

TECHNICAL DATA SHEETEffective date: 01.2020
Rev.0**Glass Roll-on, 50 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 (Phthalates);
- 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.

CONFORMITY DECLARATION ON GLASS

According to the Decree 1935/2004 of 27/10/2004 we therewith declare that all glass containers:

- are classified as class "A" and therefore suitable to contain any foodstuffs including sterilisation, according to the Ministerial Decree of 21/03/1973 and any subsequent modifications;
- respect technical specifications as per technical drawing and the quality requirements as agreed in the Supply specifications. In absence of personalised supply specifications, the containers are in accordance with its Standard supply specification.
- have a lead content below the scheduled limits, in accordance with the EC's directives n°1/156 concerning refuse, n°1/689 concerning dangerous refuse and n°4/62 concerning packaging and packaging refuse, directives concerning the maximum concentration of heavy metals measured on the annual average container production.

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).

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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 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.

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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:

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.

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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 (GMO's) are not intentionally used in the formulation of this product.

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).

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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 hydroxydiphenyl 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;
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;

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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);
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, CFC's and Class II, HCFC's, 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.

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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.

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 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.

DECLARATION OF CONFORMITY ACCORDING TO REGULATION (EC) NO. 1935/2004 ARTICLE 16 FOR FITMENT WITH BALL

The materials used to manufacture this packaging and color batches meet the requirements for materials intended for this are in contact with food, according to the EU directive 2002/72 or VO (EG) No. 10/2011 and their manufacture according to VO (EG) No. 2023/2006. The substances contained in the materials, which are listed in Annex XIV of the REACH regulation 1907/2006 do not exceed the reportable value of <0.1 mass percent.

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Typical glass compositions of our soda-lime-silica glasses are as follows:-

Constituent	AMBER	WHITE FLINT
	%	%
SiO ₂	73.0	73.0
Al ₂ O ₃	1.6	1.6
Fe ₂ O ₃	0.3	0.04
CaO	11.5	11.5
MgO	0.1	0.1
Na ₂ O	12.9	13.1
K ₂ O	0.9	0.6
SO ₃	0.1	0.3

All glass testing is performed by Glass Technology Services, Sheffield.

The soda-lime-silica glass manufactured in both amber and white flint by Beatson Clark plc meets the requirements of the British Pharmacopoeia and the European Pharmacopoeia 2002 for hydrolytic resistance type III and the U S Pharmacopoeia (25) Type III for hydrolytic resistance.

Amber glass also meets the requirements for light transmission in the U S and European Pharmacopoeiae and the British Standard BS1679 - Containers for Pharmaceutical Dispensing.

All glass testing is performed by Glass Technology Services, Sheffield.

Both white flint and amber glass also meet the Materials and Articles in Contact with Food (England) Regulations 2005 and the Regulation (EC) No. 1935/2004.

Beatson Clark has U S Food and Drug Administration Drug Master Files (DMF) covering both amber and white flint glass containers, with the following designations:-

Amber	DMF No 10500
White Flint	DMF No 10501

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We herewith confirm that our amber and flint glass containers Type III and II comply with the current European Pharmacopoeia (EP) and United States Pharmacopoeia (USP).

Average composition of our amber and flint glass type III:

Flint Glass		Amber Glass	
SiO ₂	71,5 ± 0,3 %	SiO ₂	71,3 ± 0,3 %
Al ₂ O ₃	1,7 ± 0,15 %	Al ₂ O ₃	2,3 ± 0,2 %
Fe ₂ O ₃	< 0,035 %	Fe ₂ O ₃	0,3 ± 0,05 %
CaO	9,80 ± 0,2 %	CaO	9,90 ± 0,30 %
MgO	3,10 ± 0,30 %	MgO	2,6 ± 0,15 %
Na ₂ O	12,30 ± 0,50 %	Na ₂ O	12,20 ± 0,20 %
K ₂ O	1,20 ± 0,2 %	K ₂ O	0,54 ± 0,09 %
Ti O ₂	0,02 ± 0,01 %	Ti O ₂	0,035 ± 0,02 %
SO ₃	0,15 ± 0,04 %	SO ₃	0,04 ± 0,01 %
B ₂ O ₃	0,2 ± 0,05 %	B ₂ O ₃	0,28 ± 0,04 %
		Li ₂ O	0,36 ± 0,04 %

Remark: The base glass is always Type III only the inner surface is changed to Type II by an chemical process: $(NH_4)_2SO_4 \rightarrow 2NH_3 + SO_3 + H_2O$

The **type II bottles** are to be used only once according to current, valid Ph.Eur. / USP and have to be washed prior to filling.

Examinations regarding the contents of Heavy metals specifically Pb, Cd, Hg, and Cr ⁺⁶ in our glass showed values below the limit of 100 ppm by weight. The content of arsenic is below the values of 5 ppm.

Therefore, and with the exception of marginal substances which do not affect human health, odour and taste and which cannot be avoided during manufacturing no other substances are released to food or its surface. It can be excluded that our glass contains substances like latex, gluten or lactose.

We also confirm that products delivered by us, no raw materials, excipients and further materials of animal origin are used. Due to the fact that for the manufacture of these packaging material no materials are used, which might have a TSE / BSE risk, the bottles are not affected by the general text regarding vaccines, Ph.Eur.5.2.8, "Minimizing the risk of transmitting animal spongiform encephalopathy agents via medicinal products", and by the EMEA-guideline EMEA/410/01, "Note for guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products".

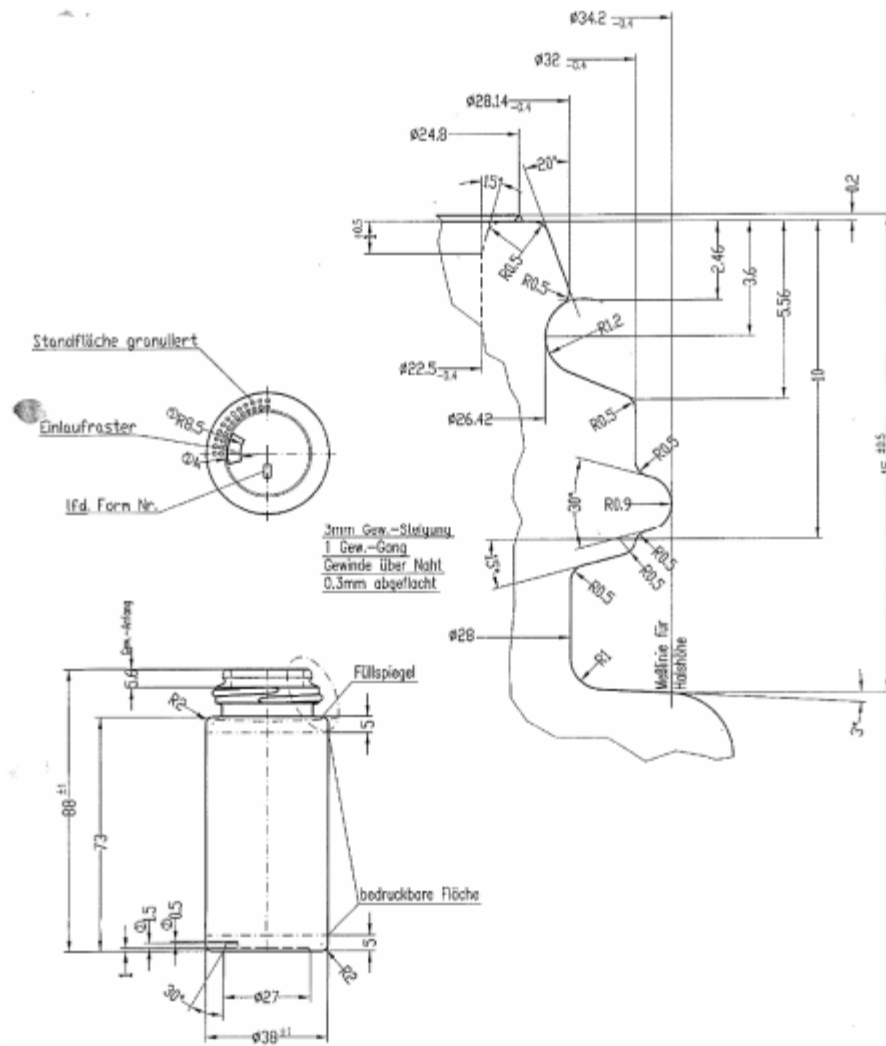
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Glass Roll-on, 50 ml

TECHNICAL DRAWINGS

50 ml white roll-on bottle (white glass), special thread



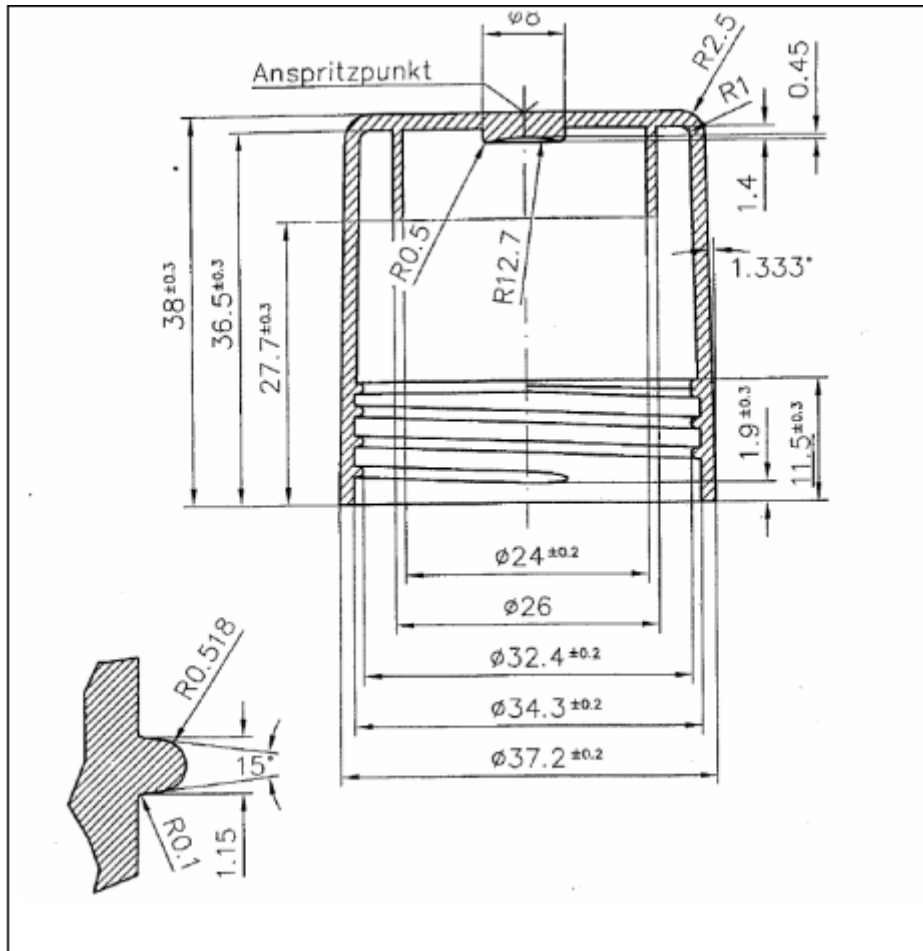
Material	Glass
Nominal / Full Volume	50 / 60 ± 2 ml
Weight	77 g

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white, glossy screw cap (PP), suitable for 50 ml roll-on bottle



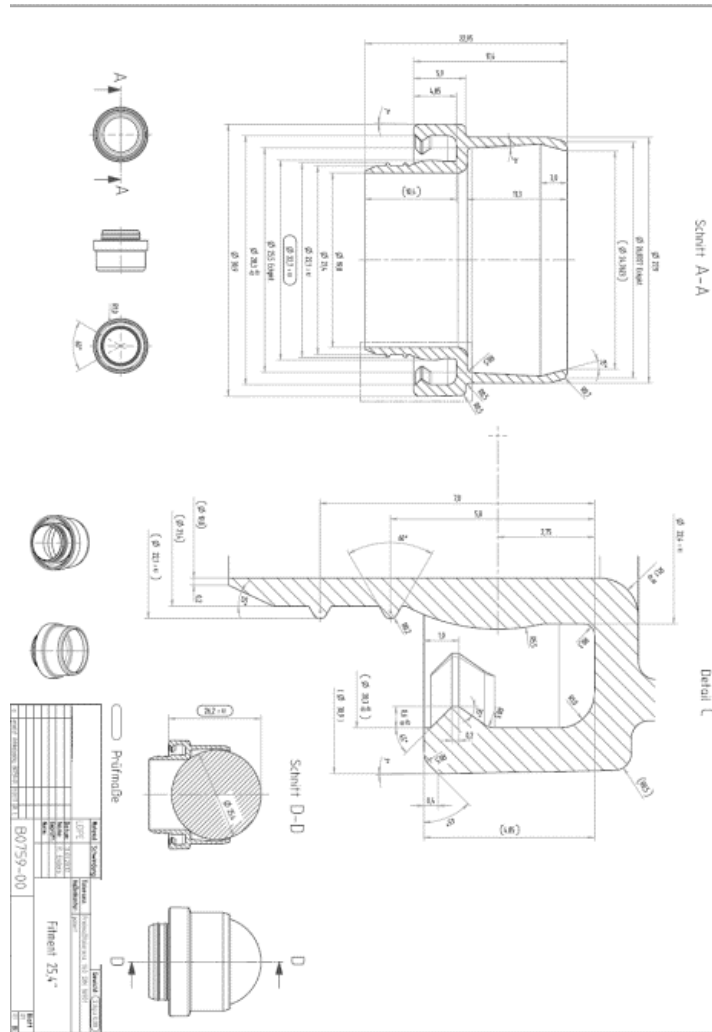
Material	PP
Nominal Volume	-
Weight	7.3 g

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natural-colored fitment (Lupolen), with assembled, natural-colored ball, with neck



Material	Lupolen
Dimensions	Outside Ø 30.9 mm / total height with ball: approx. 31.7 mm
Weight	2.6±0.8 g
Ball diameter	25,4 mm

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.