

Item: HD12361-100**Cosmetic bottle Lotus 100ml, 24/410, Flint****Packings made out of glass incl. Decoration / Finish coating (Perbuseal)****Confirmation of compliance with food laws and regulations**

Legal bases, regulations and directives:

- German Food and Feed Code (LFGB), 15 September 2021 (Federal Law Gazette (BGBl.) I, p. 1453), as amended most recently by Art. 7 of the Act of 27 September 2021 (BGBl. I, p. 4530).
- Sect. 30 LFGB; Prohibitory Provisions for the Protection of Health
- Sect. 31, clause 1 LFGB; Migration of Substances into Food

Our producer confirms that no substances which can be hazardous to health or affect the taste, odour or appearance of the packaged product migrate from the glass containers manufactured by them under normal or foreseeable conditions of use within the meaning of the above-mentioned laws and regulations.

Packaging legislation

Legal bases, regulations and directives:

- Article 11 of the European Packaging Directive 94/62/EC of 20 December 1994 (as amended by Directive 2018/852 of 30 May 2018) in conjunction with the Decisions of the EU Commission 2001/171/EC of 19 February 2001 and 2006/340/EC of 8 May 2006.
- German Packaging Act (Gesetz über das Inverkehrbringen, die Rücknahme und die hochwertige Verwertung von Verpackungen, VerpackG) of 9 June 2019, valid from January 2022.

Our producer confirms that the glass containers supplied by them comply with Sect. 5 of the German Packaging Act on substance restrictions with regard to heavy metals (lead, cadmium, mercury and chromium VI).

Please refer to Standard Sheet T 134 "Glass packaging: Recyclability and use of recyclates according to § 21 Packaging Act".

Good Manufacturing Practice (GMP-Regulation)

Our producer confirms that the goods that are produced by them are fabricated in conformity with the "Kosmetik - GMP (Guidelines for the Cosmetical Good Manufacturing Practices) from July 1992, amended in April 2006.

HACCP declaration

Legal bases, regulations and directives:

- Regulation (EC) No. 852/2004 of 28 April 2004
- German Food Hygiene Ordinance (LMHV) of 8 August 2007, (BGBl. I, No. 39) in the current, consolidated version.
- German Food and Feed Code (LFGB), 3 June 2013 (BGBl. I, p. 1426), as amended most recently by Art. 28 of the Act of 20 November 2019 (BGBl. I, p. 1626).

Our producer confirms, as a supplier of high-quality packaging for the food industry, that they have implemented an HACCP system which is specifically adapted to their production process in accordance with the principles of the above-mentioned laws and regulations.

HACCP (Hazard Analysis and Critical Control Points) as mandated by the EC Food Hygiene Regulation (852/2004/EC) has been adopted by companies in the food industry as part of the quality assurance process.

Traceability

Legal bases, regulations and directives:

- Article 17 of EC Regulation No. 1935/2004 of 27 October 2004.

Our producer confirms, based on the information imprinted on the pallet label, that they comply with traceability requirements for materials and articles intended to come into contact with food in accordance with EC Regulation No. 1935/2004.

EC Regulation No. 1935/2004 requires, inter alia, that traceability of materials and articles intended to come into contact with food should be ensured at all stages in order to facilitate control, the recall of defective products, consumer information and the attribution of responsibility.

With due regard to technological feasibility, business operators shall have in place systems and procedures to allow identification of the businesses from which and to which materials or articles and, where appropriate, substances or products covered by the Regulation and its implementing measures used in their manufacture are supplied.

Glass composition and migration of substances into foods

Legal bases, regulations and directives:

- EC Regulation No. 1935/2004 of 27 October 2004.
- DIN ISO 719, version 1989-12; Hydrolytic resistance of glass grains at 98 degrees C, method of test and classification

Our producer confirms that the glass manufactured by them is conventional soda-lime glass which is tested in accordance with DIN ISO 719. This test confirms that the produced glass containers correspond to hydrolytic class 3 on account of the fact that the hydrochloric acid (0.01mol/l) consumption per gram of glass grains does not exceed 0.85 ml.

Our producer confirms compliance with the provisions of EC Regulation No.1935/2004 that under normal or foreseeable conditions of use, the glass packaging products do not transfer their constituents to food in quantities which could:

- endanger human health or;
- bring about an unacceptable change in the composition of the food or;
- bring about a deterioration in the organoleptic characteristics thereof.

Guideline for proof of compliance

Legal bases, ordinances and directives:

- Regulation (EC) No. 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food-stuffs and repealing Directives 80/590/EEC and 89/109/EEC (Official Journal of the European Union L 338/4 of 13 November 2004).
- German Consumer Goods Ordinance in the version promulgated on 23 December 1997 (BGBl. 1998 I, p.5), as amended most recently by Article 5 of the Ordinance of 13 December 2011 (BGBl. I, p. 2720).
- Directive 94/62/EC on packaging and packaging waste and Directive (EU) 2018/852 amending Directive 94/62/EC
- Regulation (EC) No. 1895/2005 of 18 November 2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food (Official Journal of the European Union L 302/28 of 19 November 2005)
- DIN EN 13427: 2004-10: Packaging: Requirements for the use of European Standards in the field of packaging and packaging waste

Article 16 of Regulation (EC) No. 1935/2004 states that materials and articles covered by the specific measures must be accompanied by a written declaration stating that they comply with the rules applicable to them.

These specific measures are set out in Regulation (EC) 1935/2004, i.e. specific rules and quality requirements for food contact materials made of plastics, ceramics and regenerated cellulose. The specific measures are implemented in the national consumer goods ordinances and the European Regulation on the restriction on the use of certain epoxy derivatives also applies. There are no specific legal regulations and therefore no obligation to issue declarations of compliance for food contact materials (e.g. food packaging) made from other materials, such as glass, steel, aluminium, paper and corrugated board. Only the general requirements of Regulation (EC) No. 1935/2004, such as good manufacturing practice, inertness and traceability, apply.

REACH declaration

Legal bases, regulations and directives:

- Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as amended by the Commission Regulation (EC) No. 987/2008 of 8 October 2008 as regards Annexes IV and V of Regulation (EC) No. 1907/2006.

Our producer confirms that all raw materials on the supply chain side which are necessary to the glass manufacturing process comply with the requirements of the REACH Regulation, particularly with regard to registration.

Products manufactured by the glass industry (e.g. glass containers for packaging use) are articles as defined in the REACH Regulation because their shape, surface or design determines their function to a greater degree than their chemical composition. Therefore, these articles are not subject to mandatory registration requirement under REACH.

US FDA Compliance

Under US FDA guidelines, glass is exempt from Food Contact Substance packaging material regulations as there is no concern of chemical migration from substrate. Therefore, the supplier is fully compliant with EU and US Food Contact Materials (FCM) manufacturing rules and guidelines.

The following explains that specific non-glass substances are not used in the glass manufacturing process.

Allergenic substances or products

The manufacturer confirms that the glass packaging contains none of the substances or products listed in Annex II of Regulation (EU) No. 1169/2001 of the European Parliament. Thus, they are exempted from the labelling requirement.

Bisphenol A (BPA)

Regulation (EU) No. 2016/1179 of 19 July 2016 amending Regulation (EC) No. 1272/2008 considers BPA to be a reproductive toxicant and assigns it to the higher category of 1B “May damage fertility”. The European law has prohibited the manufacture and sale of BPA-based plastic infant feeding bottles. (EU Directive No. 08/2011/EU of 28 January 2011 on the restriction of use of Bisphenol A in plastic infant feeding bottles). Some of the requirements of EU Directive No. 08/2011/EU will be applied in congruent way to other types of packaging. Some European countries have introduced national restrictions on the use of BPA-based materials in the food sector. The manufacturer confirms that the glass packaging is Bisphenol A-free.

Phthalates

The manufacturer confirms that the glass packaging does not contain any of the following specified phthalates.

- DINP (diisononyl phthalate), DIDP (diisodecyl phthalate) and DPHP (dipropyl heptyl phthalate).
- Low molecular weight phthalates DEHP, DBP, BBP and DIBP, which have been identified as “substances of very high concern (SVHC)”

Genetically Modified Organisms (GMO)

The manufacturer confirms that the glass packaging is free of genetically modified organisms (GMO). Thus, they are exempted from the labelling requirement of Regulation (EU) No. 1829/2003 pertaining to the approval of and labelling requirements for genetically modified food and feed.

Not added Substances

The following substances are not subject to the glass production process and therefore not a constitutional part of the glass packaging.

- | | |
|---|---|
| • Benzene | • Benzophenone (Diphenylmethanone) |
| • Bisphenol B, Bisphenol F, Bisphenol S | • Ethylene benzene |
| • 2-Ethylhexanoic acid | • MOAH (Mineral Oil Aromatic Hydrocarbon) |
| • MOSH (Mineral Oil Saturated Hydrocarbon) | • Nanoform substances |
| • Nitrosamine | • PAO (Poly alpha olefins) |
| • PFAS (Per- and Polyfluoronic alky substances) | • PFCA (Perfluorcarbon acid) |
| • PFOA (Perfluorooctanoic acid) | • PFOS Perfluorooctanesulfonic acid) |
| • PFSA (Perfluoronic sulfon acids) | • POP substances* |
| • PVC (Polyvinylchlorid) | • POSH (Polyolefinic oligomeric saturated hydrocarbons) |
| • Xylene | • PVDC (Polyvinylidenchlorid) |

**according to Regulation (EU) 2019/1021 on persistent organic pollutants*

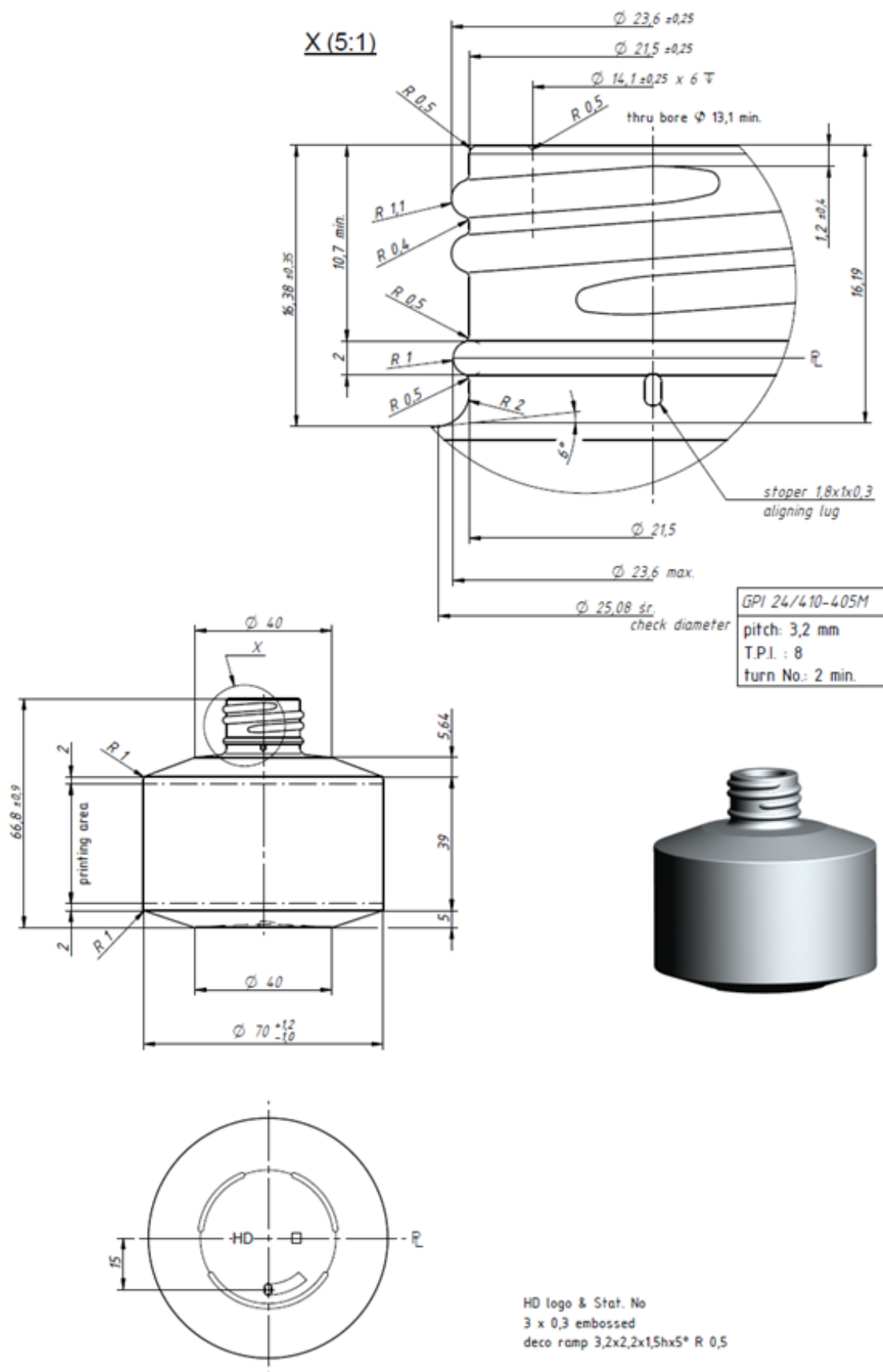
Storage and transport

Safety aspects do not require any special precautions in terms of storage.

There are no special requirements to temperature or humidity. However, high fluctuations in temperature have to be avoided, so that no condensation should be caused.

- Screen off from direct thermal radiation (distance at least 1m) and protect from direct solar radiation
- Storage in closed areas, protect against direct wetness and frost proof store
- Protect from mechanical effects, packaging should not be damaged

Technical drawing (HD12361-100)



This document is created electronically and is valid without a signature.

Filling capacity: 100ml
Brimfull: 110 ± 3 ml
Weight: approx. 181g