mg/kg (requirement 0.05 ¹)	nitrosatable in mg/kg (requirement 1.0 ¹)	label non-compliance ²	assessment and action ³
Globos Decorativos pearl green 100 pcs, S5078313000008	Green	0.65	3.68	Natural rubber latex warning; warning >8 years; CE marking; name and address details missing	Safety risk. Sales are forbidden.
36" 90cm latex balloon, 422139	Green	0	1.18 ⁴	Natural rubber latex warning; warning >8 years; CE marking; name and address details missing	Safety risk. Sales are forbidden without a correct label.
7.5-inch heart-shaped balloons mixed colours, 472686	Pink	0.07 ⁴	1.99	Natural rubber latex warning; warning >8 years; CE marking; name and address details missing	Safety risk. Sales are forbidden.
Pearl latex party balloons 100	Gold	0.14	1.12 ⁴	Natural rubber latex warning; warning >8 years; CE marking; name and address details missing	Safety risk. Sales are forbidden without a correct label.
Clear birthday wedding party decor Tai cheng	Off-white	0	0.91	Natural rubber latex warning; warning >8 years; CE marking; name and address details missing	Safety risk. Sales are forbidden without a correct label.

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2. Requirement in accordance with EN71-1 and Directive 2009/48/EC.

3. Assessment based on the safety requirements assessed.

4. Adjusted for measurement uncertainty, the result is below the limit.

Table 2: Results for nitrosamines, nitrosatable substances and the labelling of balloons (continuation of page 5)

make, type and identification	colour tested	nitrosamines in mg/kg (requirement 0.05 ¹)	nitrosatable in mg/kg (requirement 1.0 ¹)	label non-compliance ²	assessment and action ³
SES Balloon figures, 00959.03	Green	0	0	None	No safety risk
Prénatal balloons 1 year 8 pcs, 74-3642496 1210	Yellow	0	0.04	None	No safety risk
My little day - My Unicorn Balloons, 12-21-45	White	0	0.51	Not in the Dutch language	Safety risk. Sales are forbidden without a correct label.
Meri meri balloons 8 star-pattern balloons	Transparent	0	0.02	None	No safety risk
Globos Fashion Maroon Latex Round 16 inch/ 40 cm, art. No 57133	Brown	0	0.20	Natural rubber latex warning; warning >8 years; CE marking; name and address details missing	Safety risk. Sales are forbidden without a correct label.
White balloons with red dots on them	White	0	3.25	Natural rubber latex warning; warning >8 years; CE marking; name and address details missing	Safety risk. Sales are forbidden.

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Published by:

Netherlands Food and Consumer Product Safety Authority

Catharijnesingel 59 | PO Box 43006 | 3540 AA Utrecht

www.nvwa.nl

February 2019