



EKOTEKS

**EKOTEKS LABORATUVAR ve GÖZETİM
HİZMETLERİ A.Ş.**
Esenyurt Firuzköy Bulvarı No:29 34325 Avcılar
İstanbul/ TÜRKİYE



AB-0583-T

2400009429-
RER

03.25

TEST REPORT
DENEY RAPORU

Report Nr / Revision Nr : 2400009429
Customer name : ALDO BEBEK ÜRÜNLERİ SANAYİ VE TİCARET LTD.ŞTİ
Applicant Address : AKTİM AKÇAB URGAZ MH AKÇABURGAZ CD
/ İSTANBUL
Buyer name : -
Contact Person : -
Sample Accepted on : 21.11.2024
Re-submitted/re-confirmation date : -
Date of test : 22.11.2024 / 23.12.2024
Fiber Composition : Claimed to be :-
Sample Description : GREEN-BLUE-PINK PACIFIER

Order No : -
Model Number : 115-116-117-Mini Orthodontic Soother No:1 No:2 No:3
118-119-120- Tiny Orthodontic Soother No:1 No:2 No:3
121-122-123- Rainbow Orthodontic Soother No:1 No:2 No:3
Previous Report No : -

Sampling : The results given in this report belong to the received sample by vendor.
End use : -
Care label : -

Decision Rule : -
Disclaimer Statement : -
Conformity Assessment : -

The Turkish Accreditation Agency (TURKAK) is signatory to the multilateral agreements of the European co-operation for the Accreditation (EA) and of the International Laboratory Accreditation (ILAC) for the Mutual recognition of test reports. EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş. accredited by TÜRKAK under registration number [AB-0583-T] for ISO 17025:2017 as test laboratory.

The test and/or measurement results, the uncertainties (if applicable) with confidence probability and test methods are given on the following pages which are part of this report.

Seal

Date
06.03.2025

Customer Representative
YAGMUR OKUMUS

Laboratory Manager
Sevim A. RAZAK
06.03.2025



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TEST RESULTS

TEST	METHOD	EVALUATION
COLOR FASTNESS TO SALIVA AND SWEAT	DIN 53160:2023	P
PACIFIERS	TS EN 1400+A2:2018	P
PACIFIERS	TS EN 1400+A2:2018/EN 71-3	P
DETERMINATION OF FORMALDEHYDE	EN 1400+A2 MADDE 10.1	P
DETERMINATION OF BISPHENOLS	TS EN 1400+A2:2018 Madde10.6	P
MATERIAL ALLOCATION	EKOTEKS 40-FTIR ÖLÇÜMÜ	-
DETERMINATION OF RELEASE OF N-NITROSAMINE AND N-NITROSABLE SUBSTANCES	EN 12868:2017-EN14350+A1 MADDE 8.5-EN1400 MADDE 10.4	P
DETERMINATION OF VOLATILE COMPOUNDS	TS EN 14350+A1:2023 /TS EN 1400+A2:2018	P

REMARK: Original samples are kept for 3 months and all technical records are kept for 5 years unless otherwise specified.If requested, measurement uncertainty will be reported. But unless otherwise specified, measurement uncertainty is not considered while stating compliance with specification or limit values The reported uncertainty is based on a standard uncertainty multiplied by a coverage factor k=2, providing a level of confidence of approximately 95%. The declaration of conformity was given in accordance with the Simple Acceptance Decision Rule. (without considering the level of confidence and measurement uncertainty , evaluation of suitability or non-conformity based on whether the test result obtained is only within the specified limits) Tests marked (*) in this report are not included in the accreditation schedule.

Note: The report dated 23.12.2024 dated 2400009429 has been added to the 2400009429 -RER due to the change of "Customer name" and has been replaced with the report dated 06.03.2025

TEST RESULTS

Photo of the sample received



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TEST RESULTS

Sample ID	Part No.	Part ID	Explanatory Information
A	1	BLUE, PINK, GREEN SILICONE TIP	
A	2	BLUE AND WHITE PLASTIC PARTS	
A	3	BLUE-PINK-GREEN PLASTIC PARTS	
A	4	PURPLE-WHITE PLASTIC PARTS	
A	5	PINK AND WHITE PLASTIC PARTS	
A	6	SILIKON ENDS	
A	7	GREEN AND WHITE PLASTIC PARTS	

Summary of Results

Parts & Results															
Parts	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
DETERMINATION OF FORMALDEHYDE	P	NA	NA	NA	NA	NA	NA	-	-	-	-	-	-	-	-
DETERMINATION OF BISPHEOLS	NA	NA	P	NA	NA	NA	NA	-	-	-	-	-	-	-	-
MALZEME TAYINI	P	NA	P	NA	NA	NA	NA	-	-	-	-	-	-	-	-
DETERMINATION OF RELEASE OF N-NITROSCAMINE	P	NA	NA	NA	NA	NA	NA	-	-	-	-	-	-	-	-
DETERMINATION OF VOLATILE COMPOUNDS	P	NA	NA	NA	NA	NA	NA	-	-	-	-	-	-	-	-

P Pass
F Fail
LS Lack of sample.
NA Not applicable
R Refer to retailer technologist

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DETERMINATION OF FORMALDEHYDE

EN 1400+A2 MADDE 10.1

The amount of formaldehyde in sample determined using UV-VIS spectrophotometer.

Tested Parts	RESULT	REQUIREMENT	Evaluation
1	N.D	<0,5	PASS

Formaldehyde (Cas No:50-00-0)

Total Uncertainty:%9,4

DETERMINATION OF BISPENOLS

TS EN 1400+A2:2018 Madde10.6

Tested Parts	RESULT	REQUIREMENT	Evaluation
3	ND	< 0,01 mg/l	PASS

ND: Not Detected

BISFENOL A (CAS No : 80-05-7)

Total Uncertainty;
For antioxidant; 5.3%
For BPA: 20.8%

VOLATİLE COMPOUND CONTENT; TS EN 14350 + A1 2023 /TS EN 1400 + A2:2018			
Place the sample in the oven at (100 ± 5)°C for (60 ± 5) min and (200 ± 5) °C for 4 h ± 5 min.			
	WEIGHING RESULT (g)		
Weight A	20,9690		
Weight B	28,7241		
Weight C	28,7001		
Measurement	[(B-C)/(B-A)] X 100		
	RESULT	REQUIREMENT	
	0,3	%0,5 (m/m)	

N.D ⁽¹⁾: Not detected

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TEST RESULTS

SPECIMEN DESCRIPTION : / BLUE-PINK-GREEN PLASTIC PARTS

MATERIAL ALLOCATION

EKOTEKS 40-FTIR ÖLÇÜMÜ

FT-IR Spectrophotometer Test Machine

This test result was determined by comparing it with the reference materials in the device's library using the FT-IR spectrometer method.

Parameters	RESULT (% Similarity)	EVAULATION
Polipropilen	98	-

SPECIMEN DESCRIPTION : / BLUE, PINK, GREEN SILICONE TIP

MATERIAL ALLOCATION

EKOTEKS 40-FTIR ÖLÇÜMÜ

FT-IR Spectrophotometer Test Machine

This test result was determined by comparing it with the reference materials in the device's library using the FT-IR spectrometer method.

Parameters	RESULT (% Similarity)	EVAULATION
Poli dimetil siloksan	93	-

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TEST RESULTS

N-NİTROSAMİNES AND N-NİTROSATABLE SUBSTANCES; TS EN 1400 + A2:2018 (Test Clause No 10.4.2) / EN 1400:2013+A2:2018 (Test Clause No 10.4.2) (ref:TS EN 12868: 2003)			
Sample is extracted in a nitrite-containing artificial saliva test solution and determined using LC/MSMS.			
	CAS NO	RESULT	REQUIREMENT
N-Nitrosamines			
N-nitrosodimethylamine (NDMA)	62-75-9	N.D.⁽¹⁾	
N-nitrosodiethylamine (NDEA)	55-18-5	N.D.⁽¹⁾	
N-nitrosodipropylamine (NDPA)	621-64-7	N.D.⁽¹⁾	
N-nitrosodibutylamine (NDBA)	924-16-3	N.D.⁽¹⁾	
N-nitrosoprolidin (NPYR)	930-55-2	N.D.⁽¹⁾	
N-nitrosodiisononylamine (NDİNA)	1207995-62-7	N.D.⁽¹⁾	
N-nitrosomorpholine (NMOR)	59-89-2	N.D.⁽¹⁾	
N-nitrosopiperidine (NPIP)	100-75-4	N.D.⁽¹⁾	
N-nitrosodibenzylamine (NDBzA)	5336-53-8	N.D.⁽¹⁾	
N-nitroso-N-methyl-N-phenylamine (NMPHA)	614-00-6	N.D.⁽¹⁾	
N-nitroso-N-ethyl-N-phenylamine (NEPhA)	612-64-6	N.D.⁽¹⁾	
Total concentration		N.D.⁽¹⁾	<0.01 mg/kg
N-Nitrosatable substances			
N-nitrosodimethylamine (NDMA)	62-75-9	N.D.⁽¹⁾	
N-nitrosodiethylamine (NDEA)	55-18-5	N.D.⁽¹⁾	
N-nitrosodipropylamine (NDPA)	621-64-7	N.D.⁽¹⁾	
N-nitrosodibutylamine (NDBA)	924-16-3	N.D.⁽¹⁾	
N-nitrosoprolidin (NPYR)	930-55-2	N.D.⁽¹⁾	
N-nitrosodiisononylamine (NDİNA)	1207995-62-7	N.D.⁽¹⁾	
N-nitrosomorpholine (NMOR)	59-89-2	N.D.⁽¹⁾	
N-nitrosopiperidine (NPIP)	100-75-4	N.D.⁽¹⁾	
N-nitrosodibenzylamine (NDBzA)	5336-53-8	N.D.⁽¹⁾	
N-nitroso-N-methyl-N-phenylamine (NMPHA)	614-00-6	N.D.⁽¹⁾	
N-nitroso-N-ethyl-N-phenylamine (NEPhA)	612-64-6	N.D.⁽¹⁾	
Total concentration		N.D.⁽¹⁾	<0.1mg/kg

N.D ⁽¹⁾: Not detected

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TEST RESULTS

SPECIMEN DESCRIPTION : / PURPLE-WHITE PLASTIC PARTS

COLOR FASTNESS TO SALIVA AND SWEAT

DIN 53160:2023

37±2°C. 24 hours

Assessed using the ISO 105 A03 standart grey scale.

Parameters	RESULT	REQUIREMENT	EVALUATION
Ter Çözeltisi	5	>4	PASS
Tükürük Çözeltisi	5	>4	PASS

Total Uncertainty (grade): ±0.5

COLOUR FASTNESS RATING

COLOUR STAINING

5 Negligible or no staining

4 Sightly stained

3 Noticeably stained

2 Considerably stained

1 Much stained

SPECIMEN DESCRIPTION : / GREEN AND WHITE PLASTIC PARTS

COLOR FASTNESS TO SALIVA AND SWEAT

DIN 53160:2023

37±2°C. 24 hours

Assessed using the ISO 105 A03 standart grey scale.

Parameters	RESULT	REQUIREMENT	EVALUATION
Ter Çözeltisi	5	>4	PASS
Tükürük Çözeltisi	5	>4	PASS

Total Uncertainty (grade): ±0.5

COLOUR FASTNESS RATING

COLOUR STAINING

5 Negligible or no staining

4 Slightly stained

3 Noticeably stained

2 Considerably stained

1 Much stained

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TEST RESULTS

SPECIMEN DESCRIPTION : / BLUE AND WHITE PLASTIC PARTS

COLOR FASTNESS TO SALIVA AND SWEAT

DIN 53160:2023

37±2°C. 24 hours

Assessed using the ISO 105 A03 standart grey scale.

Parameters	RESULT	REQUIREMENT	EVALUATION
Ter Çözeltilisi	5	>4	PASS
Tükürük Çözeltilisi	5	>4	PASS

Total Uncertainty (grade): ±0.5

COLOUR FASTNESS RATING

COLOUR STAINING

- 5 Negligible or no staining
- 4 Slightly stained
- 3 Noticeably stained
- 2 Considerably stained
- 1 Much stained

SPECIMEN DESCRIPTION : / PINK AND WHITE PLASTIC PARTS

COLOR FASTNESS TO SALIVA AND SWEAT

DIN 53160:2023

37±2°C. 24 hours

Assessed using the ISO 105 A03 standart grey scale.

Parameters	RESULT	REQUIREMENT	EVALUATION
Ter Çözeltilisi	5	>4	PASS
Tükürük Çözeltilisi	5	>4	PASS

Total Uncertainty (grade): ±0.5

COLOUR FASTNESS RATING

COLOUR STAINING

- 5 Negligible or no staining
- 4 Slightly stained
- 3 Noticeably stained
- 2 Considerably stained
- 1 Much stained

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TEST RESULTS

SPECIMEN DESCRIPTION : / SILICONE TIPS

COLOR FASTNESS TO SALIVA AND SWEAT

DIN 53160:2023

37±2°C. 24 hours

Assessed using the ISO 105 A03 standart grey scale.

Parameters	RESULT	REQUIREMENT	EVALUATION
Ter Çözeltisi	5	>4	PASS
Tükürük Çözeltisi	5	>4	PASS

Total Uncertainty (grade): ±0.5

COLOUR FASTNESS RATING

COLOUR STAINING

5 Negligible or no staining

4 Slightly stained

3 Noticeably stained

2 Considerably stained

1 Much stained

PACIFIERS

TS EN 1400+A2:2018/EN 71-3

Tested Parts	Result (ppm)	Limit Value (ppm)	Evaluation
1+2	< 0.02	It is set out below.	PASS

Aluminum, Al(CAS NO 7429-90-5) Antimony, Sb(CAS NO 7440-36-0) Arsenic, As(CAS NO 7440-38-2) Barium, Ba(CAS NO 7440-39-3) Boron, B(CAS NO 7440-42-8) Cadmium, Cd(CAS NO 7440-43-9) Chromium, Cr III(CAS NO 13548-38-4) Chromium, Cr VI(CAS NO 18540-29-9) Cobalt, Co(CAS NO 7440-48-4) Copper, Cu(CAS NO 7440-50-8) Lead, Pb(CAS NO 7439-92-1) Manganese, Mn(CAS NO 7439-96-5) Mercury, Hg(CAS NO 7439-97-6) Nickel, Ni(CAS NO 7440-02-0) Selenium, Se(CAS NO 7783-49-2) Strontium, Sr(CAS NO 7440-24-6) Tin , Sn(CAS NO 7440-31-5) Organic tin, Sn(CAS NO -) Zinc, Zn(CAS NO 7440-66-6)

Total Uncertainty;

For antioxidants; 16.3%

For formaldehyde; 9.4%

For primary aromatic amine; 21.77%

For glass products; 30.88%

For metal products; 23.26%

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TEST RESULTS

GENERAL AND MECHANICAL PROPERTIES; TS EN 1400+A2:2018

Number of samples tested:20 pieces

Artificial aging and conditioning procedures were applied to the test sample according to 6.3.

CLAUSE	REQUIREMENT	RESULT
7	Printing and Decals	
8	CONSTRUCTION PROPERTIES AND TESTS	P
8.1	General	P
8.2	Teat	P
8.3	Shield	P
8.4	Shield Ventilation	P
8.5	Ring	P
8.6	Plug	P
8.7	Knogs, plubs and /or covers made from non- flexible materials	P
8.8	Rings, knobs, plugs and /or covers made of flexible materials	NA
8.9	Openings	P

CLAUSE	REQUIREMENT	RESULT
9	MECHANICAL PROPERTIES	
9.1	Impact Resistance	P
9.2	Puncture Resistance	P
9.3	Tear Resistance	P
9.4	Knob, plug and/or cover retention	P
9.5	Bite endurance of elastomeric compenents	P
9.6	Rotation Endurance	NA
9.7	Integrity	P

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TEST RESULTS

GENERAL AND MECHANICAL PROPERTIES: TS EN 1400+A2:2018

CLAUSE	REQUIREMENT	RESULT
11	TEAT PROTECTORS	NA
11.2	Visual/Tactile	NA
11.3	Size	NA
11.4	Ventilation holes	NA
11.5	Openings	NA
11.6	Cup-shaped teat protectors	NA
11.7	Impact resistance	NA
12	Consumer packaging	P
13	Product information	P
13.1	General	P
13.2	Purchase information	P
13.3	Instructions for use	P
13.4	Supply chain information for products that contain vulcanised rubber	P

Note: P = Pass F = Fail NA = Not applicable

CLAUSE	REQUIREMENT	RESULT
10	CHEMICAL PROPERTIES AND TEST	
10.3	Migration of Certain Elements	P
10.4	N-Nitrosamines and N-Nitrosatable Substance Release	P
10.5	2- Mercaptobenzothiazole Release(MBT Release)	NA
10.5	Antioxidants release	NA
10.5	Formaldehyde Release	P
	Bisfenol A(BPA) Release	P
10.7	Colour Fastness	P
10.8	Volatile Organic Compounds Content	P

TEST RESULTS

	Migration of certain elements	N-Nitrosamines and N-Nitrosatables release	2-Mercaptobenzothiazole release	Antioxidants release	Formaldehyde release	Bisphenol A release	Colour Fastness	Volatile compound content
Requirement Clause	10.3.1	10.4.1	10.5.1	10.5.1	10.5.1	10.6.1 a	10.7.1	10.8.1
Test Clause	10.3.2	10.4.2	10.5.2	10.5.2	10.5.2	10.6.2	10.7.2	10.8.2
Vulcanised rubber	x	x	x	x	x		x	
Silicone rubber	x	x			x		x	x
All Thermoplastics	x						x	
Polycarbonate and Polysulphone	x					x	x	
TPEs	x	x					x	
All Decorations	x						x	
^a Bisphenol A Migration is only carried out on thermoplastics that use Bisphenol A in their manufacture, such as polycarbonates. Bisphenol A is not used in the production of other common thermoplastics, such as polypropylene and polyethylene.								

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TEST RESULTS

GENERAL AND MECHANICAL PROPERTIES: TS EN 1400+ A2:2018

Using the applicant's specification, make sure that you receive your packaging and product information with the relevant information

CUSTOMER PACKAGING (Clause 12)

Soothers shall be sold in a clean condition in closed packs.

The pack as received by the consumer shall include clear, legible instructions for use and hygienic care of the soother.

These instructions shall be given as described in 13.3 and may be included on a separate leaflet placed inside the packaging.

It is recommended that consumer packaging should not contaminate the product in any way.

Manufacturers when designing consumer packaging should consider environmental issues, such as disposal instructions and recycling.

INSTRUCTION FOR USE (Clause 13.3)

General (Clause 13.3.1)

The following information shall be provided either on the packaging or in a leaflet:

- information on the safe use of the product;
- at least one method of cleaning;
- unsuitable common methods of cleaning, storage and use which might damage the soother.