

TECHNICAL DATA SHEETEffective date: 01.2020
Rev.0**Oly Airless bottle, 100 ml**

CONFORMITY DECLARATION

We do hereby certify that the quality of the above mentioned items delivered to you is conform to our Sales Specifications in force at the present date.

Is a customer's responsibility to check the chemical compatibility as well as the seal with the specific products.

Furthermore we do declare that the packaging for the cosmetic and pharmaceutical field supplied by us is fully conform to what foreseen by the current law.

Plastic

- D.M: of 21/03/73 published on the G.U. 104 del 20/04/1973 with D.M. 220 of 26/04/1993 and subsequent updates (for material intended to come in contact with food and drugs);
- 94/62/CEE Directive, granted by D.L. N° 22 of 05/02/97 Art. 43 C 4 on the content of heavy metals.;
- 2023/2006/CE Directive, 1935/2004/CE Regulation and 10/2011 UE Regulation (Materials and objects intended to get in contact with food);
- 1907/2006 CE Regulation (Reach-SVHC);
- 282/2008/UE Regulation (Material recycling);
- 2007/19/CE Directive (Fhthalates);
- Bisphenol-A and Nitrite Substances: we state that this materials are not used during the production or intentionally incorporated;
- Recycling: the material is recyclable. The mainly operation is the mechanical material's recall. Most of the packaging components are divisible to allow the separate collection.

Pharmaceutical glass and Rubber

- Same references as for "Plastic", excluding 282/2008/UE Regulation;
- European Pharmacopea currently in force;
- American Farmacopea USP currently in force.

Cosmetic glass

- Same references as for "Plastic", excluding 282/2008/UE Regulation;
- Containers for its chemical composition and characteristics are conform to what foreseen for objects in glass of Category A (Encl. 2° Sect. 5 D.M. dd 21 March 1973) and from Art. 2 paragraph 1, a) b) c) from D.L. N° 108/92 and are suitable for food packaging.

GLOBAL FOOD CONTACT STATUS FOR BOTTLE CAP**European Union**

This product complies with the relevant requirements of Regulation 1935/2004/EC (Framework Regulation) as applicable to intermediate materials (e.g. plastic powders, plastic granules or plastic flakes).

This product complies with the relevant requirements of Regulation 2023/2006/EC (GMP) and as amended, applicable to intermediate materials (e.g. plastic powders, plastic granules or plastic flakes). This product complies with the relevant requirements of Regulation 10/2011/EC (PIM) as amended, applicable to intermediate materials (e.g. plastic powders, plastic granules or plastic flakes). The monomers and additives used to produce this product are listed in the Union List of Authorized Substances of Regulation 10/2011/EC and subsequent amendments.

EU Regulation 10/2011/EC specifies 10 mg/dm² as the maximum overall migration (OML) from the finished plastic food contact material or article. The OML and SMLs (when applicable) should be determined according to the requirements specified in EU Regulation 10/2011/EC and subsequent amendments. The OML and SML determinations are the responsibility of the manufacturer of the finished plastic food contact material or article. In

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addition, we remind you that the manufacturers of the finished food contact material or article must verify that the finished material or article, manufactured according to good manufacturing practices, does not modify the organoleptic properties of the food.

SML Components

This product contains one or more components with Specific Migration Limits (SMLs).

39815; 9,9-bis(methoxymethyl)-9H-fluorene; SML = 0.05mg/kg

SML = 1 mg/kg (expressed as Aluminium)

39090; N,N-bis(2-hydroxyethyl)alkyl (C8-C18)amine; SML(T) = 1.2 mg/kg

39120; N,N-bis(2-hydroxyethyl)alkyl (C8-C18)amine hydrochlorides; SML(T) = 1.2 mg/kg (Expressed as tertiary amine excluding Hcl)

68320; Octadecyl 3(3,5-Di-tert-butyl-4-hydroxyphenyl) propionate; SML = 6 mg/kg

Dual Use Additives This product contains one or more Dual Use Additives as defined in Regulation 10/2011/EC.

E 470a Calcium salts of fatty acids

United States

The base resin in this product meets the FDA requirements contained in the Code of Federal Regulations in 21 CFR 177.1520(a)(1)(i) and (c)1.1a. This product may contain adjuvant substances that may be safely used in polymers used for the manufacture of articles that come into direct contact with food. According to our information, these substances used in this product meet the requirements of their respective FDA regulations, FCNs, and 21 CFR 177.1520(b).

This product meets the FDA criteria in 21 CFR 177.1520 for food contact applications, including cooking, listed under conditions of use A through H in 21 CFR 176.170(c), Table 2, and can be used in contact with all food types as listed in 21 CFR 176.170(c), Table 1.

China

GB4806.1-2016 - Food Contact Material & Articles General Safety Requirement

This product complies with relevant requirements of GB4806.1-2016 - Food Contact Material & Articles General Safety Requirement, as applicable to Plastic Resins.

GB4806.6-2016 - National Food Safety Standard: Food Contact Resins

The base resin in this product complies with the specifications established in GB4806.6-2016, National Food Safety Standard: Food Contact Resins, Appendix A.1, Serial Number 74, resin type: PP."

No monomer(s) with SMLs are present in this base resin.

GB9685-2016 - National Food Safety Standard: Additives for use in Food Contact Materials and Articles The additives used in this product comply with the requirement of "GB9685-2016 National Food Safety Standard: Additives for use in Food Contact Materials and Articles" and relevant approval announcements.

Please note that some additives could have migration (SML, SML (T)) and/or Maximum Residual (QM) restrictions applicable to final food contact articles, the identities of which may or may not be disclosed in this document.

One or more additives with Maximum Residual (QM) specifications may be used in this product.

SML/SML(T) Additives:

The following additives with Specific Migration Limit (SML) and/or Total Specific Migration Limit (SML (T)) specifications are used in this product:

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FCA 0576; Octadecyl 3-(4-hydroxy-3,5-di-tert-butylphenyl)propionate; SML = 6mg/kg

General Remarks

GB4806.1-2016 "Food Contact Materials & Articles -General Safety Requirement" Clause 8.4, requires only the manufacturer of the finished plastic food contact article to declare compliance with OML specification.

Final plastic food contact articles may have additional compliance requirements and are the responsibility of the manufacturer of the finished plastic food article.

Allergen Statements**Allergen - Food Allergen European Regulation 1169/2011**

The food ingredients listed in Annex II of Regulation (EU) No 1169/2011, are not used in the manufacture of or formulation of this product. However, this product has not been tested for these substances.

Biomedical Policy

This product(s) may not be used in:

(i) any U.S. FDA Class I, Health Canada Class I, and/or European Union Class I Medical Devices, without prior notification to Seller for each specific product and application; or (ii) the manufacture of any of the following, without prior written approval by Seller for each specific product and application: (1) U.S. FDA Class II, Health Canada Class II or Class III, and/or European Union Class II Medical Devices; (2) film, overwrap and/or product packaging that is considered a part or component of one of the aforementioned Medical Devices; (3) packaging in direct contact with a pharmaceutical active ingredient and/or dosage form that is intended for inhalation, injection, intravenous, nasal, ophthalmic (eye), digestive, or topical (skin) administration; (4) tobacco related products and applications; (5) electronic cigarettes and similar devices.

(iii) Additionally, the product(s) may not be used in: (1) U.S. FDA Class III, Health Canada Class IV, and/or European Class III Medical Devices; (2) applications involving permanent implantation into the body; (3) life-sustaining medical applications. All references to U.S. FDA, Health Canada, and European Union regulations include other countries equivalent regulatory classifications.

Animal Based Raw-Materials (BSE/TSE)

Tallow Tallow derived additives may be used in the manufacture of this product.

Europe - BSE/TSE - "Mad Cow"

Tallow derived materials used in this product fulfill the requirements laid down in the Regulations 1069/2009/EC, and 142/2011/EC, and the "Note for Guidance EMA/410/01, and as amended.

Epoxy Derivatives

The materials BADGE, BFDGE or NOGE are not intentionally added in this product as referenced in Commission Regulation 1895/2005/EC, on the use of certain epoxy derivatives in materials and articles intended to come into contact with foodstuffs as plasticizers, additives or raw materials.

Genetically Modified Organisms (GMO)

Additives derived from Genetically Modified Organisms (GMOs) are not intentionally used in the formulation of this product.

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Halal Certification

We do not certify our resins to be HALAL or in compliance with HALAL requirements.

Kosher Certification

We do not certify our resins to be Kosher or in compliance with Kosher requirements.

Latex

No materials containing latex or natural rubber are used in the manufacturing, handling and packaging processes for this product.

Metals Content**US CONEG**

Based on the available documentation provided by our raw material suppliers, this product complies with the CONEG Model Legislation for requirements regarding the defined limit for the sum of heavy metals (lead, mercury, cadmium and hexavalent chromium).

EU Packaging and Packaging Waste

Based on the available documentation from raw materials suppliers, this product complies with the directive 94/62/EC and as amended concerning the defined limit(s) of heavy metals.

Restriction of Hazardous Substances in Electric and Electronic Equipment (RoHS)

RoHS Regulation refers to electrical and electronic equipment and not specifically to plastic raw materials. However, based on the available documentation from raw materials suppliers, this product complies with the requirements of the Directives 2002/95/EC and 2011/65/EU, as amended, concerning the limits of cadmium, lead, mercury, hexavalent chromium, polybrominated biphenyls (PBB), polybrominated diphenyl ethers (PBDE), bis(2-ethylhexyl)phthalate (DEHP), butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP) and diisobutyl phthalate (DIBP).

Nanomaterials

Nanomaterials (defined as natural, incidental or manufactured materials containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm - 100 nm) are not used in the manufacture of or the formulation of this grade. However, this product has not been tested for these chemical substances.

Other Chemicals

The chemical materials listed below are not intentionally used in the manufacture or the formulation of this product.

However, this product has not been tested for these chemical materials:

2-(2H-1, 2, 3-Benzotriazol-2-yl)-4,6-di-tert-butylphenol; (Benzotriazole); CAS# 3846-71-7;

Trichloro-2,2',4,4'-dihydroxydiphenyl ether; (Triclosan); CAS# 3380-34-5;

2-mercaptobenzothiazole; MBT; CAS# 149-30-4;

Acrolein; (propenal); (CAS# 107-02-8);

Acrylamide; CAS# 79-06-1;

Aromatic amines;

Asbestos;

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Azo Dyes and Pigments;
 Polyaromatic Hydrocarbons - PAHs:
 1,2-dihydro-acenaphthene; (CAS# 83-32-9);
 Acenaphthylene; (CAS# 208-96-8);
 Anthracene; (CAS# 120-12-7);
 Benz(a)anthracene; (CAS# 56-55-3);
 Benzo(a)pyrene; (CAS# 50-32-8);
 Benzo(b)fluoranthene; (CAS# 205-99-2);
 Benzo(e)pyrene; (CAS# 192-97-2);
 Benzo(ghi)perylene; (CAS# 191-24-2);
 Benzo(j)fluoranthene; (CAS# 205-82-3);
 Benzo(k)fluoranthene; (CAS# 207-08-9);
 Chrysene; (CAS# 218-01-9);
 Dibenz(a,h)anthracene; (CAS# 53-70-3);
 Fluoranthene; (CAS# 206-44-0);
 Indeno(1,2,3-cd)pyrene; (CAS# 193-39-5);
 Naphthalene; (CAS# 91-20-3);
 Phenanthrene; (CAS# 85-01-8);
 Pyrene; (CAS# 129-00-0);
 Bisphenol A; (BPA); CAS# 80-05-7;
 Bisphenol A diglycidyl ether; (BADGE); CAS# 1675-54-3;
 Bisphenol F diglycidyl ether; BFDGE; CAS# 2095-03-6;
 Butylated hydroxyanisole; (BHA); CAS# 121-00-6 & 25013-16-5;
 Butylated hydroxytoluene; (BHT); CAS# 128-37-0
 Chlorinated paraffins;
 Cyanuric acid; (Isocyanuric Acid or CYA); CAS# 108-80-5;
 Dimethyl fumarate; (DMF); CAS# 624-49-7;
 Dioxins;
 Epichlorohydrin; (ECH); CAS# 106-89-8;
 Fluorocarbons;
 Fluorotelomers
 Formaldehyde; CAS# 50-00-0;
 Formaldehyde in specific conditions could be formed during further resin processing (see SDS)
 Gold(Au); CAS# 7440-57-5;
 Halogenated Flame Retardants
 Melamine; (1,3,5-Triazine-2,4,6-triamine); CAS# 108-78-1;
 Nonylphenol; CAS# 25154-52-3;
 Nonylphenol ethoxylates;
 Novolac glycidyl ether;
 Organotin compounds;
 Perfluorochemicals; (PFCs);
 Perfluorooctane sulfonate; (PFOS); CAS# 1763-23-1;
 Perfluorooctanoic acid; (PFOA); CAS# 335-67-1;
 Polybrominated biphenyls; (PBBs);
 Polybrominated diphenyl ethers; (PDBEs);

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Polybrominated terphenyls; (PBTs);
Polychlorinated biphenyls; (PCBs);
Polychlorinated naphthalenes; (PCNs);
Polychlorinated terphenyls; (PCTs);
Polystyrene;
Polyvinyl chloride; (PVC); CAS# 9002-86-2;
Styrene monomer; CAS# 100-42-5;
Sulphur dioxide; CAS# 7446-09-5;
Tin oxide (SnO₂); (Cassiterite); CAS# 8062-08-6;
Tris-nonylphenol phosphite; (TNPP); CAS# 26523-78-4;
Vinyl chloride; CAS# 75-01-4;
Wolframite; Tungsten (W); CAS# 1332-08-7;

Ozone Depleting Substances**European Union**

The ozone-depleting substances (ODS), listed in the Annexes I & II of the Regulation (EC) No 1005/2009 of 16 September 2009, are not intentionally used in the manufacture of or formulation of this product.

United States

Materials listed in the Clean Air Act Amendments of 1990 (Class I, CFCs and Class II, HCFCs, Halons and the solvents, carbon tetrachloride and 1,1,1-trichloroethane) are not intentionally used in the production of this product.

Phthalates

Polyolefins do not require the use of plasticizers (such as phthalates) to make them soft and flexible. Lyondellbasell does not add phthalates to its polyolefin products as plasticizers. However, traces of phthalates may be present in some products as impurities from the catalytic system.

REACH Substances of Very High Concern (SVHC)

This product does not contain any of the Annex XIV substances on the Authorisation list or Annex XIV candidate chemicals proposed to be Substances of Very High Concern for Authorisation (List as of July 16, 2019) above the 0.1 % threshold as stated in REACH (Article 57, Regulation No. 1907/2006) determined either through (i) non-use of the substance, (ii) mass balance calculation, or (iii) specific testing. The current list of all SVHCs can be found at ECHA website link listed below:

<https://www.echa.europa.eu/candidate-list-table>

Global Chemical Control Regulations

All ingredients in this product are in compliance with the following chemical inventories: See Section 15, of the SDS (Safety Data Sheet) for Global Chemical Inventories.

Global Toy Regulations:

CEN EN Standards refer to safety of toys and not specifically to plastic raw materials. According to the information provided by our raw material suppliers, we deem this product should comply with the requirements of CEN standards

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EN71-3 / EN71-9 (as amended) as applicable to plastic raw materials (pellets, powder, flakes). However, this product has not been tested according to these CEN Standards.

VOC Content

Switzerland VOC Declaration

This product contains less than 3% VOC's of the substances in the positive lists of the Switzerland Regulations "VOC-LENKUNGSABGABE."

CEN Standard EN 13432:2004

This product is not suitable for composting.


Energy Recovery - CEN Standard EN 13431:2004

The calorific gain from polypropylene in an energy recovery process is 24 MJ/kg.

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Description			
Part list	Material	Color	Others
Container including piston (lower set)			
Piston (standard)	HDPE / VLDPE (Blend)	Natural	Standard piston position - see drawing Customized piston position upon request
Piston (optional)	HDPE / TPO (Blend)	Natural	Standard piston position - see drawing Customized piston position upon request
Container	PP	Transparent / White ²	Available sizes: 30 ml, 50 ml, 75 ml, 100 ml
Pump (upper set)			
Cap	PP	Transparent / White ²	-
Actuator outer	PP	Transparent / White ²	Different versions according to product overview
Upper valve (standard)	EVA	Natural	-
Upper valve (optional)	TPO	Natural	-
Upper valve (optional)	VLDPE	Natural	-
Actuator inner	PP	Natural	-
Reduction plug	PP	Natural	-
Bellows (standard)	VLDPE	Natural	-
Bellows (optional)	TPO	Natural	-
Adaptor	PP	Transparent / White ²	Different versions according to product overview
Adaptor ring	PP	Transparent / White ²	-
² Color: Customized colored components are available upon request			
Packaging: Layer packed in cardboard box with inserted PE-bag			
General information: Different kinds of decoration upon request e.g.: hot stamping, full cover hot stamping, silk screening, metallization, lacquering, printing, labeling			
Revision	Dated	Modifications	
00	16.04.2018	Release	
Release			
Aptar Villingen GmbH			
Name:	Mr. Hakuk Cimentepe		
Function:	Director - Expert Center Mass Airless		
Date:	16.04.2018		
Signature:	<i>This document is valid without signature!</i>		
Name:	Mr. Helmut Hauschel		
Function:	Director - Quality		
Date:	16.04.2018		
Signature:	<i>This document is valid without signature!</i>		
			
<i>Dispenser configuration selected for the qualification. Exemplary for all dispensers with open orifice actuators.</i>			

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Controls	Dev.*	Prod.**	Values	Methods
General appearance				
Visual checks of molded, assembled and decorated components	S	S	According to the "Quality Standard APTAR Beauty + Home Europe"	View distance of 60 cm for a few seconds
Decoration	S	S	Depending on decoration types	Adhesion test with SCOTCH Tape 600
Dimensions				
Lower set	S	S	According to current drawings	Measurement or test gauge
Upper set	S	S	According to current drawings	Measurement or test gauge
Piston position	S	S	According to current drawings	Measurement
Functionality				
Standard viscosities are from 5.000 cps up to 40.000 cps - filling and snapping under atmospheric conditions. Function tests with a bulk viscosity > 40.000 cps have to be performed in the laboratory.				
Indicated values determined without embedded air pockets, and/or sticky, and/or abrasive effects of the bulk. Measurements are determined using a Brookfield viscometer at a speed of 20 rpm at 25 °C bulk temperature. The spindle of the viscometer has to be adapted to the specific bulk in each case (viscosity/properties).				
Indications above do not replace the achievement of functionality - and compatibility test.				
The measured value determined in the data sheet are based on the usage of the standard materials and standard dispenser configuration.				
Priming of the pump (actuations)	S	-	≤ 6 actuations	Result based on recommended maximum fill volume
-	-	-	500 µl (nominal) 800 µl (nominal) 1.000 µl (nominal)	-
Dosage of the pump	S	-	560 µl ± 15 % 880 µl ± 15 % -	Determination with glycerol. Result depending on individual bulk properties
Actuation force (without bulk) - maximum	S	-	22 N	Determination by dynamometer
Pump (upper set)				
Pump performance	S	S	Functionality test	100 % functional test on the assembly line
Pump performance - minimum pressure	S	S	- 150 mbar	Vacuum measuring device
Cap retention force - minimum	S	-	10 N	Determination by dynamometer
Cap retention force - maximum	S	-	30 N	Determination by dynamometer
Container including piston (lower set)				
-	-	-	30 ml 50 ml 75 ml 100 ml	-
Recommended fill volume - maximum	S	-	34,5 ml 55,6 ml 82,0 ml 102,4 ml	Determination with colored water
Brimful capacity (OFC) - maximum	S	-	42,4 ml 63,7 ml 90,2 ml 110,7 ml	Determination with colored water
Tolerance	S	-	± 0,5 ml ± 0,5 ml ± 0,8 ml ± 1,0 ml	Filling according to the current filling recommendation
Assembled package (lower set with upper set)				
Dead volume	S	-	≤ 2,1 ml	Depending on the actuator system and bellows size Performed with glycerol
Vacuum seal test	S	-	No visible leakage	Test bulk viscosity ≥ 1.400 cps Tested in vacuum chamber at -250 mbar incremental pressure (-750 mbar absolute pressure) lasting 2 minutes of each phase (apply vacuum, hold vacuum, release vacuum)
Drop test	S	-	Still functional	Drop height 0,85 m (horizontally dropped on vinyl plate), without initial speed
Pump assembly force - minimum	S	-	300 N	Determination by dynamometer
Pump assembly force - maximum	S	-	450 N	Determination by dynamometer
Pump retention force - minimum	S	-	100 N	Determination by dynamometer
Actuator retention force - minimum	S	-	10 N	Determination by dynamometer
* = Development				
** = Production				
S = Systematic				

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Filling Information



Filling information for Top Fill dispensers

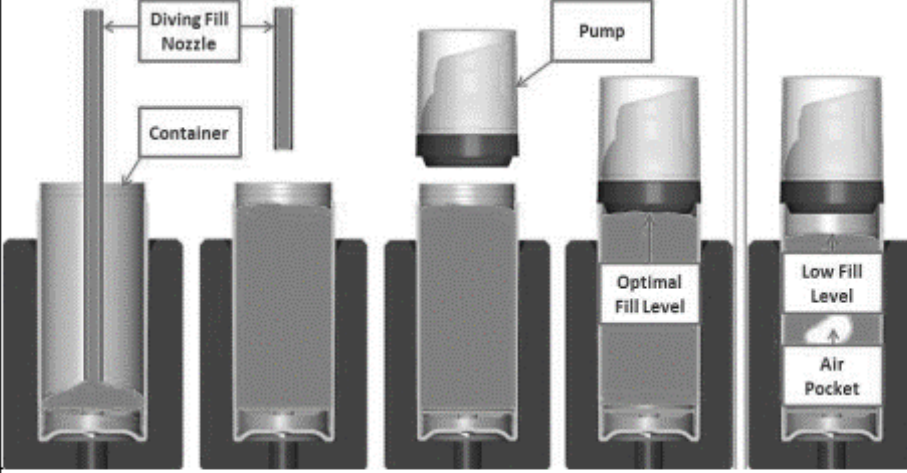
In order to avoid leakage of the bulk through the orifice, while snapping the pump onto the container, the maximum recommended fill volume should not be exceeded.

When dispensers are extremely underfilled, the resulting air pocket between the bulk and the bottom of the pump might cause a higher number of strokes to prime.

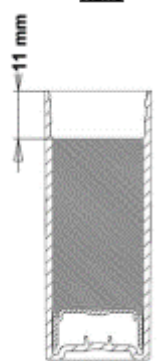
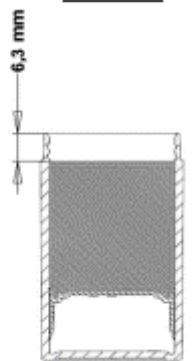
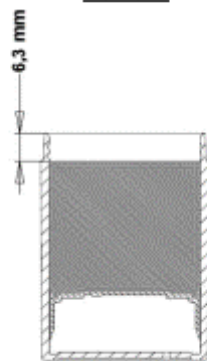
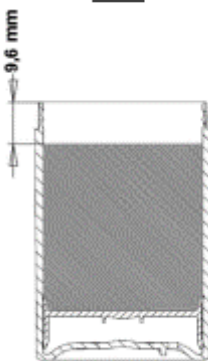
High underfilling or big air pockets, embedded inside the bulk, can result in leakage problems during air transportation. In order to avoid air pockets, we recommend using diving fill nozzles.

System filled at optimal fill level

Underfilled system



In order to determine the optimal fill level please see chart below.

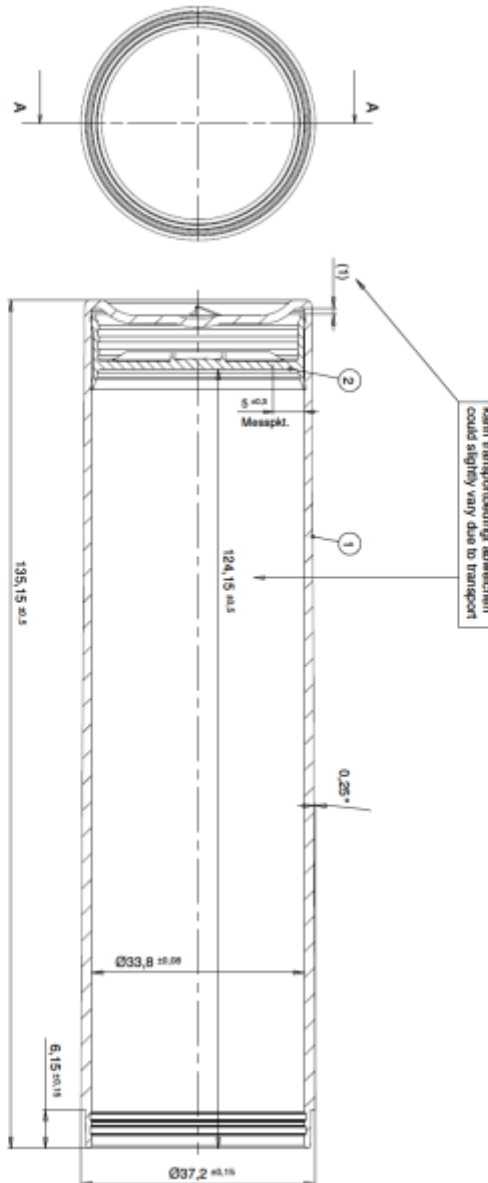
Nano	Micro round	Micro oval	Mezzo
 <p>11 mm</p>	 <p>6,3 mm</p>	 <p>6,3 mm</p>	 <p>9,6 mm</p>

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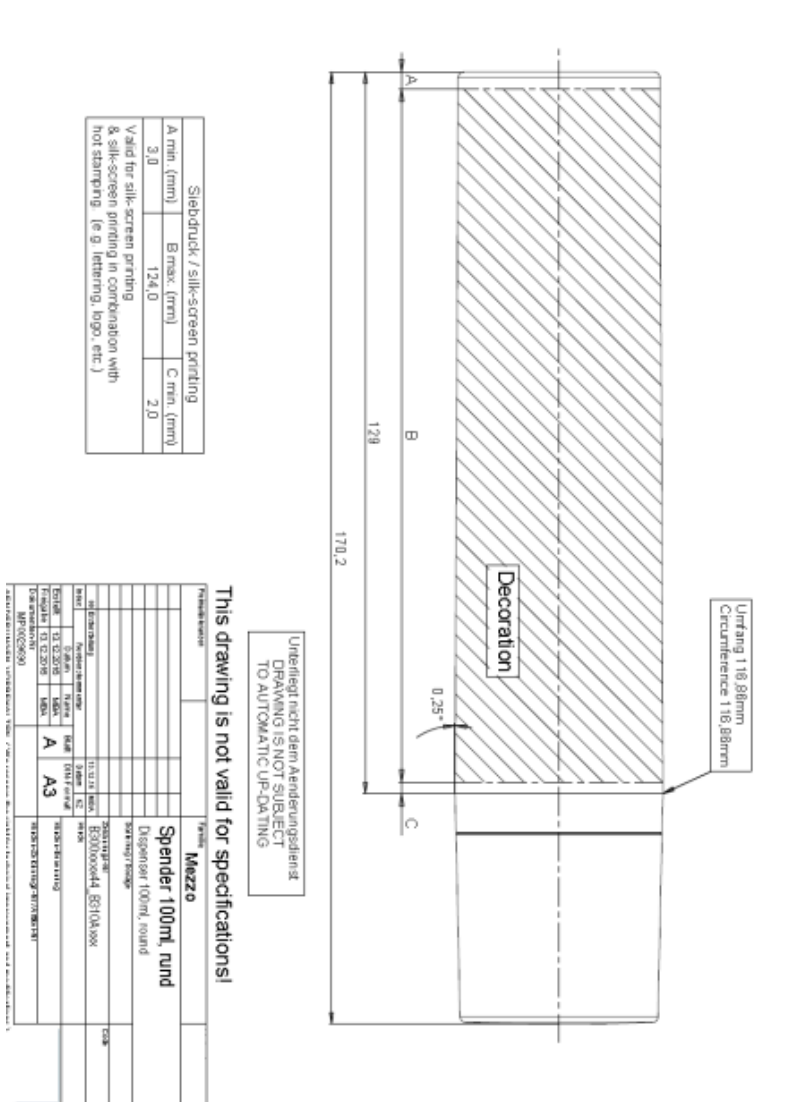
100 ml glossy white container for snap-on pump Adapter "Mezzo Round" (PP), diameter 37 mm, assembled, natural-colored piston, approx. 21 g



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Ultimately customers must make their own determination that their use of our product is safe, lawful (except as provided in the above certifications) and technically suitable in their intended applications.