

SGS INSTITUT FRESENIUS GmbH Im Maisel 14 D-65232 Taunusstein

Order No.: 3380422  
Client: 5436300



Gabriele Götttsch/ab  
t +49 6128 744 - 151  
f +49 6128 744 - 534  
gabriele.goettsch@sgs.com

Consumer Testing Services  
Non Food

Taunusstein, 01/JUN/2015

SGS INSTITUT FRESENIUS GmbH  
Im Maisel 14  
D-65232 Taunusstein

Your order : Testing for Nitrosamines  
Your reference : -  
Order date : 12/MAY/2015  
Sample No. : 150447680  
Test period : 18/MAY/2015 – 29/MAY/2015

**Test Report no.: 3380422-01**  
**Determination of the Release of N-Nitrosamines and N-Nitrosatable Substances from Elastomers or Rubber Teats and Soothers**

Dear Mr. Saw,

As per your order we have analysed the sample material we received on May 15<sup>th</sup>, 2015 for migratable N-nitrosamines and N-nitrosatable substances according to EN 12868:1999.

Sample No.	Designation
150447680	Pacifier teat, Batch No. 2015/05/749

Detailed results are given on the following page(s).


**Assessment:**

In the tested item migratable N-nitrosamines and N-nitrosatable substances the sample meets the requirements of DIN EN 12868 and is in this test item in conformity with the requirements of EN 1400:2002/ EN 1400:2014.

Yours sincerely,

**SGS INSTITUT FRESENIUS GmbH**

  
i. V. Gabriele Götttsch  
(Project Manager)

  
i. A. Alexandra Beck  
(Team Assistant)

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**Photo documentation:**



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## Test results:

### Migratable N-nitrosamines and N-nitrosatable substances

DIN EN 12868 (1999)

Pacifier teat, Batch No. 2015/05/749

Compound	Abbr.	migratable N-nitrosamines [mg/kg]	migratable, N-nitrosatable sub- stances [mg/kg]	Limit of quantifi- cation [mg/kg]
N-Nitrosodimethylamine	NDMA	n. d.	n. d.	0.001
N-Nitrosodiethylamine	NDEA	n. d.	n. d.	0.001
N-Nitrosodipropylamine	NDPA	n. d.	n. d.	0.001
N-Nitrosodibutylamine	NDBA	n. d.	n. d.	0.001
N-Nitrosomorpholine	NMOR	n. d.	n. d.	0.001
N-Nitrosopyrrolidine	NPYR	n. d.	n. d.	0.001
N-Nitrosopiperidine	NPIP	n. d.	n. d.	0.001
N-Nitrosoethylphenylamine	NEPhA	n. d.	n. d.	0.005
N-Nitrosomethylphenylamine	NMPPhA	n. d.	n. d.	0.005
N-Nitrosodiisononylamine	NDiNA	n. d.	n. d.	0.005
N-Nitrosodibenzylamine	NDBzA	< LoQ	< LoQ	0.005
<b>Total:</b>		-	-	
Corrected value <sup>1)</sup> :		-	-	
Quantity allowed <sup>2)</sup> :		max. 0.01	max. 0.1	

For the summation of all Nitrosamines only those with a result over the limit of quantification will be taken into account.

n. d. = not detectable < LoQ = trace below the limit of quantification

<sup>1)</sup>: Taking into account the results of a collaborative trial initiated by CEN, the standard DIN EN 12868 (9. Analytical tolerances) provides for an adjustment of the results of the analysis with regard to the sum of the migratable N-nitrosamines by 0.01 mg/kg and of the migratable N-nitrosatable substances by 0.1 mg/kg if the established value is above the required value of 0.01 mg/kg or 0.1 mg/kg, respectively (in accordance with a tolerance of 100 per cent at the required limit of 0.01 mg/kg or 0.1 mg/kg, respectively).

<sup>2)</sup>: according to guideline 93/11/EG, Art. 2 (Abl. EG Nr. L 93 S. 37)

**SGS INSTITUT FRESENIUS GmbH**

*C. Götsch*  
 i. V. Gabriele Götsch  
 (Project Manager)

*A. Beck*  
 i. A. Alexandra Beck  
 (Team Assistant)