Apoteket Product Approval Criteria

Version 25

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Product Approval

- The products are assessed in the context of legality, safety, and trustworthiness.
- The products must be Legal, Safe and Trustworthy and meet the requirements in this document.
  - **Legal:** The products must be correctly categorized/classified and fully comply with all applicable legislation, including both horizontal (e.g. REACH, GPSR) and product-specific legislations (e.g. cosmetics, biocides, toys, etc). Products must not contain prohibited substances. Product claims and marketing texts are reviews to ensure legal compliance.
  - **Safe:** Products must be designed, formulated, and intended for use in a manner that does not present an unacceptable risk to consumers, either in the short or long term. In addition to substances prohibited by law, Apoteket may restrict or prohibit certain substances or substance groups, see page *Product Criteria Overview*.
  - **Trustworthy:** Products must support and be consistent with Apoteket´s values and position as a trusted pharmacy retailer.

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Product Criteria Overview

Prerequisites

Apoteket's Product Approval Criteria covers all the products sold in our stores and on the web. All new products or changes of existing products shall pass the quality control in the supplier portal.

For pharmaceuticals, we rely on the Medical Product Agency or the European Commission approval.

All products must be fully compliant with applicable legislation for its product type.

Documents that need to be provided to Apoteket are stated in the following checklists in this document.

The criteria in this document is valid for new and existing products.

If the product(s) contain any substance from ECHA's candidate list this must be communicated to Apoteket, see https://echa.europa.eu/en/candidate-list-table. New knowledge with the supplier of addition of substances from candidate list in their products must be communicated to Apoteketet without delay.

Substances prohibited by Apoteket

Cyclic siloxanes
E.g. Cyclotetrasiloxane (D4), Cyclopentasiloxane (D5), Cyclohexasiloxane (D6) and Cyclomethicone (mixture)

Kathon preservatives
E.g. Methylchloroisothiazolinone (MCI), Methylisothiazolinone (MI).

Formaldehyde releasers
E.g. Diazolidinyl Urea, DMDM Hydantoin Imidazolidinyl Urea, Quaternium-15, Methenamine, Sodium hydroxymethylglycinate etc.

PFAS
PFAS are substances that contain at least one fully fluorinated methyl group (-CF3) or fully fluorinated methylene group (-CF2-) without any hydrogen, chlorine, bromine, or iodine atom attached to it (OECD, 2021). E.g. substances with the wording per- and polyfluoro anywhere in the chemical name.

Apoteket may allow substances from this list under certain specific exceptions.

Approval

An approvement can be conditional, i.e.. connected to certain counter measures that the supplier agrees to take.

The approval is continuously reevaluated based on customer feedback and scientific evidence

The information uploaded (excluding public information) is treated as confidential.

Check list color code

Blue boxes shows the main regulations connected to the product type

Red boxes shows the mandatory documentation to be provided to Apoteket

Green boxes with solid line shows the responsibility of the supplier

Green boxes with dotted line shows the responsibility of the supplier and Apoteket

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Product Information from Validoo

- Validoo is a database for storing and sharing product information and product images.
- Apoteket retrieves product information to the Supplier Portal from Validoo.
- To enable Apoteket to display mandatory product information on www.apoteket.se, all relevant information must be correctly entered in Validoo and match the product packaging, in particular:
  - Ingredient list/INCI
  - Hazard statements and precautionary statements for chemical products
  - Precautions and warnings for other product categories
  - Consumer usage instructions
  - Consumer storage instructions
  - Adress and contact information
  - Dangerous goods

- GS1 has a guideline for the Pharmacy channel that shall be followed:

Handledning Artikelinformation för apoteksbranschen » GS1 Sweden

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Checklist - Cosmetics

The function must be indicated if this is not clearly apparent from the product's presentation.

The nominal content (weight or volume).
Content less than 5 g or 5 ml does not need to be stated.

Batch number: if the container is too small for the number to fit, the information only needs to be on the packaging.

Requested Documentation
- Artwork (pdf format) for primary and secondary packaging

Main Legislation
- CPR (EC) 1223/2009
- Cosmetic Claims (EU) 655/2013
- Technical document on cosmetic claims (2017)
- REACH (EC) 1907/2006

The consumer must be able to understand the purpose of the product and how it must be used in a safe way. The text shall be <u>indestructible, easy to read and easy to find</u>.
List of the parts of the label that must be in **Swedish**:
- function/purpose of the product
- nominal content
- reference to shelf-life
- Particular precautions, such as warnings and important user instructions

When applicable, particular precautions such as **warnings** and **important user instructions**.

List of ingredient only needs to be on the outer packaging. Substances must be listed with INCI names in decreasing weight order down to 1%. Thereafter, in any order. The list should follow the word "Ingredients".

Name and address to the **responsible person** within EU

<u>Shelf-life of up to 30 months</u>:
Must be specified and preceded by an hourglass symbol or 'bäst före utgången av'.
<u>Durability of more than 30 months:</u>
Indicated by the open jar symbol in which is stated months or years.

Aerosol Dispensers
Additional labelling requirements are needed in accordance with **Aerosol Directive (75/324/EEC)**

For **wet wipes** and **sheet masks** that **contain plastic** and have a packaging with the surface area of 10 cm2 or more, shall bear the following printed marking. The marking should be placed and sized in accordance with the Regulation (EU) 2020/2151

Sunscreen products must be tested and labelled according to EU Commissions Recommendation 2006/647/EC.

Dangerous goods information

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Checklist – Chemical Products

The text on the product shall consist of indelible, easily legible and visible lettering on a contrasting background.

The nominal quantity of the substance or mixture in the package made available to the general public.

Name and address of the manufacturer.

Requested Documentation
- Artwork (primary- and secondary packaging, including leaflet)
- MSDS (in Swedish)

Main Legislation
- CLP Regulation (EC) 1272/2008
- REACH (EC) 1907/2006
- GPSR (EU) 2020/878
- Detergents Regulation (EC) 648/2004, (EU) 2026/405

Dangerous goods information

For certain products tactile warning labels and child-resistant fastenings are mandatory (CLP Annex II).

The intended use and instructions

The identity of up to four substances in the mixture primarily responsible for the product´s major health hazards. (CLP art 18).

Hazard statements, appropriate precautionary statements and supplemental information as special precautions and warnings (when applicable).

The 16-digit UFI code should be printed at the label.

The batch identification (in this case imprinted on the bottle)

The product must, when applicable, be labeled with hazard pictograms and signal words in accordance with article 17 in CLP.

For wet wipes that contain plastic and have a packaging with the surface area of 10 cm2 or more, shall bear the following printed marking. The marking should be placed and sized in accordance with the Regulation (EU) 2020/2151

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Checklist - Biocides

Directions for use, frequency of application and dose rate, expressed in metric units, in a manner which is meaningful and comprehensible to the user.

Type of formulation. For example, liquid, gel, spray or solid stick.

Name and address of the authorization holder.

Requested Documentation
- Artwork
  - For biocidal products containing approved active substances: Artwork in accordance with BPR article 69 and MSDS (in Swedish).
  - For biocidal products containing active substances in the review program: Artwork in accordance with KIFS 2008:3, Annex 2 and MSDS (in Swedish).
- MSDS (in Swedish)

Main Legislation
- BPR (EU) 528/2012
- PRP (EU) 1062/2014
- CLP (EC) 1272/2008
- KIFS 2022:3
- REACH (EC) 1907/2006

Information on the period of time needed for the biocidal effect, the interval to be observed between applications of the biocidal product or the next access by humans or animals to the area where the biocidal product has been used.

Instructions for safe disposal of the biocide product and its packaging.

For certain products tactile warning labels and child-resistant fastenings are mandatory (CLP Annex II).

Area of use must be declared following the text: “All annan användning är otillåten om den inte särskilt tillåtits” (not applicable for review program substances).

Warnings and precautions for use

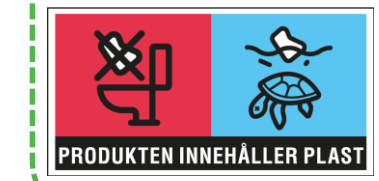
Information on possible direct or indirect adverse side effects and directions for first aid.

The identity of every active substance and its concentration in metric units must be declared.

The authorization number (4-digit) allocated to the biocidal product by the competent authority or the Commission (not applicable for review program substances).

The 16-digit UFI code should be printed at the label

For wet wipes that contain plastic and have a packaging with the surface area of 10 cm2 or more, shall bear the following printed marking. The marking should be placed and sized in accordance with the Regulation (EU) 2020/2151



If the product comes with a leaflet the text “Läs medföljande anvisning” must be on the label.

Information of specific environmental hazard.

Batch number and the expiry date relevant to normal conditions of storage.

Dangerous goods information in Validoo

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Checklist - Medical devices

Information on the product shall be given in Swedish

Instruction for use as a leaflet (with date) shall be included (not mandatory for class I, class IIa)

Essential information in order to identify the product (ex. when separated from package)

If applicable the word "sterile" and information about the sterilization method

Requested Documentation
- Artwork packaging and leaflet (pdf format)
- EU Declaration of Conformity

Main Legislation
- LVFS 2003:11
- MDR (EU) 2017/745, IVDR (EU) 2017/746

Each product shall have the necessary information in order to be used in a safe way

Information about any warnings

If applicable information how the product shall be stored / handled

Information if the product is one-time-use (shown as a crossed over 2)

The product shall be CE marked and information in text/symbol that the product is a medical device

The manufacturers name and address (incl. Street address), if applicable the distributors/EC-rep name and address

Dangerous goods information in Validoo

Wherever possible use symbols according to ISO 15223

Unique device identifier (UDI)

Information about how long the product is safe to use (usually the time glass symbol)

A lot symbol and the lot identification

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Checklist - Food

If an ingredient or category of ingredients is highlighted in the presentation or labeling through words, images, or graphics, its quantity shall be stated in the declaration.

Mandatory food information shall be placed on a clear visible position on the package or label and be in Swedish.

Information about specific conditions for storage.

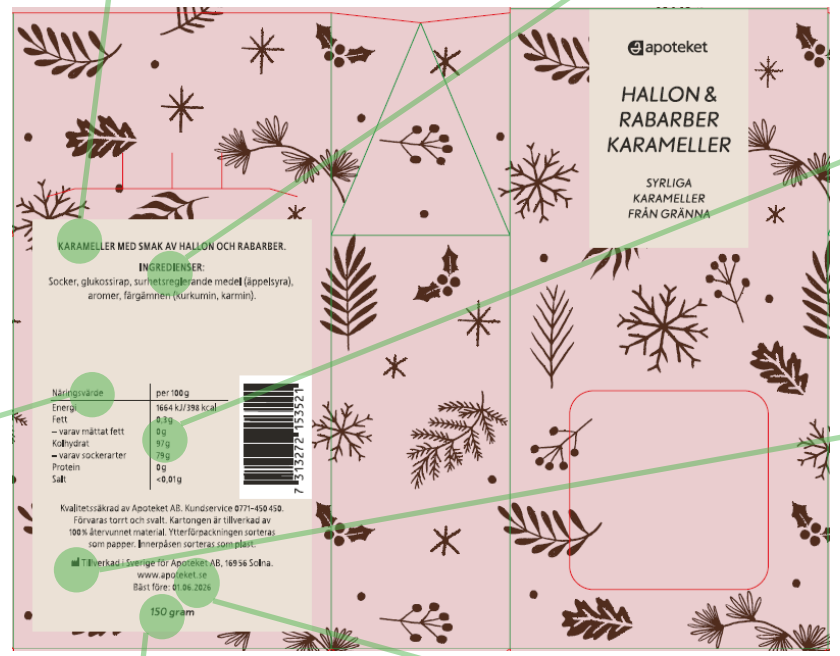
Mandatory nutrient declaration per 100 g or 100 ml.

Requested Documentation
- Artwork (in Swedish)
- EU organic certification for organic products

Main Legislation
- FIC (EU) 1169/2011
- NHCR (EC) 1924/2006
- Food Additives Regulation (EC) 1333/2008
- GFL (EC) 178/2002
- Contaminants Regulation (EU) 2023/915
- Organic Production Regulation (EU) 2018/848

Name of the food

The ingredient list shall have the initial name "Ingredienser" and the ingredients shall be listed in descending order in Swedish.



Name of product, net weight/volume/units

Information about durability and batch information.

Organic products shall have the European Union organic logo

Energy drinks may contain maximum 32 mg caffeine per 100 ml.

Allergen substances must be highlighted in ingredient list, preferably in **bold** text

The mandatory nutrition declaration shall contain information regarding energy content, fat, saturated fat, carbohydrates, sugar, protein (fibre) and salt.

If sweetener is added this must be informed on the same side as name of the food.

Name and adress of the food business operator and if needed country of origin

Illustrations, pictures, words in the presentation of the product that can be interpreted as an unspecific health claim and must follow with a specific health or nutrient claim.

All health and nutrition claims must be approved by the EU. Any unspecific health and nutrition claim must directly be followed by a direct health claim.

If reference intake is given for energy and macronutrients the following explanation must be in close proximity: "Referensintag för en genomsnittlig vuxen (8 400 kJ/2000 kcal)".

Packages shall have a text size of ≥ 1.2 mm, package with a area of less than 80 cm^2 shall have a text size of ≥ 0.9 mm.

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Checklist - Food supplements

Allergen substances must be highlighted in the ingredient list, preferably in **bold** text

No claims that suggests that a well-balanced food intake isn't enough

Health claims that are used are either approved by EU or botanical claims that have been put on hold pending for the Commission and Member States final consideration. The food business operator must be able to provide scientific support for the botanical claims they make. Any unspecific claim must be followed by a direct claim (beauty claims does not follow this rule) . It is not acceptable to rephrase the approved claim from "Substance x contributes to..." to "Product y contributes to...".

The amount of each declared substance and the reference intake must be declared as DRI (Dagligt Referensintag) with an explanation of the abbreviation in the labeling.

Food supplements should not be used as an alternative to well balanced food intake and a healthy lifestyle

Weight/volume/units

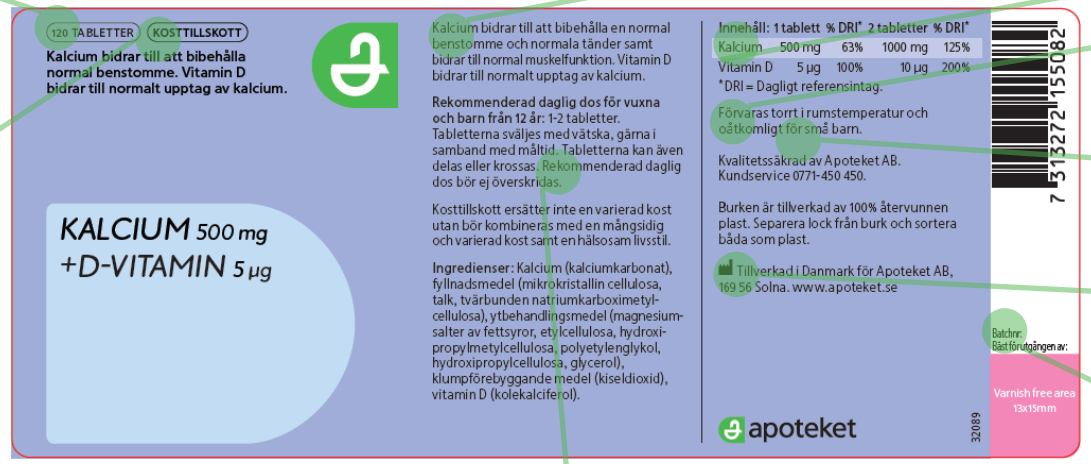
Information about that the product shall be placed without reach from small children

If sweetener is added this must be informed on the same side as "Kosttillskott"

Information about that the product is a food supplement preferably on the front side (kosttillskott)

Information about specific conditions for storage.

Candy form (gummies) that are intended for children or contain substances (e.g. retinol) where a risk of overdose must have a child proof cap.



Name and adress of the food business operator

Information about durability and batch ID

The amount of the nutritional substances shall be given in a numerical values. Vitamins and minerals shall be stated as a percentage of the reference values listed in Annex XIII EU 1169/2011

Requested Documentation
- Artwork (in Swedish)
- EU organic certification for organic products

Main Legislation
- FIC (EU) 1169/2011
- Regulation (EU) 1170/2009
- GFL (EC) 178/2002
- NHCR (EC) 1924/2006
- LIVSFS 2003:9
- Organic Production Regulation (EU) 2018/848

Illustrations, pictures, words in the presentation of the product that can be interpreted as an unspecific health claim and must follow with a specific health or nutrient claim.

Warning about not to exceed the recommended dose

Name of the categories of the nutritional substances or substances that characterize the product

The recommended daily intake of vitamins and minerals must not exceed EFSA's proposed upper level (UL). The exception is magnesium, for which the daily reference intake exceeds the UL.

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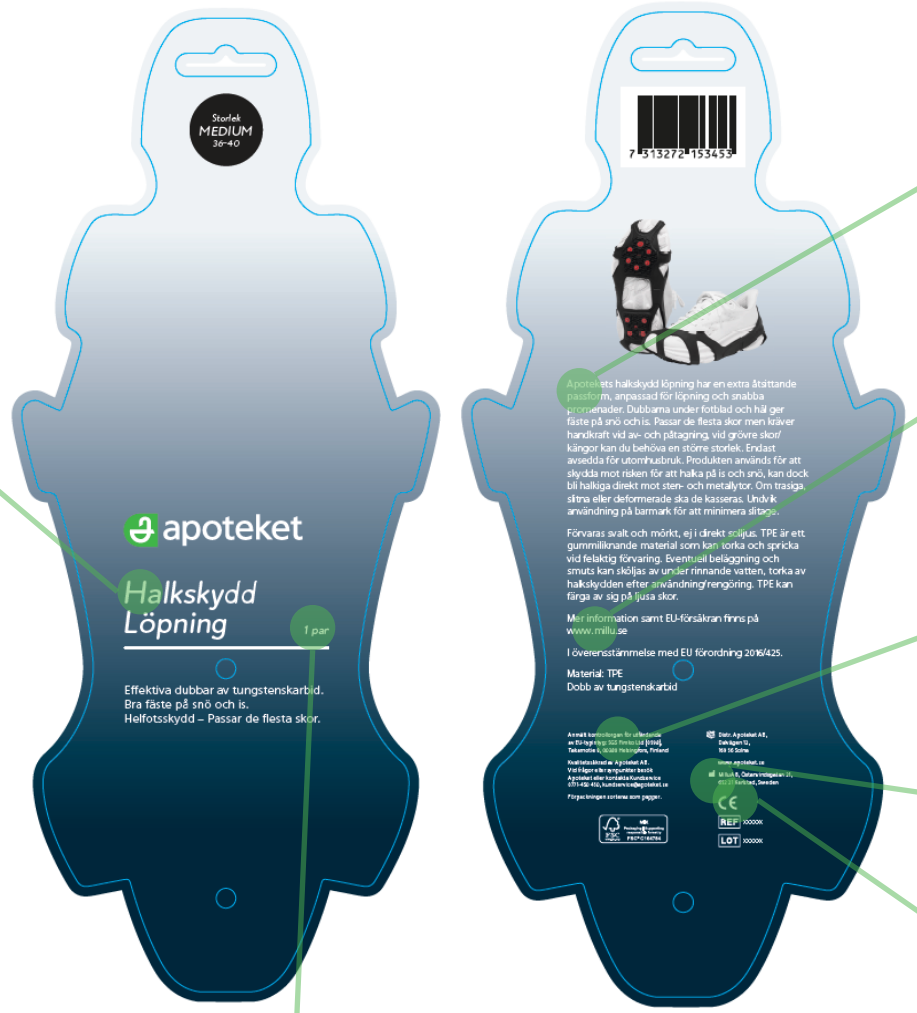
Checklist - Personal Protective Equipment

The text shall be indestructible, easy to read and easy to find.

The intended use (in Swedish)

Requested Documentation
- Artwork (in Swedish)
- EU Declaration of Conformity
- EU Test Type Certificate when applicable

Main Legislation
- PPE Regulation (EU) 2016/425
- Law (2018:125) och
- Regulation (2018:127)
- REACH (EC) 1907/2006
- GPSR (EU) 2023/988



The quantity (weight, volume or number of products) at the time the product was packed.

Instructions and Safety Information in Swedish

The product shall have EU Declaration of Conformity. The internet address where the EU declaration of conformity can be accessed.

For Category II and III:
The name, address and identification number of the notified body or bodies involved in the conformity assessment of the PPE.

Name and address of the manufacturer and when applicable importer and distributor

The product shall be CE marked.

PPE Category III: The NB identification number shall be available next to the CE mark.

Performance data, if applicable.

The product must be tested according to applicable EN or ISO standard.

References to the relevant harmonised standard(s) used, including the date of the standard(s), or references to the other technical specifications used

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Checklist – Toys and Child Use and Care Articles

Information on the product shall preferably be given in Swedish. However, instruction for use, safety information and precautions must be in Swedish

If applicable information how the product shall be stored

A lot symbol and the lot identification

Soothers for babies and young children should comply safety requirements and test methods in EN 1400:2013+A2:2018.
A Declaration of Compliance is mandatory.

Materials and articles that are in contact with food must comply with food contact material legislation EU Regulation 1935/2004
A Declaration of Compliance is mandatory for food contact materials

The manufacturers name, address (incl. Street adress) and electronic address, if applicable the distributors/EC-rep name and adress

Soother holders should comply safety requirements and test methods in EN 12586:2025.
A Declaration of Compliance is mandatory.

Requested Documentation
- Artwork
- Leaflet/Instruction for use (if exists)
- EU Declaration of Conformity (DoC)
- Declaration of Compliance

Drinking equipment (feeding teats) for babies and young children should comply safety requirements and test methods in EN 14350:2020+A1:2023.
A Declaration of Compliance is mandatory.

Main Legislation
- TSD (EC) 2009/48
- TSR (EU) 2025/2509
- FCM Regulation (EC) 1935/2004
- REACH (EC) 1907/2006
- GPSR (EU) 2023/988

Toys shall be CE marked by the manufacturer.
An EU Declaration of Conformity (DoC) is mandatory.

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Checklist - Feminine care

All product the text shall be indestructible, easy to read and easy to find.

Information on the product shall preferably be given in Swedish.
However, information instruction for use, safety information and precautions must be in Swedish

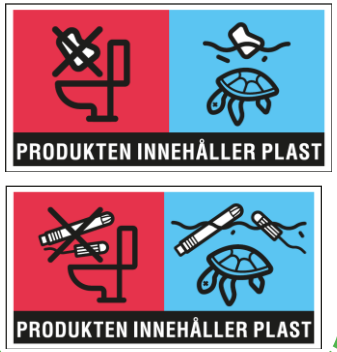
We recommend that the materials comply with EDANA femcare testing guidelines and the EDANA CODEX™ stewardship programme, including performance testing and trace-chemical limits.

Requested Documentation
- Artwork

Main Legislation
- GPSR (EU) 2023/988
- REACH (EC) 2006/1907
- SUP Directive (EU) 2019/904

The quantity (weight, volume or number of items) at the time the product was packed.

For wet wipes, sanitary towels (pads) and tampons and tampon applicators that contain plastic and have a packaging with the surface area of 10 cm2 or more, shall bear the following printed marking. The marking should be placed and sized in accordance with the Regulation (EU) 2020/2151



Name and address of the manufacturer (including electronic address)

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Checklist – Electrical and Electronic Equipment

Product information, e.g.:
- Product function
- Instructions for use
Must be given in Swedish

The manufacturers name and address (incl. Street address).
Importer name and postal address if manufacturer is outside of EU.

The product must carry a type, model, batch, or serial number for identification that links directly to the DoC.

Information how the product shall be stored, and proper disposal of the product must be provided.

Shall be CE marked by the manufacturer.

Where LVD and RED is applicable:
Electrical ratings (voltage, current, power, frequency)
On the product and preferably packaging.

Requested Documentation
- Complete Artwork/Label files for product and packaging including Leaflet/Product description/User manual
- EU Declaration of Conformity (DoC)

Critical warnings must be placed on the product.
Other safety information can be placed on the product or instruction manual.
All warnings and safety information must be provided in Swedish.

Must carry crossed-out wheeled bin (WEEE symbol)

Main Legislation
- GPSR (EU) 2023/988
- REACH (EG) 1907/2006
- LVD (EU) 2014/35
- EMC (EU) 2014/30
- RoHS (EU) 2011/65
- WEEE (EU) 2012/19
- Ecodesign Directive (2009/125/EC) (Pending legislation ESPR (EU) 2024/1781)

Products with batteries:
- Battery Regulation (EU) 2023/1542

Products that intentionally transmit and/or receive radio waves for radiocommunication or radiodetermination:
- Radio Equipment Directive (RED) 2014/53/EU

Battery labelling:
- Crossed-out wheeled bin (WEEE symbol)
- Battery Chemistry
- Capacity information
- Manufacturer name
- Traceability information (e.g. batch, serial number)
- Safety information/warnings (when appliable) in Swedish.
- CE marking for the battery

For integrated batteries (non-accessible):
- Crossed-out wheel bin and CE mark must be on the product.
- Other elements can be placed on the product, on label or documents accompanied by the product.

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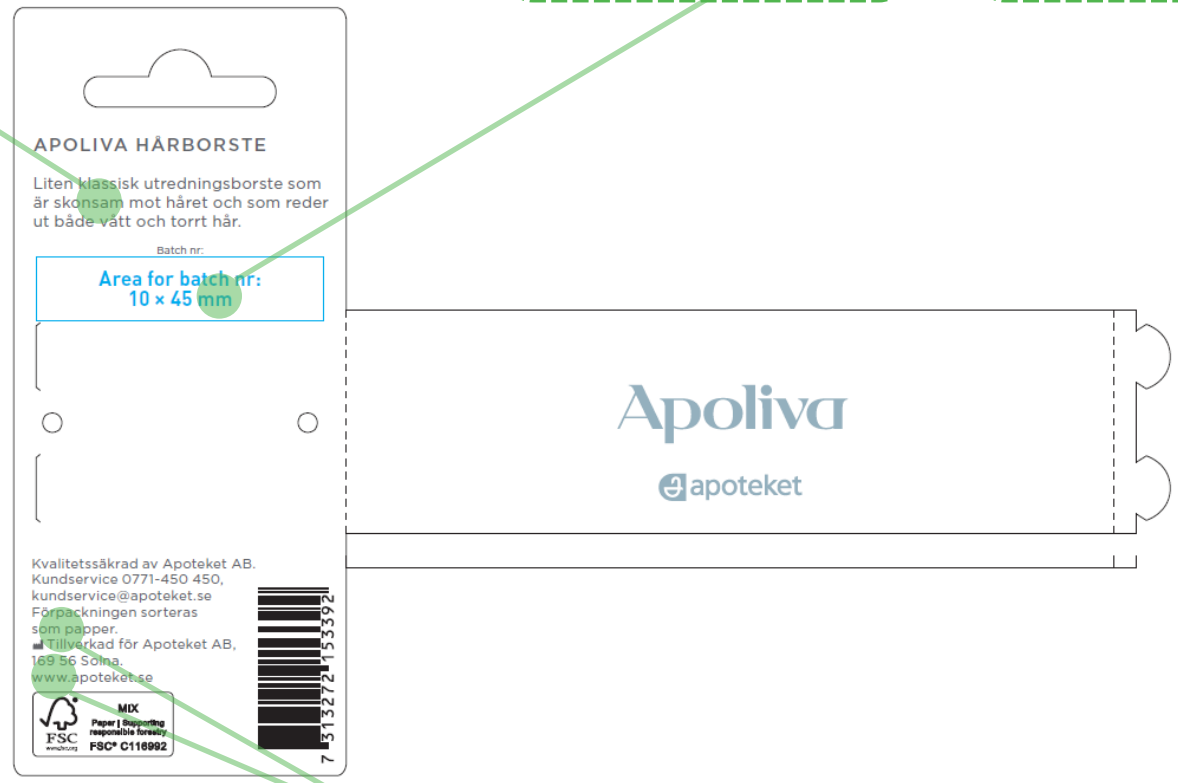
Checklist – Other merchandise

Information on the product shall preferably be given in Swedish. However, instruction for use, safety information and precautions must be in Swedish

Information how the product shall be store, if applicable.

Product must carry batch number/traceability system, or another identifier.
If impossible due to size or shape, it could be placed on packaging or in an accompanying document

Textile products must be labelled according to Regulation (EU) 1007/2011, including correct fiber composition and approved fiber name.



Requested Documentation
- Artwork
- Article 33 of REACH, Suppliers will provide appropriate information to Apoteket if certain products or its packaging contain one or more of these SVHC in a concentration above 0.1% (weight) per article, as soon as we become aware of the fact.
Candidate List of substances of very high concern for Authorisation - ECHA (europa.eu)
- When deemed necessary, proof of compliance with REACH Annex XIV & XVII will be requested. That can include submitting test reports to Apoteket.

Main Legislation
- GPSR (EU) 2023/988
- REACH (EC) 1907/2006

Textile:
- Textile Labelling Regulation (EU) 1007/2011

The manufacturers name, postal address (incl. street address), and electronic address.
If applicable the distributors/EC-rep name and address

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Changes from last version.

- Removed Microplastic Restriction due to legal requirement under REACH.
- New section about production information from Validoo.
- Food - Energy drinks may contain maximum 32 mg caffeine per 100 ml.
- Food supplements -The recommended daily intake of vitamins and minerals must not exceed EFSA's proposed upper level. Food supplements in candy form (gummies) that are intended for children or contain substances (e.g. retinol) where a risk of overdose must have a child proof cap.
- SUP labelling requirements for wet wipes, sheet masks, tampons and sanitary towels which contains plastic.
- Requirements for electrical and electronic equipment have been updated.
- Minor editorial changes.
- Reference to Main Legislation for each product classification is update due to new or updated legislations.

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