

Erstellt am Datum / *created at Date:* 10.04.2025
 Artikelbezeichnung / *product:* Nitrilhandschuhe Prime Source, puderfrei, unsteril
 Material / *material:* Nitril

Wir bestätigen hiermit, dass das oben angeführte Produkt den folgenden rechtlichen Anforderungen entspricht:
We hereby confirm that the product listed above complies with the following legal requirements:

Verpackungsmaterial / *Packaging materials:*

904562

EG Gesetzgebung/ <i>EU legislation:</i>	gültig in der jeweils aktuellen konsolidierten Fassung / <i>valid in each current version:</i>
1935/2004	Verordnung über Materialien und Gegenstände, die dazu bestimmt sind, mit Lebensmitteln in Berührung zu kommen. <i>Regulation on materials and articles intended to come into contact with food.</i>
2023/2006 (GMP)	Verordnung über gute Herstellungspraxis für Materialien und Gegenstände, die dazu bestimmt sind, mit Lebensmitteln in Berührung zu kommen. <i>Regulation on good manufacturing practice for materials and articles intended to come into contact with food.</i>
10/2011 2020/1245	Kunststoffverordnung über Materialien und Gegenstände aus Kunststoff, die dazu bestimmt sind, mit Lebensmitteln in Berührung zu kommen. <i>Regulation on plastic materials and objects made of plastic, which are intended to come into contact with food.</i>
2016/425	Verordnung des Europäischen Parlaments und des Rates vom 9. März 2016 über persönliche Schutzausrüstung und zur Aufhebung der Richtlinie 89/686/EWG <i>Regulation of the European Parliament and of the Council of March 9, 2016 on personal protective equipment and repealing Directive 89/686/EEC</i>
Deutschland/ <i>Germany:</i>	Bewertung / Stellungnahmen in Übereinstimmung mit: <i>Evaluation / Opinions in accordance with:</i>
LFGB § 30 & § 31	Lebensmittel-, und Futtermittelgesetzbuch <i>German Food and Feed act (LFGB)</i>
BfR III, L & VI	Bundesinstitut für Risikobewertung <i>Federal Institute for Risk Assessment</i>

Verweise auf die angewandten einschlägigen harmonisierten Normen, auf deren Grundlage die Konformität erklärt wird:
References to the relevant harmonized standards applied, on the basis of which conformity is declared:

EN ISO 21420:2020
 EN ISO 374-1:2016+A1:2018
 EN ISO 374-4:2019
 EN ISO 374-5:2016
 EN 421:2010

enthält keine Rezyklate / *does not contain recycled materials*

Migration / Migration:

Zur Bestimmung der Migration werden die Simulanzlösemittel, Zeit und Temperaturen gemäß den Regeln der EU-Verordnung 10/2011 wie folgt gewählt:

To determine the migration simulant, time and temperatures according to the rules of EU-Regulation 10/2011 are selected as follows:

1.2) Overall migration

Method: EN 1186-1:2002 & EN 1186-3:2002 & EN 1186-2:2002

Test condition: 40°C for 0.5h in 10% Ethanol / 3% Acetic acid / Olive oil.

Simulant Used(s)	Unit	Limit(s)	RL	Result(s)	Conclusion(s)
				1	
10% Ethanol	mg/dm ²	10	3	N.D.	PASS
3% Acetic acid	mg/dm ²	10	3	3.8	PASS
Olive oil	mg/dm ²	10	3	N.D.	PASS

1.3) Specific migration of Primary Aromatic Amine (PAA)

Method: EN 13130-1: 2004, analysis by HPLC-MS-MS.

Test condition: 40°C for 0.5h in 10% Ethanol / 3% Acetic acid.

No.	Test Item(s)	RL (mg/kg)	Limit (mg/kg)	Result (mg/kg)	
				1	
				10% Ethanol	3% Acetic acid
(1)	o-Toluidine	0.002	N.D.	N.D.	N.D.
(2)	2-Methoxyaniline	0.002	N.D.	N.D.	N.D.
(3)	p-Chloroaniline	0.002	N.D.	N.D.	N.D.
(4)	p-Kresidine	0.002	N.D.	N.D.	N.D.
(5)	2,4,5-Trimethylaniline	0.002	N.D.	N.D.	N.D.
(6)	4-Chloro-o-Toluidine	0.002	N.D.	N.D.	N.D.
(7)	2,4-Toluylenediamine	0.002	N.D.	N.D.	N.D.
(8)	2,4-Diaminoanisole	0.002	N.D.	N.D.	N.D.
(9)	2-Naphthylamine	0.002	N.D.	N.D.	N.D.
(10)	2-Amino-4-nitrotoluene	0.002	N.D.	N.D.	N.D.
(11)	4-Aminodiphenyl	0.002	N.D.	N.D.	N.D.
(12)	p-Aminoazobenzene	0.002	N.D.	N.D.	N.D.
(13)	4,4'-Oxydianiline	0.002	N.D.	N.D.	N.D.
(14)	Benzidine	0.002	N.D.	N.D.	N.D.
(15)	4,4'-Diaminodiphenylmethane	0.002	N.D.	N.D.	N.D.
(16)	o-Aminoazotoluene	0.002	N.D.	N.D.	N.D.
(17)	3,3'-Dimethyl-4,4'-diaminodiphenylmethane	0.002	N.D.	N.D.	N.D.
(18)	3,3'-Dimethylbenzidine	0.002	N.D.	N.D.	N.D.
(19)	4,4'-Thiodianiline	0.002	N.D.	N.D.	N.D.

(20)	3,3'-Dichlorobenzidine	0.002	N.D.	N.D.	N.D.
(21)	4,4'-Methylene-bis-(2-chloraniline)	0.002	N.D.	N.D.	N.D.
(22)	3,3'-Dimethoxybenzidine	0.002	N.D.	N.D.	N.D.
(23)	1,3-Phenyldiamine	0.002	N.D.	N.D.	N.D.
(24)	Other Primary Aromatic Amine	0.01	Sum≤0.01	N.D.	N.D.
Conclusion				PASS	PASS

Test condition: 40°C for 0.5h in 95%Ethanol / Isooctane.

No.	Test Item(s)	RL (mg/kg)	Limit (mg/kg)	Result (mg/kg)	
				1	
				95%Ethanol	Isooctane
(1)	o-Toluidine	0.002	N.D.	N.D.	N.D.
(2)	2-Methoxyaniline	0.002	N.D.	N.D.	N.D.
(3)	p-Chloroaniline	0.002	N.D.	N.D.	N.D.
(4)	p-Kresidine	0.002	N.D.	N.D.	N.D.
(5)	2,4,5-Trimethylaniline	0.002	N.D.	N.D.	N.D.
(6)	4-Chloro-o-Toluidine	0.002	N.D.	N.D.	N.D.
(7)	2,4-Toluylendiamine	0.002	N.D.	N.D.	N.D.
(8)	2,4-Diaminoanisole	0.002	N.D.	N.D.	N.D.
(9)	2-Naphthylamine	0.002	N.D.	N.D.	N.D.
(10)	2-Amino-4-nitrotoluene	0.002	N.D.	N.D.	N.D.
(11)	4-Aminodiphenyl	0.002	N.D.	N.D.	N.D.
(12)	p-Aminoazobenzene	0.002	N.D.	N.D.	N.D.
(13)	4,4'-Oxydianiline	0.002	N.D.	N.D.	N.D.
(14)	Benzidine	0.002	N.D.	N.D.	N.D.
(15)	4,4'-Diaminodiphenylmethane	0.002	N.D.	N.D.	N.D.
(16)	o-Aminoazotoluene	0.002	N.D.	N.D.	N.D.
(17)	3,3'-Dimethyl-4,4'-diaminodiphenylmethane	0.002	N.D.	N.D.	N.D.
(18)	3,3'-Dimethylbenzidine	0.002	N.D.	N.D.	N.D.
(19)	4,4'-Thiodianiline	0.002	N.D.	N.D.	N.D.
(20)	3,3'-Dichlorobenzidine	0.002	N.D.	N.D.	N.D.
(21)	4,4'-Methylene-bis-(2-chloraniline)	0.002	N.D.	N.D.	N.D.
(22)	3,3'-Dimethoxybenzidine	0.002	N.D.	N.D.	N.D.
(23)	1,3-Phenyldiamine	0.002	N.D.	N.D.	N.D.
(24)	Other Primary Aromatic Amine	0.01	Sum≤0.01	N.D.	N.D.
Conclusion				PASS	PASS

Test condition: 40°C for 0.5h in Olive oil.

No.	Test Item(s)	RL (mg/kg)	Limit (mg/kg)	Result (mg/kg)
				1
(1)	o-Toluidine	0.002	N.D.	N.D.
(2)	2-Methoxyaniline	0.002	N.D.	N.D.
(3)	p-Chloroaniline	0.002	N.D.	N.D.
(4)	p-Kresidine	0.002	N.D.	N.D.
(5)	2,4,5-Trimethylaniline	0.002	N.D.	N.D.
(6)	4-Chloro-o-Toluidine	0.002	N.D.	N.D.
(7)	2,4-Toluylenediamine	0.002	N.D.	N.D.
(8)	2,4-Diaminoanisoole	0.002	N.D.	N.D.
(9)	2-Naphthylamine	0.002	N.D.	N.D.
(10)	2-Amino-4-nitrotoluene	0.002	N.D.	N.D.
(11)	4-Aminodiphenyl	0.002	N.D.	N.D.
(12)	p-Aminoazobenzene	0.002	N.D.	N.D.
(13)	4,4'-Oxydianiline	0.002	N.D.	N.D.
(14)	Benzidine	0.002	N.D.	N.D.
(15)	4,4'-Diaminodiphenylmethane	0.002	N.D.	N.D.
(16)	o-Aminoazotoluene	0.002	N.D.	N.D.
(17)	3,3'-Dimethyl-4,4'-diaminodiphenylmethane	0.002	N.D.	N.D.
(18)	3,3'-Dimethylbenzidine	0.002	N.D.	N.D.
(19)	4,4'-Thiodianiline	0.002	N.D.	N.D.
(20)	3,3'-Dichlorobenzidine	0.002	N.D.	N.D.
(21)	4,4'-Methylene-bis-(2-chloraniline)	0.002	N.D.	N.D.
(22)	3,3'-Dimethoxybenzidine	0.002	N.D.	N.D.
(23)	1,3-Phenylendiamine	0.002	N.D.	N.D.
(24)	Other Primary Aromatic Amine	0.01	Sum≤0.01	N.D.
Conclusion				PASS

1.4) Specific Migration of heavy metals

Method: Refer to EN 13130-1:2004 (Total Immersion Method), analysis were performed by ICP-OES & UV-vis.

Test condition: 40°C for 2h in 3% Acetic acid.

Test Item(s)	Unit	Limit(s)	RL	Result(s)
				1
Barium(Ba)	mg/kg	1	0.01	N.D.
Cobalt(Co)	mg/kg	0.05	0.01	N.D.
Copper(Cu)	mg/kg	5	0.01	N.D.
Iron(Fe)	mg/kg	48	0.01	0.04
Lithium(Li)	mg/kg	0.6	0.01	N.D.
Manganese(Mn)	mg/kg	0.6	0.01	N.D.
Zinc(Zn)	mg/kg	5	0.01	3.47
Aluminum (Al)	mg/kg	1	0.01	0.07

Nickel (Ni)	mg/kg	0.02	0.01	N.D.
Antimony(Sb)	mg/kg	0.04	0.01	0.02
Arsenic(As)	mg/kg	N.D.	0.01	N.D.
Cadmium(Cd)	mg/kg	N.D.	0.002	N.D.
Chromium(Cr)	mg/kg	N.D.*	0.01	N.D.
Europium(Eu)	mg/kg	SUM:0.05	0.01	N.D.
Gadolinium(Gd)	mg/kg		0.01	N.D.
Lanthanum(La)	mg/kg		0.01	N.D.
Terbium(Tb)	mg/kg		0.01	N.D.
Lead(Pb)	mg/kg	N.D.	0.01	N.D.
Mercury(Hg)	mg/kg	N.D.	0.01	N.D.
Magnesium(Mg)	mg/kg	--	0.01	2.86
Potassium(K)	mg/kg	--	0.01	0.41
Sodium(Na)	mg/kg	--	0.01	1.69
Calcium(Ca)	mg/kg	--	0.01	N.D.
Conclusion				PASS

Test condition: 40°C for 2h in Olive oil.

Test Item(s)	Unit	Limit(s)	RL	Result(s)
				1
Barium(Ba)	mg/kg	1	0.01	N.D.
Cobalt(Co)	mg/kg	0.05	0.01	N.D.
Copper(Cu)	mg/kg	5	0.01	N.D.
Iron(Fe)	mg/kg	48	0.01	N.D.
Lithium(Li)	mg/kg	0.6	0.01	N.D.
Manganese(Mn)	mg/kg	0.6	0.01	N.D.
Zinc(Zn)	mg/kg	5	0.01	N.D.
Aluminum (Al)	mg/kg	1	0.01	N.D.
Nickel (Ni)	mg/kg	0.02	0.01	N.D.
Antimony(Sb)	mg/kg	0.04	0.01	N.D.
Arsenic(As)	mg/kg	N.D.	0.01	N.D.
Cadmium(Cd)	mg/kg	N.D.	0.002	N.D.
Chromium(Cr)	mg/kg	N.D.*	0.01	N.D.
Europium(Eu)	mg/kg	SUM:0.05	0.01	N.D.
Gadolinium(Gd)	mg/kg		0.01	N.D.
Lanthanum(La)	mg/kg		0.01	N.D.
Terbium(Tb)	mg/kg		0.01	N.D.
Lead(Pb)	mg/kg	N.D.	0.01	N.D.
Mercury(Hg)	mg/kg	N.D.	0.01	N.D.
Magnesium(Mg)	mg/kg	--	0.01	N.D.
Potassium(K)	mg/kg	--	0.01	N.D.
Sodium(Na)	mg/kg	--	0.01	N.D.
Calcium(Ca)	mg/kg	--	0.01	N.D.
Conclusion				PASS

1.5) Specific migration of Nitrosamine and nitrosatable substances[✱]

Method: EN 12868:2017 and analysis by GC-MS.

Test condition: 40°C for 0.5h in 3% Acetic acid.

Test Item(s)	Unit	Limit(s)	RL	Result(s)	Conclusion(s)
				1	
Specific migration of Nitrosamines	mg/kg	0.01	0.01	N.D.	PASS
Specific migration of Nitrosatable substances	mg/kg	0.1	0.1	N.D.	PASS

Test condition: 40°C for 2h in Olive oil.

Test Item(s)	Unit	Limit(s)	RL	Result(s)	Conclusion(s)
				1	
Specific migration of Nitrosamines	mg/kg	0.01	0.01	N.D.	PASS
Specific migration of Nitrosatable substances	mg/kg	0.1	0.1	N.D.	PASS

2) German Food, Articles of Daily Use and Feed Code of September 1, 2005 (LFGB), Section 30 & 31 with amendments and BfR recommendation III and BfR Recommendation L&VI. & European Commission Regulation (EU) No 10/2011 with amendments.

Total butadiene

Test Method: With reference to EN 13130-4:2004, analysis was performed by GC-MS.

Test Item(s)	RL(mg/kg)	Limit(mg/kg)	Result(mg/kg)	Conclusion
			1	
Total butadiene	0.1	Absent	N.D.	PASS

Nicht absichtlich eingebrachte Stoffe (NIAS) / *Non-intentionally introduced substances (NIAS):*

Es werden nicht systematisch spezifische analytische Tests durchgeführt, um das Nichtvorhandensein dieser Stoffe zu überprüfen. Wir können nicht garantieren, dass keine Spuren dieser Stoffe als Verunreinigungen, Rückstände oder Anderweitige in diesem Artikel vorhanden sind. Die folgenden Stoffe sind in diesem Artikel voraussichtlich nicht enthalten.

Specific analytical tests are not systematically performed to verify the absence of these substances. We cannot guarantee the absence of traces of these substances as impurities, residues or otherwise in this article. The following substances are not expected to be present in this article.

Das Material ist, unter normalen und vorhersehbaren Bedingungen ohne Veränderung der Zusammensetzung oder der organoleptischen Eigenschaften, für folgende Kontakte und Anwendungen geeignet:

The material is suitable, under normal and foreseeable conditions without change in composition or organoleptic properties, for the following contacts and applications:

- Alle Lebensmittelarten
- saure Lebensmittel
- wässrige Lebensmittel
- fette Lebensmittel
- alkoholische Lebensmittel
- trockene / staubförmige Lebensmittel

Hinweise zur Lagerung der Verpackung bzw. zum Abpackvorgang:

The storage of the packaging or the packaging process:

- Lagerung bei Raumtemperatur 5 – 30 °C, 40 – 60 % rel. Luftfeuchtigkeit.
- In der Originalverpackung lagern, vor Lichteinwirkung schützen.
- Das Verpackungsmaterial muss 48h vor Gebrauch bereits unter den klimatischen Bedingungen des Abpackprozesses gelagert werden
- *Store at room temperature 5 - 30 °C, 40 - 60 % rel. humidity.*
- *Store in the original packaging, protect from light.*
- *The packaging material must be stored approx. 48 h before use already under the climatic conditions of the packaging process.*

Allgemeines / *General Information:*

Die vorstehenden Angaben stützen sich auf den derzeitigen Stand unserer Kenntnisse über das gegenständliche Produkt.

The above information is based on the current state of our knowledge of the product in question.

Der Anwender muss sich über die Anforderungen der Spezifikation und die in dieser Konformitätserklärung angegebene Eignung hinaus, von der Eignung des Produktes für das vorgesehene Füllgut überzeugen.

The user must satisfy himself of the suitability of the product for the intended filling product beyond the requirements of the specification and the suitability stated in this declaration of conformity.

Anwendungen des Kunden, die über den angegebenen Anwendungsbereich hinausgehen, obliegen nicht unserem Einflussbereich, und sind dementsprechend vom Kunden sicherzustellen.

Applications by the customer that go beyond the specified area of application are beyond our control and must therefore be ensured by the customer.

Diese schriftliche Erklärung ist gültig in aktueller Fassung und wird im Falle wesentlicher Änderungen in der Produktion sowie bei Vorliegen neuer wissenschaftlicher Erkenntnisse erneuert.

This written declaration is valid in the most current version and will be renewed in the event of significant changes in production or if new scientific knowledge is available.

Dieses Dokument wurde elektronisch erstellt und ist daher ohne Unterschrift gültig.

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