Product Approval Criteria

Product approval

- The products are assessed in the context of legality, safety, and trustworthiness.
- The products must meet the requirements in this document.
- **Legal** - The products must be correctly categorized/classified and not contain prohibited substances. Product claims on packaging are reviewed depending on product category. Product claims in the Supplier Portal, which is the basis for product information on www.apoteket.se, are reviewed and violations are pointed.
- **Safe** - The products should have content, function, and user description that is acceptable and does not pose an unacceptable risk in the short or long term. In addition to illegal substances, certain substances/substance groups are not accepted and shall be phased out (se next side)
- **Trustworthy** - The products should be in line with the Pharmacy's vision, values, and positioning.

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Product Criteria Overview

Prerequisites

Apotekets product approval 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.

Requirements and documental support needed is stated in checklists.

The criteria in the product approval is valid for new products, existing products is handled via the phase out plan. If the product(s) contain any substance from ECHA's candidate list this must be communicated to Apoteket, see https://echa.europa.eu/sv/candidate-list-table.

All products must be legal and comply with guidelines set by different trade associations

Phase out

Cyclic siloxanes
Cyclotetrasiloxane (D4), Cyclopentasiloxane (D5), Cyclohexasiloxane (D6), Cyclomethicone (mixture), Polysilicone-11. **Phased out 2015**

Kathon preservatives
Eg. Mefamthylchloroisothiazolinone (MCI), Methylisothiazolinone (MI). **Phased out 2015**

Microplastic & Microbeads
Microbeads is striclty prohibited. Synthetic polymers should preferably be ingredients which are exempted from Regulation (EU) 2023/2055 on Microplastic. e.g., Water soluble polymers. Water soluble polymers are defined as polymers with a water solubility of >2g/L. **Phase out 2024.**.

Formaldehyde releasers
Eg. Diazolidinyl Urea, DMDM Hydantoin Imidazolidinyl Urea, Quaternium-15, Methenamine, Sodium hydroxymethylglycinate etc. **Phased out 2016**

PFAS
PFAS substances are prohibited in any product except pharmaceuticals, supplied to Apoteket AB. The definition of which substances concerned can be found in Annex XVII to Regulation (EC) No 1907/2006. Some examples are perfluorocarboxylic acids with 9-14 carbon atoms in the chain (C9-C14 PFCAs), their salts and C9-C14 PFCA-related substances. As well as Undecafluorohexanoic acid (PFHxA), its salts and PFHxA-related substances (PFHxA-related substances are substances that, based on their molecular structure, are considered to have the potential to degrade or be transformed to PFHxA. **Phased out 2022**

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 sent in 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 the responsibility for Apoteket

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Checklist - Cosmetics

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

The quantity of contents (weight or volume). Content less than 5 g or 5 ml does not need to be stated.

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

Documentation demands
Artwork (pdf format)

Legislation
- EC 1223/2009
- EU No 655/2013
- Recommendation (2006/647/EC) on sunscreen products
- Technical document on cosmetic claims (2017)
- MPAs guidance on proper marketing

When applicable, particular precautions such as warnings and important instructions (e.g., sunscreen texts).

Dangerous goods information (ADR – Avsändare)

List of contents
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

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

The consumer must be able to understand the purpose of the product and how it must be used in a safe way. The text (in Swedish) shall be indestructible, easy to read and easy to find.
List of the parts of the label that must be in Swedish:

- nominal content
- reference to shelf-life
- precautions for use
- function/purpose of the product.

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Checklist - Medical devices

The product shall be CE marked and have the EU declaration of conformaty. Information in text/symbol that the product is a medical device

Information on the product shall be given in Swedish

Dangerous goods information (ADR – Avsändare)

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

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

Documentation demands
Artwork (pdf format)
Declaration of Conformity

Legislation
- LVFS 2003:11
- MDR 2017/745, IVDR 2017/746
- Läkemedelslag (1992:859)

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

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

A leaflet (with date) shall be included (not mandatory for class I, class IIa)

Wherever possible use symbols according to ISO 15223)

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)

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

The quantity of an ingredient or category if ingredients shall be listed near the nutrition declaration if included in the presentation and labeling in words, pictures or graphics.

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.

Name of the food

Documentation demands
Artwork (in Swedish)
EU organic certification and "non GMO" certificate (for organic products)

Legislation
- EG 1169/2011
- EG 1924/2006
- EG 1333/2008
- EG 178/2002
- EG 1881/2006
- EG 2018/84

Name of product, net weight/volume/units

Mandatory nutrient declaration per 100 g or 100 ml.

Information about durability and batch information.

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.

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

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.

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.

Organic products shall have the European Union organic logo

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.

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Checklist - Food supplements

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

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

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

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

Documentation demands
Artwork (in Swedish)
EU organic certification and “non GMO” certificate (for organic products)

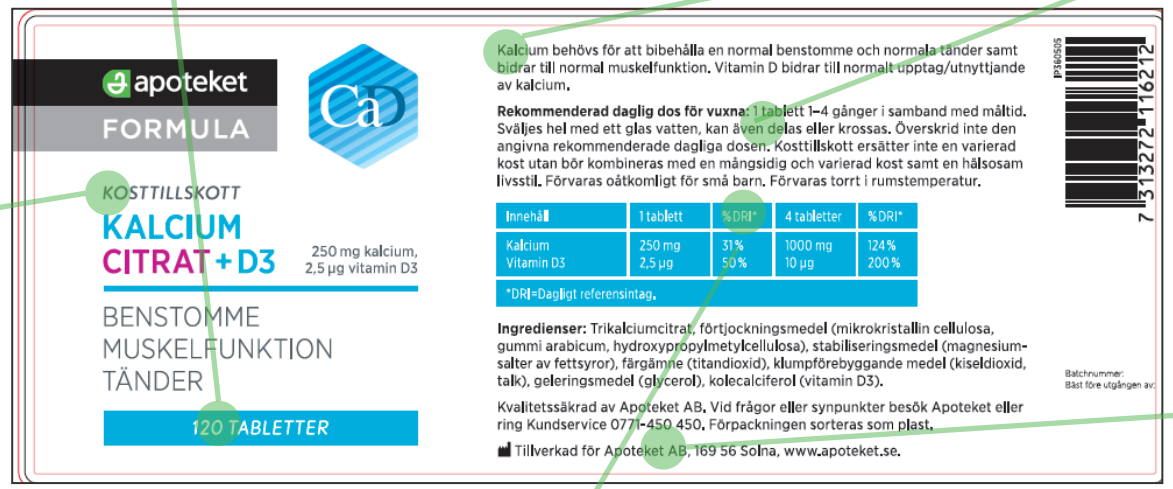
Legislation
- EG 1169/2011
- EG 1170/2009
- EG 178/2002
- EG 1924/2006
- LIVSFS 2003:9
- EG 2018/84

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

Weight/volume/units

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.

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.

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

Information about durability and batch ID

Warning about not to exceed the recommended dose

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

Information about specific conditions for storage.

Information about durability and batch information.

Name and adress of the food business operator

The amount of the nutritional substances shall be given in a numerical values and in the order described in EG 1170/2009

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Checklist - Feminine care

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

The intended use and instructions (in Swedish)

Information about any warnings

The quantity (weight or volume) at the time the product was packed.

Documentation demands
Artwork

Legislation
- 2001/95/EG
- Regulation (EU) 2020/2151

Packaging of wet wipes, sanitary towels (pads) and tampons and tampon applicators, 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

Material specification, Edana compliance

Name and address of the manufacturer

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Checklist - Personal safety

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

The intended use and instructions (in Swedish)

The quantity (weight or volume) at the time the product was packed.

Documentation demands
Artwork (in Swedish)
test type certificate

Legislation
- EU 2016/425
- AFS 1997 07
- EN 352:2
- EN 14683:2019+AC:2019

The product shall be CE marked and have the EU declaration of conformance

Information about any warnings

Test certificate

Performance data

Name and address of the manufacturer

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Checklist - Chemicals

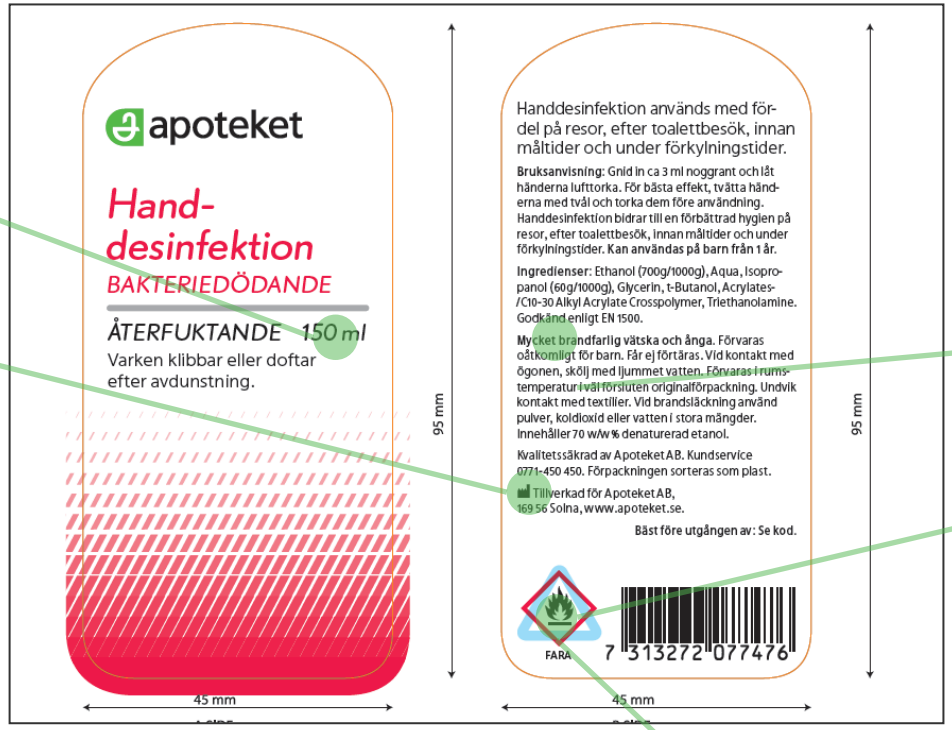
The text shall consist of indelible, easily legible and visible lettering on a contrasting background.

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

Name and address of the manufacturer

Documentation demands
Artwork,
MSDS (in Swedish)

Legislation
- EC 1272/2008 CLP Regulation
- EU 2020/878



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

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

Dangerous goods information (ADR – Avsändare)

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

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Checklist - Biocides

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

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

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

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

Documentation demands
Artwork, MSDS (in Swedish)

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).

Legislation
- BPR - EU 528/2012
- EU 1062/2014
- CLP - EG 1272/2008
- KIFS 2008:3
- EU 2020/878

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.

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

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

Information of specific environmental hazard.

Dangerous goods information (ADR – Avsändare)

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

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).

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

Name and address of the authorization holder.

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Checklist – Child use and care articles

Information on the product shall be given in Swedish

If applicable information how the product shall be stored / handled

A lot symbol and the lot identification

Information about any warnings

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

Documentation demands
Artwork
Leaflet/Product description (if exists)
Declaration of Conformity (DoC)
Declaration of Compliance (DoC)

Legislation
- EU Directive 2009/48 Toys
- EU Regulation 1935/2004
- EN 1400:2013+A2:2018
- EN 14350:2020+A1:2023
- EN 12586:2007+A1:2011

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

Soother holders should comply safety requirements and test methods in EN 12586:2007+A1:2011.
A Declaration of Compliance (DoC) is necessary.

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 (DoC) is necessary.

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

Toys shall be CE marked by the manufacturer.
EC Declaration of Conformity (DoC) is mandatory
Shall have a traceability label, which can be linked to the DoC.

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Checklist – Electronic equipment

Information on the product shall be given in Swedish

Information about any warnings

Information how the product shall be stored / handled

A lot symbol and the lot identification

Shall be CE marked by the manufacturer.
EC Declaration of Conformity (DoC) is mandatory
Shall have a traceability label, which can be linked to the DoC.

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

Documentation demands
Artwork
Leaflet/Product description
Declaration of Conformity (DoC)

Legislation RoHS
- EU Directive 2011/65

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Checklist – Other merchandise

Information on the product shall be given in Swedish

Information about any warnings

Information how the product shall be stored / handled

A lot symbol and the lot identification

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

Documentation demands
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)

Legislation
- REACH 1907/2006
Product requirements
The product must not contain any substances from Annex XIV & XVII

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apoteket	Dokumentnamn Product Approval Criteria		Sidor 12 (12)
Ansvarig enhet Sortiment	Gäller fr.o.m. 2024-09-24	Dokumenttyp Rutin	Informationsklass Öppen	Dokumentnummer, version D-7000, 23.0
Författare, namn, enhet Åsa Knutsson Kvalitet, farmaci och hållbarhet		Namnteckning		Datum
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Changes from last version.
Product approval information added
“Checklist – Suppliers” excluded
PFAS included in phase out. Refined information about microbeads and microplastics.