



## **Product Approval Criteria**

# Product Criteria Overview

## Prerequisites

Apotekets quality control 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 pharmaceutical drugs, 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

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

Methylchloroisothiazolinone (MCI), Methylisothiazolinone (MI). **Phased out 2015**

Microplastics (intentionally added solid particles (<5mm) that are non-soluble in water) in rinse off products. **Phase out 2017.**

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

## Approval

An approval 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

# Checklist - Suppliers

Check that the agreement is signed and uploaded in our supplier portal.

Assess that the stated manufacturer is the true manufacturer

Verify that certificates are valid (date and product type), verify that certificates in high-risk countries are legit.

Certification or audits in several areas lowers the overall risk. Ask for documental evidence if answers are inconclusive.

## Documentation demands

Certificates, own audit plans, third party audits.

## Legislation

- International Human Rights
- UN Guiding Principles on Business and Human Rights (UNGPR, 2011)
- ILO Declaration on Fundamental Principles and Rights at Work
- Local laws and regulations

Manufacturing Country (of physical products)	Minimum Requirements
<p><b>Low risk</b> Andorra, Australia, Austria, Belgium, Canada, Denmark, Estonia, Finland, France, Germany, Iceland, Ireland, Liechtenstein, Luxembourg, Monaco, Netherlands, New Zealand, Norway, Portugal, San Marino, Slovakia, Slovenia, Sweden, Switzerland, United Kingdom</p>	<p>General information such as company reports, information on third party certificates (mandatory information in the supplier portal).</p>
<p><b>Moderate risk</b> Antigua and Barbuda, Barbados, Bhutan, Chile, Costa Rica, Croatia, Cyprus, Czech Republic, Dominica, Grenada, Israel, Italy, Japan, Latvia, Lithuania, Malta, Mauritius, Poland, Saint Kitts and Nevis, Saint Lucia, Saint Vincent and The Grenadines, Samoa, Singapore, South Korea, Spain, Taiwan, Trinidad and Tobago, Tuvalu, United States, Uruguay</p>	<p>Third party audit ex GMP, ISO 9001, 13485, 45000, 22000, BRC etc.</p> <p>Upload certificate.</p>
<p><b>High risk</b> Albania, Algeria, Angola, Argentina, Armenia, Azerbaijan, Bahamas, Bahrain, Bangladesh, Belarus, Belize, Benin, Bolivia, Bosnia and Herzegovina, Botswana, Brazil, Brunei, Bulgaria, Burkina Faso, Burundi, Cabo Verde, Cambodia, Cameroon, Chad, China, Colombia, Comoros, Congo, Côte d'Ivoire, Cuba, Djibouti, Dominican Republic, Ecuador, Egypt, El Salvador, Ethiopia, Fiji, Gabon, Georgia, Ghana, Greece, Guatemala, Guinea, Guinea-Bissau, Guyana, Haiti, Honduras, Hungary, India, Indonesia, Jamaica, Jordan, Kazakhstan, Kenya, Kiribati, Kosovo, Kuwait, Kyrgyzstan, Laos, Lebanon, Lesotho, Liberia, Macedonia, Madagascar, Malawi, Malaysia, Maldives, Mali, Marshall Islands, Mauritania, Mexico, Micronesia, Moldova, Mongolia, Montenegro, Morocco, Mozambique, Namibia, Nauru, Nepal, Nicaragua, Niger, Nigeria, Oman, Palau, Palestinian Occupied Territory, Panama, Papua New Guinea, Paraguay, Peru, Philippines, Qatar, Romania, Russia, Rwanda, Sao Tome and Principe, Saudi Arabia, Senegal, Serbia, Seychelles, Sierra Leone, Solomon Islands, South Africa, Sri Lanka, Suriname, Swaziland, Tajikistan, Tanzania, Thailand, Timor-Leste, Togo, Tonga, Tunisia, Turkey, Uganda, Ukraine, United Arab Emirates, Vanuatu, Vietnam, Zambia, Zimbabwe</p>	<p>Third party audit equivalent to SMETA / BSCI / GOTS / SA8000 / GRI.</p> <p>Minimum level = improvement needed</p>
<p><b>Very high risk</b> Afghanistan, Central African Republic, DR Congo, Equatorial Guinea, Eritrea, Iran, Iraq, Libya, Myanmar, North Korea, Pakistan, Somalia, South Sudan, Sudan, Syria, The Gambia, Turkmenistan, Uzbekistan, Venezuela, Yemen</p>	<p>Annual third-party audit equivalent to SMETA/ BSCI / GOTS / SA8000 / GRI.</p> <p>Minimum level = improvement needed</p>

# 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.

# Checklist - Medical devices

The product shall be CE marked and have the EU declaration of conformance. 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 address), if applicable the distributors/EC-rep name and address

**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

# 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.

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.

**apoteket**

**CASHW MED CHOKLADSMÅK**

**GOTT SOM MELLANMÅL**

- ✓ LÅG SOCKERHALT
- ✓ PROTEINKÄLLA
- ✓ HÖGT FIBERINNEHÅLL

**60 gram**  
Innehåller sötningsmedel.  
Innehåller en källa till fenylalanin.

**Innehåll per 100 g**

Energi	2239 kJ (27%)
	533 kcal (27%)
Fett	40 g
- varav mättat fett	22 g
Kolhydrat	12 g
- varav sockerarter	2,5 g (3%)
Fiber	21 g
Protein	21 g (42%)
Salt	0 g

**Innehåll per 60 g**

Energi	1340 kJ (16%)
	320 kcal (16%)
Fett	24 g
- varav mättat fett	13 g
Kolhydrat	7 g
- varav sockerarter	1,5 g (2%)
Fiber	12 g
Protein	13 g (26%)
Salt	0 g

\*Referensintag för en genomsnittlig vuxen (8400 kJ/2000 kcal).

Bäst före utgången av: \_\_\_\_\_  
Lot nr: \_\_\_\_\_

**Ingredienser:** Cashewnötter, ohärdat vegetabiliskt fett (palmkärnolja, palmoja, sheaolja), fiber (polydextrose), mjölkprotein-koncentrat, fettreducerad kakao (8,5%), skummjölkspulver, emulgeringsmedel (sojalecithin), sötningsmedel (aspartam, acesulfam K), naturliga aromer, ytbehandlingsmedel (akaciagummi, glukos, shellack).

Kan innehålla spår av andra nötter inklusive Jordnöt.

Kvalitetssäkrad av Apoteket AB. Vid frågor eller synpunkter besök Apoteket eller ring Kundservice 0771-450 450.

Förpackningen sorteras som plast.

Tillverkad för Apoteket AB, 169 56 Solna, www.apoteket.se.

Barcode: 7 313272 111620

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  $\geq 1.2$  mm, package with a area of less than 80 cm<sup>2</sup> shall have a text size of  $\geq 0.9$  mm.

Organic products shall have the European Union organic logo

# 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

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..."

Information about durability and batch ID

Warning about not to exceed the recommended dose

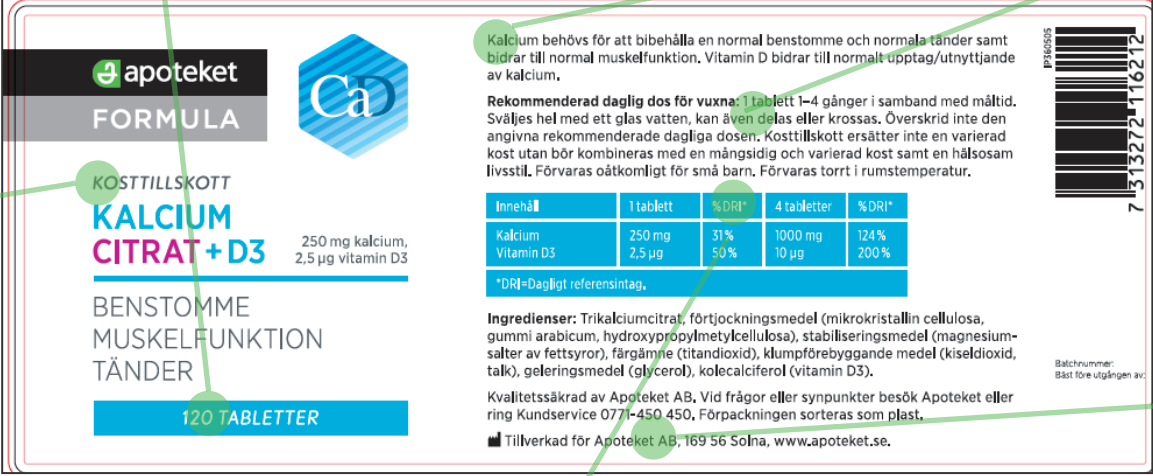
Food supplements should not be used as an alternative to well balanced food intake and a healthy lifestyle

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



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.

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

# 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 cm<sup>2</sup> 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

# 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, test type certificate

## Legislation

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

**ONE SIZE**

**apoteket**

**Öronproppar**

**SKYDDAR EXTRA BRA MOT STÖRANDE LJUD**

5 par

**Extra hög-dämpande**

**Högdämpande öronpropp för de flesta hörselgångar. Utestänger störande ljud vid tex sömn och studier. One size, 6-11 mm. Om hudirritation finns i hörsel-gången, kontakta läkare före användning.**

**Instruktioner**

1. Rulla proppen mellan tummen och pekfingret till en smal cylinder.
2. Ta därefter motsatta händer över huvudet och rita ut hörselgången genom att dra örat uppåt/utåt.
3. Sätt sedan med en lätt vridning in den höra i den smala proppens änden i hörselgången. Den jämde toppen skall vara långsamt i hörselgången.
4. Håll kvar med ett finger på proppen till du känner att den expanderat klart. Rätt insatt skall proppen inte sticka ut ur örat.

Fel insatt propp ger sämre ljuddämning. Kontrollera alltid att proppen dämpar utan läckage. Om inte, prova med annan storlek. För att undvika skador på trumhinnan, dra långsamt och vrid samtidigt lite lätt ut öronproppen ur respektive hörselgång. Använd propparna under hela den tid som du är utsatt för skadligt ljud. Varning! Förvaras oöskligt för små barn. Kvalitetsrisk, föreligger om proppen fastnar i hörförstrupen. När öronpropparna inte används, förvara dem rent och torrt. Om instruktionerna inte följs, kan skyddet och funktionen försämrats avsevärt. Vissa kemikalier kan påverka denna produkt.

Testad och godkänd enligt EN 352-2:2002, INSPEC International Ltd. (Anmäln. organ nr.: 0194.) 56 Leslie Hough Way, Salford, Greater Manchester, M6 6AJ

**Dämpdata**

Frekvens Hz	63	125	250	500	1000	2000	4000	8000
Medelvärde dB	27,2	30,4	33,5	37,4	37,6	35,4	46,8	48,1
Standardavvikelse dB	5,1	5,5	7,5	7,4	7,1	3,9	4,0	4,8
Förväntad skyddseffekt dB (APV)	22,1	24,9	26,0	30,0	30,5	31,5	42,1	39,3

H: 34dB M: 31dB L: 28dB SNR: 34dB

Kvalitetssäkrad av Apoteket AB. Vänd dig till oss om du inte är nöjd med produkten. Har du frågor eller synpunkter besök Apoteket närmast dig (se [www.apoteket.se](http://www.apoteket.se)) eller ring Kundenservice 0771-450 450. Propparna och förpackningen sorteras som plast.

BC 4238-675

7 313272 071993

CE EN 352 Tillverkad för Apoteket AB 118 81 Stockholm.

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

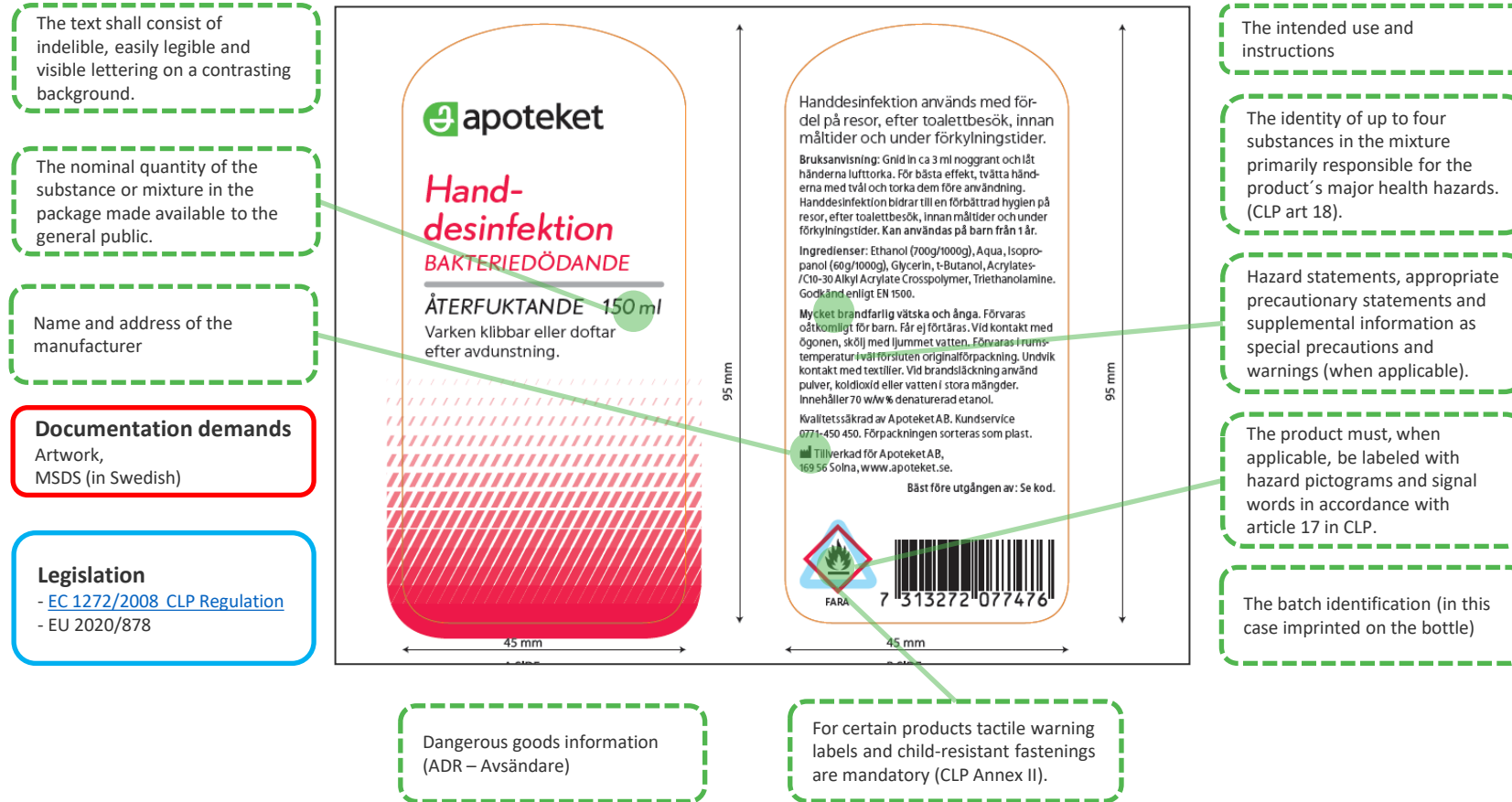
Information about any warnings

Test certificate

Performance data

Name and address of the manufacturer

# Checklist - Chemicals



# 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



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 tillåts" (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.

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.

# 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 address), if applicable the distributors/EC-rep name and address

## 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.

# 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



# 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



 apoteket		Dokumentnamn Product Approval Criteria		Sidor 12 (12)
Ansvarig enhet Sortiment	Gäller fr.o.m. 2023-11-02	Dokumenttyp Rutin	Informationsklass Öppen	Dokumentnummer, version D-7000, 22.0
Författare, namn, enhet Åsa Knutsson, Kvalitet & Farmaci		Namnteckning		Datum
Godkänd och granskad av, namn, enhet		Namnteckning		Datum
Fastställd av, namn, enhet Louise Skalin, Kvalitet & Farmaci		Namnteckning		Datum

*Changes from last version.*