



D28. Physical and chemical data Aluminium caps 11/16

Mechanical properties	TEMPER H34*
U.T.S. [N/mm ²]	110-150
Y.S. [N/mm ²]	>80
Elongation [%] (A100)	>3
Erichsen without lube (mm)	>4

* Tensile test according to UNI EN 10002

Chemical data:	ALLOY 8011 (UNI EN 573-3)
Main components [approx. Weight %]	
Si	0,5 – 0,9
Fe	0,5 – 0,9
Cu	0 – 0,05
Mn	0 – 0,1
Mg	0 – 0,1
Zn	0 – 0,1
Ti	0 – 0,05
Others each	0,05
Other total	0,15
Al	REST

Source: Italcot Technical information coated alluminium alloy foil, dated 2015/10/29 151103

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D28.1 Physical data laquer aluminium caps

	Inside top lacquer	Outside top lacquer	Inside top lacquer	Outside top lacquer
Layer code (Italcoat)	VAE393 PA	VAE088 PA	VAE181 PA	VAE019 PA
Colour	Gold	Red	Green	Blue
Layer grammage	3-4 g/m ²	5-6 g/m ²	5-6 g/m ²	5-6 g/m ²
Adhesion	Erichsen + tear with adhesive tape – no delamination (in according with ECCA T6)	Erichsen + tear with adhesive tape – no delamination (in according with ECCA T6)	Erichsen + tear with adhesive tape – no delamination (in according with ECCA T6)	Erichsen + tear with adhesive tape – no delamination (in according with ECCA T6)
MEK resistance (polymerization evaluation)	>50 double rubs (in according with ECCA T11)	>50 double rubs (in according with ECCA T11)	>50 double rubs (in according with ECCA T11)	>50 double rubs (in according with ECCA T11)
Sterilization in water steam at 121°C for 20 minutes	OK – no white spots	OK – no white spots	OK – no white spots	OK – no white spots

Food contact approvals

This product is in compliance with:

Commission regulation:

- Framework regulation 1935/2004
- Commission regulation EC 2023/2006
- 1895/2005 (for epoxy derivates)
- 372/2007
- 975/2009

EC directive:

- 2002/72 and its amendments
- EN 602:2004
- Directive 94/62 and its amendment 2004/12/EC and US-CONEG 2002/95/CE RohS
- Directive 1907/2006 – REACH directive

Italian regulation:

- Decreto Ministeriale 21/03/1973
- Decreto Ministeriale 76 del 18/04/2007
- DPR 777/82 and its amendments
- Decreto Legge n.22 del 05/02/1997 art 43 and its amendments

It's also certified that:



The resin in contact with the foodstuff is in compliance with:

- CFR, title 21, §175.300 of the FDA, Washington D.C.

The product supplied from Italcoat is conform to the following requirements:

- Absence of cancerogen substances
- Absence of toxic substances
- Absence of phthalates
- Absence of organic substances of animal origin

Source: Italcoat Technical information coated aluminium alloy foil, dated 2015/10/29 151103

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D29. Physical data Chlorobutyl rubber inlay 6320 GS

	Inlay
Material:	Chlorobutyl rubber
Principal applications	SVP, LVP & Lyophilization closures
Specification	Conform to Eur. Ph. 3.2.9 (type I closures) ISO 8871 USP <381> JP<7.03>
Sterilization *	Steam, ethylene oxide, radio sterilization
Color	Grey
Material: Elastomer Filler Curing agent Coloring agent Doesn't contain	Chlorobutyl rubber Calcined clay Zinc oxide Carbon black + titanium oxide Thiazoles (2-McBT) Nitrosamines Natural rubber (latex) Phthalates Bisphenol A
General Characteristics	Non cytotoxic Low reactivity: the 6320 GS formulation is compatible with most liquids, powders and lyophilizates, including the most unstable Highly resistant to the effects of aging

* Change from one sterilization method to another may require new compatibility studies.



BSE risk: complies with "Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products", EMEA/410/01 current version

Non cytotoxic

Low reactivity: the 6320 GS formulation is compatible with most liquids, powders and lyophilizates, including the most unstable ones.

Highly resistant to the effects of aging.

Source: Aptar Stelmi product specification 6320GS dated 2014/07/03 151029



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D29.1 Physical data chlorobutyl rubber inlay 6320 GS

Test	Testing according to the European Pharmacopoeia*	
	Results	Specification
Identification:		
Ash (%)	48,5-52,5	
Chemical :		
Opalescence [classe (NTU)]	I (0,4)	≤II (6)
Colour [reference material]	≤JV ₅	≤ JV ₅ or ≤ CS
Acidity or alkalinity [ml (NaOH)/20 ml] [ml (HCl)/20 ml]	0,02 (NaOH)	≤ 0,3 (NaOH)
Absorbance [DO max]	≤0,2	≤ 0,2
Reducing substances [ml]	0.30	≤ 3,0
Ammonium [ppm]	< 2	≤ 2
Extractable zinc [µg/ml]	0,40	≤ 5
Extractable heavy metals [ppm]	< 2	≤ 2
Residue on evaporation [mg/50ml]	< 1	≤ 2,0
Volatile sulphides [mg/20 cm ²]	< 0,154	≤ 0,154
Functional :		
Penetrability (N)	≤10	≤ 10
Fragmentation (fragment)	≤5	≤ 5
Self-sealing test	Pass	Pass

* Average values obtained as described in the European Pharmacopoeia 3.2.9 and USP <381>.
 USP <381> refers to USP 31, 1st Supplement, Effective 1 August 2008
 Eur. Ph. Chapter 3.2.9 refers to Eur. Ph. 8.0 Effective 1 January 2014

Source: Aptar Stelmi product specification 6320GS dated 2014/07/03 151029

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D29.2 Physical data chlorobutyl rubber inlay 6320 GS

		Testing according to the ISO 8871 Standard*	
Resistance to steam sterilization		conform	
Properties	Result	Specification	
Chemical properties :			
A1 Turbidity [Classe (NTU)]	I (0,4)	≤II (6)	
A2 Colour	≤JV ₅	≤ JV ₅	
B Acidity or Alkalinity [ml]	0,02 (NaOH)	≤ 0,3 (NaOH)	
C Absorbance (DO max)**	≤ 0,2 UA	≤ 0,2 UA	
D Reducing substances [ml]	0,30	≤ 3,0	
E Extractable heavy metals [mg/l]	< 2	≤ 2	
F Extractable zinc (mg/l)	0,40	≤5	
G Extractable ammonia (mg/l)	<2	≤ 2	
H Residue on evaporation [mg/50 ml]	< 1	≤ 2,0	
I Volatile sulphides [µg 20 cm ²]	< 0,154	≤ 0,154	
J Conductivity [µs/cm]	3,2	≤ 15	
Identification:			
3.2 Hardness (shore A)***	48 ± 5		
3.3 Density	1,41 ± 0,03		
4.3 Ash (%)	50,5 ± 2		
4.4 I.R. Spectrum	See diagram		

* Average values obtained as described in the ISO 8871 Standard. The numbering used is consistent with that standard.



** See diagram

*** Nominal value obtained on ASTM D2240 standard samples; this value can be different according the shape and the surface of the piece.

Physical properties

Test	Result	Test procedure
Durometer (shore A)	48±5	ASTM D2240
100% Modulus (psi)	290	ASTM D412
Elongation (%)	650	ASTM D412
Tensile (psi)	610	ASTM D412
Compression set (%) (22h at 70°C)	31	ASTM D395 (B)

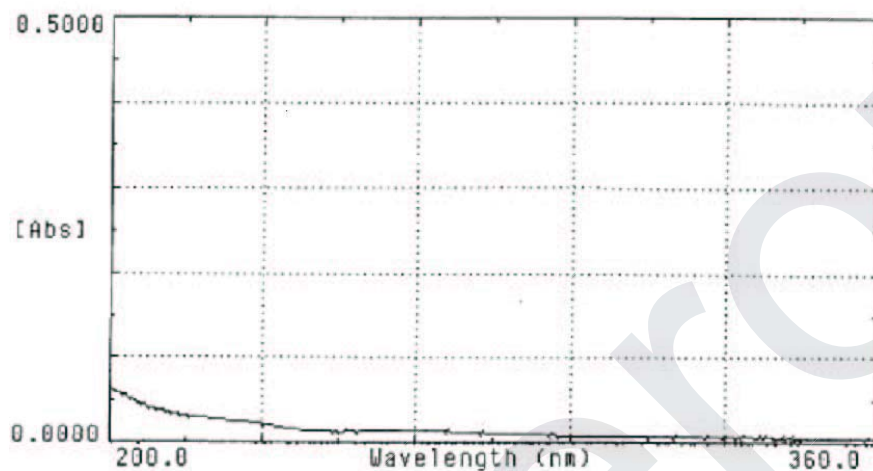
Source: Aptar Stelmi product specification 6320GS dated 2014/07/03 151029

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D29.3 Physical data chlorobutyl rubber inlay 6320 GS

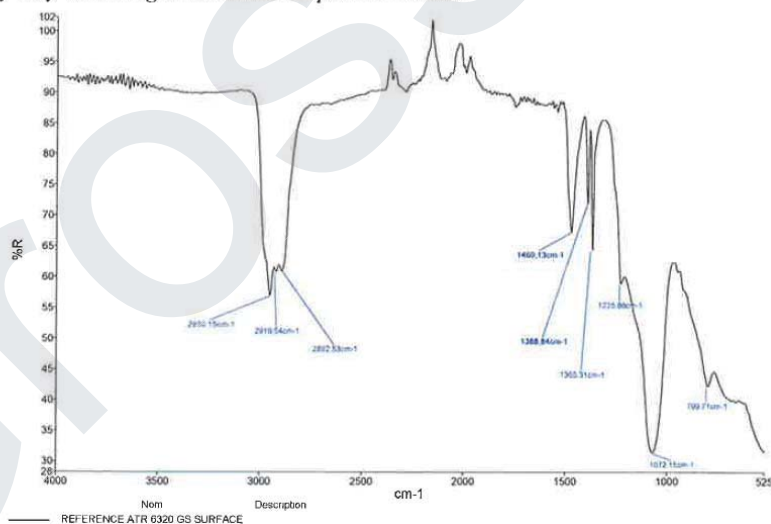
U.V. Spectrum

Ce spectre a été obtenu à partir d'un extrait (Pharmacopée Européenne / USP / procédure ISO 8871-1)
This spectrum has been obtained from an extract (European Pharmacopoeia / USP / ISO 8871-1 procedure)



I.R. Spectra

Ce spectre a été obtenu à la surface du bouchon (Ph. Eur. 3.2.9. / USP <381>). La reflectance due au silicone peut varier selon le process et le taux de silicone.
This spectrum has been obtained at the stopper surface area (Eur. Ph. 3.2.9 / USP <381>). Reflectance due to silicone may vary according to siliconization process & level.



Source: Aptar Stelmi product specification 6320GS dated 2014/07/03 151029

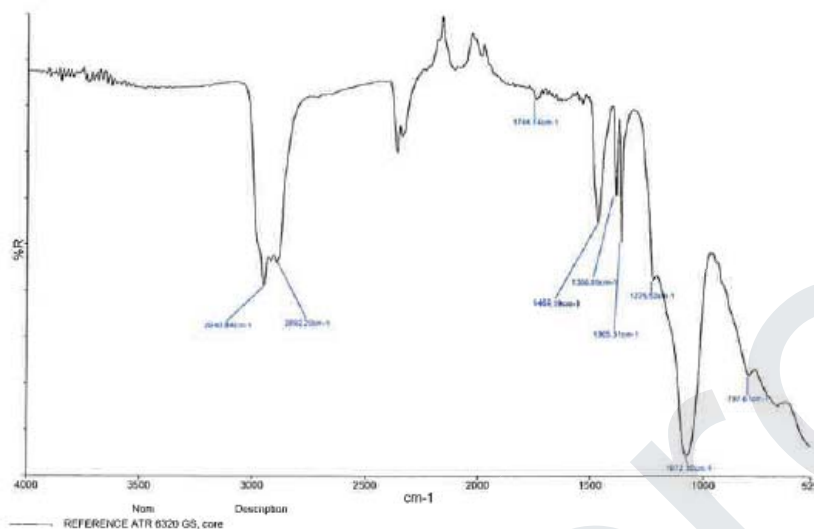
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D29.4 Physical data chlorobutyl rubber inlay 6320 GS

IR Spectra (Cont.)

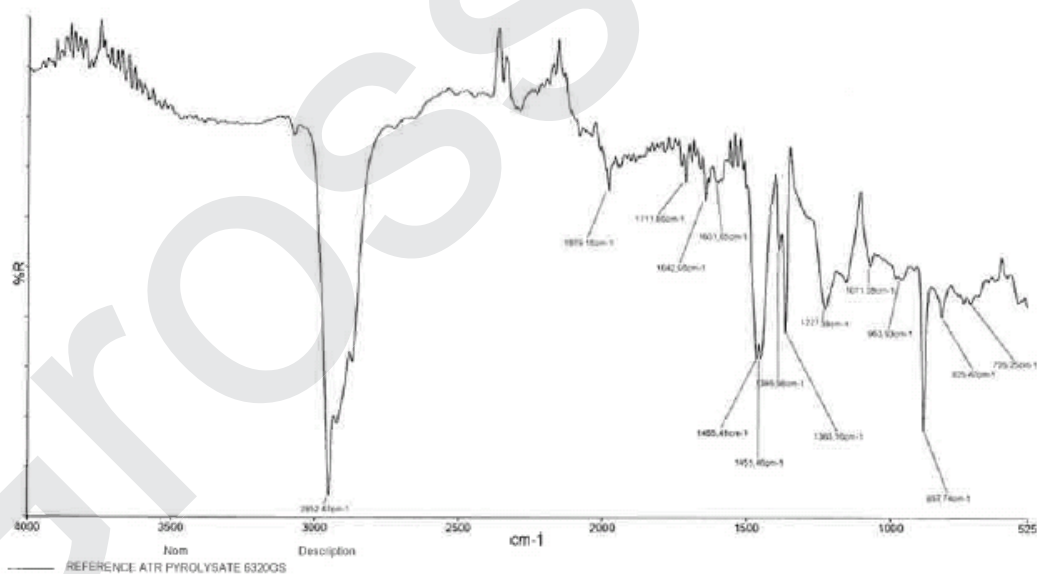
Ce spectre a été obtenu au cœur du bouchon (Ph. Eur. 3.2.9. / USP <381> / ISO 8871-2 - Annexe H). Le silicone en surface n'est pas pris en compte.

This spectrum has been obtained at the stopper core area (Eur. Ph. 3.2.9 / USP <381> / ISO 8871-2 Appendix H). Surface silicone not taken into account.



Ce spectre a été obtenu par RTA à partir d'un pyrolysate (Ph. Eur. 3.2.9. / USP <381>)

This spectrum has been obtained by ATR from a pyrolysate (Eur. Ph. 3.2.9 / USP <381>)



Source: Aptar Stelmi product specification 6320GS dated 2014/07/03 151029

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