



Guideline

for Labeling of Liquids and Predecessor Products

CLP

(Classification, Labeling and Packaging)

REACH

(Registration, Evaluation, Authorization and Restriction of Chemicals)

TabakErzG

(Tobacco Product Law)

TabakErzV

(Tobacco Product Directive)

ProdSG

(Product Safety Law)

Guideline to Labeling of Liquids and Predecessor Products

What is at issue?

The purpose of this guideline is to give the user an introductory guide to the labeling of liquids and precursors such as flavours, bases, shots and shortfills. It represents a compact, clear and as extensive as possible collection of the regulations which must be adhered to when these products are placed on the market in Germany.

Who does this concern?

The target group of this guideline is all those involved in the manufacture, import, distribution or sale of the products mentioned above. In particular, operators of outlets should be given an easy-to-use option to control the marketability of their goods.

Why this is important?

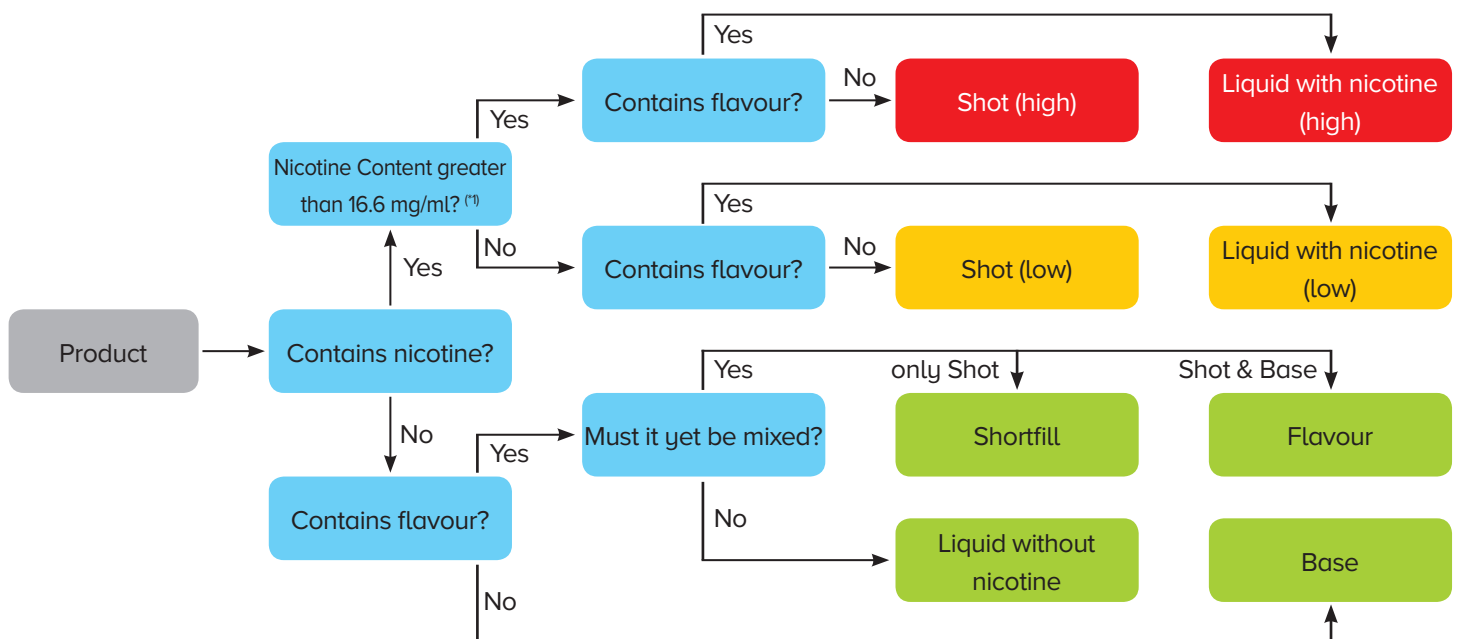
In addition to the Tobacco Products Law (TabakErzG) and the associated Tobacco Product Directive (TabakErzV), which has previously been exclusively related to liquids containing nicotine, the CLP-Regulation and the REACH-Provision is the foundation of this guideline.

How does it work?

1. The product to be labeled is assigned to a corresponding product type in the [assessment diagram](#).
2. The corresponding sample label in the [product category](#) shows the required label components.
3. The significance of the individual components, as well as their presentation and content requirements, will be described in the section [Labeling Elements](#).
4. The [General Information](#) contains additional relevant regulations that needs to be complied with.
5. If needed, the [sources](#) of the corresponding passages may be taken from the underlying legal texts.

Further examples, additional details and current news concerning the topic can be found at www.vd-eh.de/Leitfaden

1. Assessment Diagram



Product Category

Liquid with nicotine
(high)

Shot (high)

11 „Produktname“

7 18 mg/ml Nikotingehalt **12** 10 ml Inhalt

3

1 **Gefahr** Giftig bei Verschlucken **2**

10

7 Nikotinabgabe pro Dosis: 000

9 Ch. Nr.: 000-000-000

8 Hergestellt von: „Name“, „Straße/Hausnr., „PLZ & Ort“, „Telefonnummer“

13 Dieses Produkt darf nicht in die Hände von Kindern und Jugendlichen gelangen.

4 Nach Gebrauch Haut gründlich waschen. Bei Gebrauch nicht essen, trinken oder rauchen. BEI VERSCHLUCKEN: Sofort GIFTINFORMATIONSZENTRUM / Arzt anrufen. Mund ausspülen. Inhalt/Behälter einer anerkannten Abfallentsorgung zuführen.

5 Enthält: „Stoffname“
Kann allergische Reaktionen hervorrufen

14 Inhaltsstoffe: „Stoffname X“, „Stoffname Y“, „Stoffname Z“, Nikotin [ISO]

6 Gefahrbestimmende Komponente: Nikotin [ISO]

15 Dieses Produkt enthält Nikotin: einen Stoff, der sehr stark abhängig macht.

Liquid with nicotine
(low)

Shot (low)

3

7 6 mg/ml Nikotingehalt
Entspricht Nikotinabgabe pro Dosis (Dosis = 1ml)

11 „Produktname“

10

9 Ch. Nr.: 000-000-000

8 Hergestellt von: „Name“, „Straße/Hausnr., „PLZ & Ort“, „Telefonnummer“

1 **Achtung - Enthält Nikotin [ISO] - Gesundheitsschädlich bei Verschlucken.** Nach Gebrauch Haut gründlich waschen. Bei Gebrauch nicht essen, trinken oder rauchen. BEI VERSCHLUCKEN: Bei Unwohlsein GIFTINFORMATIONSZENTRUM / Arzt anrufen. Mund ausspülen. Inhalt/Behälter einer anerkannten Abfallentsorgung zuführen.

2

4

13 Dieses Produkt darf nicht in die Hände von Kindern und Jugendlichen gelangen.

5 Enthält: „Stoffname“
Kann allergische Reaktionen hervorrufen

14 Inhaltsstoffe: „Stoffname X“, „Stoffname Y“, „Stoffname Z“, Nikotin [ISO]

15 Dieses Produkt enthält Nikotin: einen Stoff, der sehr stark abhängig macht.

Liquid without
nicotine

Shortfill

Flavour

Base

11 „Produktname“

12 50 ml Inhalt

9 Ch. Nr.: 000-000-000

10

8 Hergestellt von: „Name“, „Straße/Hausnr., „PLZ & Ort“, „Telefonnummer“

3

1 **Achtung** **2** Kann allergische Hautreaktionen verursachen

4 Schutzhandschuhe / Schutzkleidung / Augenschutz / Gesichtsschutz tragen. Bei Berührung mit der Haut: Mit viel Wasser und Seife waschen. Bei Hautreizung oder -ausschlag: Ärztlichen Rat einholen / ärztliche Hilfe hinzuziehen. Inhalt/Behälter einer anerkannten Abfallentsorgung zuführen.

14 Inhaltsstoffe: Limettenöl, **6** „Stoffname X“, „Stoffname Y“, „Stoffname Z“

5 Enthält: „Stoffname“
Kann allergische Reaktionen hervorrufen

13 Dieses Produkt darf nicht in die Hände von Kindern und Jugendlichen gelangen.

15 Dieses Produkt enthält Nikotin: einen Stoff, der sehr stark abhängig macht.

Labeling Elements

1 Signal Word ^[9]

- Determined by classification, hazard category and hazard classes. ^[14]
- Must be grouped with hazard statements. ^[23]

■ „Danger“ ^[4] ■ „Attention“ ^[4] ■ depending on flavour

2 Hazard Statements ^[9]

- Determined by classification, hazard category and hazard classes. ^[15]
- Must be grouped with safety instructions. ^[23]

■ H301 ^{[4] (*)} ■ H302 ^[4] ■ depending on flavour

3 GHS Pictogram ^[9]

- Determined by classification, hazard category and hazard classes. ^[13]
- Black symbol on white background with a red frame. ^[2]
- Area at least 1cm². ^[2]
- Must be grouped with safety instructions. ^[23]

■ GHS06 ^{[4] [8] (*)} ■ GHS07 ^{[4] [8]} ■ depending on flavour

4 Precautionary statements ^[9]

- Determined by classification, hazard category and hazard classes. ^[16]
- Not more than six precautionary statements, unless necessary to reflect the nature and the severity of the hazards. ^[18]
- Avoid any double and clearly unnecessary notices. ^[18]
- Disposal information required. ^[18]
- Must be grouped together. ^[23]
- The order is freely selectable. ^[23]

■ P264, P270, P330, P501, P301+310 (■) /312 (■) ^[4]
■ depending on flavour

5 Additional Information Notices ^[9]

- Can be independent of hazard-determining components. ^{[17] [22]}
- E.g., mixtures not classified as sensitizing but containing at least one sensitizing substance (EUH208). ^[7]

■ ■ ■ depending on flavour

6 Product Identifiers of Hazardous Substances ^[9]

- Identities of all substances that contribute to the classification of the mixture (= hazard-determining components). ^[12]
- Necessity is dependent upon the classification and hazard category of the mixture (i.e., acute toxicity) ^[12]

■ ■ „Nicotine (ISO)“ ■ depending on flavour

7 Nicotine Content and Nicotine Level per Dose ^[38]

- Nicotine content typically in mg/ml.
- Nicotine level per dose currently not yet more closely defined.

■ ■ e.g. Dose = 1 ml

8 Manufacturer Information ^[9]

- Name, address and phone number of the manufacturer/importer. ^[44]

9 Batch-No. ^[39]

- Notice displays the batch to which the refill-container belongs.

10 Tactile hazard warning ^[26]

- Necessary, e.g. if classified as acute toxic. ^[6]
- Regardless of capacity. ^[6]
- Must comply with EN ISO 11683. ^[6]

■ ■ Mandatory ■ depending on flavour

11 Clear Labeling of the Product ^[45]

- Clear labeling for the identification of the consumer product.
- Typically product name, item-no./EAN Code.

■ ■ EC-ID is not mandatory yet recommended

12 Nominal volume ^[9]

- A nominal quantity of the mixture in the package.

■ ■ Max. 10ml permitted ^[32]

13 Youth Protection Note ^[40]

- This product must be kept out of reach of children and adolescents. ^[42]

■ ■ Mandatory
■ ■ affixing recommended

14 Ingredients ^[37]

- In Descending Order of Weight.

■ ■ Mandatory
■ ■ affixing recommended

15 Health Warning ^[41]

- Wording: “This product contains nicotine which is a highly addictive substance.” ^[41]
- Text: In German language, Helvetica bold, black on white background, parallel alignment to the main text, centered, must fill out at least 50% of the intended space. ^{[34] [35] (*)}
- On the two largest spaces of the packaging and outer packaging, each of 30% of these surfaces (not of the label!) ^[35]
- Should not contain comments, paraphrases or references. ^{[34] (*)}
- May be affixed as long as it is neither smudgeable nor removable. ^{[34] (*)}
- Should not be covered or separated when being marketed. ^{[34] (*)}
- Within the space, should be bordered by a 1mm black border. ^{[34] (*)}

■ ■ Cylindrical Packaging: Circumferential affixing on the lateral surface, double affixing of the safety note ^(*)

4. General Information

Safety Data Sheet (SDS)

- Structure and content are precisely regulated by the REACH-provision. [30][29]
- Must be made available by the manufacturer, importer and retailer (typically digital with possibility to print is sufficient). [28][30]
- The SDS must be provided in the official language of the member country of release. [30]
- The trade name in the SDS must be identical with the product's name. [11]
- Information on the packaging/labeling must comply with the information of the SDS.
- Classification and corresponding labeling elements to be affixed can be found in Section 2.2 of the SDS:


ABSCHNITT 2: Mögliche Gefahren

2.1. Einstufung des Stoffes oder Gemisches
Verordnung (EG) Nr. 1272/2008
Gefahrenkategorien:
Akute Toxizität: Akut Tox. 4
Gefahrenhinweise:
Gesundheitsschädlich bei Verschlucken.

2.2. Kennzeichnungselemente
Verordnung (EG) Nr. 1272/2008

6 Gefahrbestimmende Komponenten zur Etikettierung
Nikotin (ISO)

1 Signalwort: Achtung
Piktogramme:

3 

2 Gefahrenhinweise:
H302 Gesundheitsschädlich bei Verschlucken.

4 Sicherheitshinweise:
P264 Nach Gebrauch Haut gründlich waschen.
P270 Bei Gebrauch nicht essen, trinken oder rauchen.
P301+P312 Bei Verschlucken: Bei Unwohlsein Giftinformationszentrum / Arzt anrufen.
P330 Mund ausspülen.
P501 Inhalt / Behälter einer anerkannten Abfallentsorgungsanlage zuführen.

5 Besondere Kennzeichnung bestimmter Gemische
EUH208 Enthält 4-Hydroxy-2,5-dimethyl-3(2H)-furanon.
Kann allergische Reaktionen hervorrufen.

Package Leaflet

- Mandatory for liquids and shots containing nicotine. [33]
- Must display the heading “Gebrauchsinformation” (Direction for Use). [36]
- Must be in German language, in layman's terms and easily readable (see design). [36]
- Content Requirements: [36]
 - Use and Storage Instructions (i.e., refill instructions, also diagrams. [43])
 - Contraindications
 - Warnings for endangered consumer groups (in particular non-smokers, the prohibition on sales to children and adolescents).
 - Information on possible adverse health effects.
 - An indication of the addictive properties.
 - Information concerning the toxicological data.
 - Name, address and electronic contact details of the manufacturer/importer.

Refill Containers containing Nicotine

- Must be childproof, tamper-proof, shatterproof and leakproof. [32][25]
- Childproof lids must comply with EN ISO 8317. [26][5]
- Volume may not exceed 10 mL. [32]
- Nicotine level may not exceed 20mg/mL. [32]
- Must have a mechanism for leakproof refilling [32] (docking system or at least a 9mm spout, thinner than the tank opening, securely fastened, max 20 drops per minute [43]).

Design of Packaging/Labeling

- Labeling in the official language of the member country where the product is placed on the market. More languages are permitted, as long as all necessary data is printed in the languages used. [10]
- Labeling elements must be affixed horizontally, clearly legible (minimum letter size 1.2 mm „x“ height [31]) and indelibly marked. [20][21]
- Labeling elements must be affixed directly on the refill container and all other packaging unless the labeling is clearly visible through container or packaging. [24]
- Design should neither arouse children's active curiosity nor appear attractive to them. [26]
- Design should not mislead consumers by using similar packaging used for food, feed, medicines or cosmetics. [26]

Exception for Small Packaging/Labeling

- If the packaging of a substance is either in such a shape or form or is so small (52x74 mm [1]), that not all labeling elements can be affixed to it, these can also be made available on folded labels (rollup labels/sandwich labels) or hangtags or on the outer packaging. [19][3]
- The label of the inner packaging (refill container) must contain at least hazard pictograms, product identifier, name and telephone number of the supplier. [3]
- If multi-layer labels are used, special attention should be paid to the clear marking of the peel-off point.

Labeling Requirements in Advertising

- Advertising for mixtures classified hazardous must contain hazard warnings, hazard pictograms and signal words. [27]
- In online sales, the information should be held available so that the consumer must pass it before the goods can be placed in the shopping cart. [3]
- The information should be directly accessible and not via a link to other sites. [3]

5. List of Sources

Regulation (EC) No. 1272/2008

[CLP Regulation]

- [1] Annex I paragraph 1.2 Tab. 1.3
- [2] Annex I paragraph 1.2
- [3] Annex I paragraph 1.5.1
- [4] Annex I paragraph 3.1.4 3.1.3
- [5] Annex II paragraph 3.1
- [6] Annex II paragraph 3.2
- [7] Annex II paragraph 2.8
- [8] Annex V paragraph 2
- [9] Art. 17 paragraph 1
- [10] Art. 17 paragraph 2
- [11] Art. 18 paragraph 1
- [12] Art. 18 paragraph 3
- [13] Art. 19
- [14] Art. 20
- [15] Art. 21
- [16] Art. 22
- [17] Art. 25 paragraph 6
- [18] Art. 28
- [19] Art. 29 paragraph 1
- [20] Art. 31 paragraph 1
- [21] Art. 31 paragraph 3
- [22] Art. 32 paragraph 6
- [23] Art. 32
- [24] Art. 33 paragraph 2
- [25] Art. 35 paragraph 1
- [26] Art. 35 paragraph 2
- [27] Art. 48
- [28] Art. 49

Regulation (EC) No. 1907/2006

[REACH-Provision]

- [29] Annex II
- [30] Art. 31

Guideline for Labeling and Packaging under (EC) No. 1272/2008

July 2017 Version 3.0

- [31] paragraph 5.2

Law for Implementing the Guideline concerning Tobacco Products and Related Products

[TabakErzG]

- [32] §14
- [33] §15 paragraph 1 No 1

Directive for Implementing the Guideline concerning Tobacco Products and Related Products

[TabakErzV]

- [34] §11
- [35] §13 paragraph 1
- [36] §26
- [37] §27 paragraph 1 No. 1
- [38] §27 paragraph 1 No. 2
- [39] §27 paragraph 1 No. 3
- [40] §27 paragraph 1 No. 4
- [41] §27 paragraph 2-3

Second Provision for the Amendment of the Tobacco Product Directive

- [42] Art. 1 No. 3

Implementing Decision (EU) 2016/586

- [43] Art. 2

Law concerning the provision of products on the market, ProdSG

[ProdSG / Product Safety Law]

- [44] §6 paragraph 1 No. 2
- [45] §6 paragraph 1 No. 3

⁽¹⁾ Threshold value in accordance with Regulation (EC) No 1272/2008 Annex I, Section 3.1.3.6.1 (extreme case: density $\rho = 1$).

⁽²⁾ Letter from the Foodstuff Inspection Regulatory Agency Bochum.

⁽³⁾ Letter from the District Government of Cologne.

⁽⁴⁾ Application of §11 TabakErzV is not clearly prescribed, yet is strongly recommended.

Further information at www.vd-eh.de/Leitfaden

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