

*The text the Swedish Chemicals Agency reproduces here is a translation of the Swedish text contained in the Code of Statutes of the Swedish Chemicals Agency, KIFS 2008:2, last amended by KIFS 2012:3. References to EU legislation are given in footnote 1 to the Swedish KIFS regulations. [In any matters of dispute, the Swedish text only shall apply.] – August 2012.*

## **The Swedish Chemicals Agency's Chemical Products and Biotechnical Organisms Regulations (KIFS 2008:2)**

issued on 14 May 2008.

Under the provisions of Sections 18-19 of the Chemical Products and Biotechnical Organisms Ordinance (2008:245), Chapter 2, Section 3 of the Ordinance (2002:1086) on Releasing of Genetically Modified Organisms into the Environment, Sections 4, 4c, 7, 11, 11 c, 14 and 21 of the Chemical Products (Handling, Import and Export Prohibitions) Ordinance (1998:944), Chapter 5, Section 1 of the Ordinance (1998:940) on Fees on Testing and Supervision According to the Environmental Code, and Sections 11 and 14 of the Chemical Charges Etc. Ordinance (1998:942), the Swedish Chemicals Agency prescribes the following.

### ***Chapter 1. Overarching provisions***

#### **Area of application**

**Section 1** The provisions in these Regulations apply over and above rules issued within the European Union. When special requirements apply to the Swedish market, this is specifically indicated, for example that the labelling shall be in Swedish for products which are placed on the Swedish market.

Provisions on classification and labelling are contained in the Swedish Chemicals Agency's Regulations on the Classification and Labelling of Chemical Products (KIFS 2005:7) and in the Regulation of the European Parliament and of the Council (EC) No 1272/2008 of 16 December 2008 on the Classification, Labelling and Packaging of Substances and Mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. (KIFS 2009:2).

#### **Definitions**

**Section 2** Terms and concepts used in the Environmental Code and in the Chemical and Biotechnical Organisms Ordinance (2008:245) have the same meaning in these Regulations.

**Section 3** Terms and concepts used in the Swedish Chemicals Agency's Regulations on the Classification and Labelling of Chemical Products (KIFS 2005:7) have the same meaning in these Regulations.

In these Regulations, CAS no refers to the registration number assigned by Chemical Abstract Services (CAS), Columbus, Ohio.

## **Chapter 2. Packaging and storage of hazardous chemical products**

**Section 1** Sections 16 and 19-21 of the Chemical Products and Biotechnical Organisms Ordinance (2008:245) contain provisions on packaging for hazardous chemical products. These provisions in the Ordinance are applied subject to the limitations stated in the second to fourth paragraphs.

The provisions apply in professional activity when chemical products are placed on the market.

The provisions do not apply to preparations in the form of alloys and preparations which consist of polymers or elastomers, even if they are classified as hazardous. This applies provided they do not constitute any physico-chemical risk or any risk to health or the environment in the form in which they are placed on the market.

The provisions do not apply in respect of explosive goods which are placed on the market and which are intended to bring about explosive or pyrotechnic effects, even if they are classified as hazardous. The meaning of the term explosive is defined in Section 8 of the Inflammable and Explosive Goods Ordinance (1988:1145). (*KIFS 2010:4*).

**Section 1 a** If the product is classified according to Regulation (EC) No 1272/2008, the provisions in Title IV, Article 35 of the Regulation shall apply with respect to packaging, instead of the provisions in Sections 2-6 below. (*KIFS 2009:2*).

**Section 2** The provisions on storage in Sections 7-9 apply to all handling of chemicals hazardous to health and the environment in professional activity. (*KIFS 2010:4*).

### **Packaging**

**Section 3** Packaging which fulfils the requirements applicable in the transporting of hazardous materials by rail, road, inland waterway, sea or air shall also be deemed to fulfil the requirements of Section 19 of the Chemical Products and Biotechnical Organisms Ordinance (2008:245).

The requirement in Section 19(1) of Ordinance (2008:245) does not apply if special safety devices are stipulated. (*KIFS 2010:4*)

### **Child-resistant fastenings and tactile warning label**

**Section 4** Sections 20-21 of Ordinance (2008:245) specify which containers shall be provided with a child-resistant fastening and a tactile warning label.

Child-resistant fastening and tactile warning labels are not required if satisfactory measures have been taken to ensure that the products will not be offered or sold to the general public. (*KIFS 2010:4*.)

**Section 5** Child-resistant fastenings for reclosable containers shall fulfil the requirements of Swedish standard SS-EN ISO 8317:2004, edition 1.

Child-resistant fastenings for non-reclosable containers shall fulfil the requirements of Swedish standard SS-EN ISO 862, edition 3.

Certificates of compliance with the above mentioned standards are only accepted if they are issued by laboratories which fulfil the requirements of standard ISO/IEC 17025 and have relevant competence. If it is evident that a packaging is sufficiently safe for children, as they cannot access the contents without the aid of tools, tests do not need to be performed. In all other cases and when there is reason to doubt that the closure is safe for children, the Swedish Chemicals Agency may require that whosoever is responsible for placing the product on the market shall provide such a certificate. It shall be apparent from the certificate either

- that the fastening is of such a type that it does not need to be tested in relation to the above-mentioned standards, or
- that the closure has been tested and found to fulfil the requirements of the standards referred to above. (*KIFS 2010:4*).

**Section 6** Tactile warning labels shall fulfil the requirements of Swedish standard SS-EN ISO 11 683, edition 1. (*KIFS 2010:4*).

## **Storage**

**Section 7** Chemical products hazardous to human health or the environment shall be stored in such a way that health and environmental risks are prevented.

**Section 8** Chemical products hazardous to human health shall be stored in such a way that they are out of reach of small children and well separated from products which are intended for consumption.

**Section 9** Chemical products for which a permit requirement applies in accordance with the provisions of Sections 7-14 of the Chemical Products and Biotechnical Organisms Ordinance (2008:245), shall be stored out of reach of unauthorised persons.

## **Labelling of detergents**

**Section 10** Particulars that have to be indicated on the packaging according to Articles 11.3 and 11.4 of Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents shall be written in Swedish.

## ***Chapter 3. Reports to the Products Register***

### **Who is to notify**

**Section 1** Sections 3–6 of the Chemical Products and Biotechnical Organisms Ordinance (2008:245) contain provisions concerning the obligation of manufacturers and importers of chemical products and biotechnical organisms to Sweden to notify the Products Register. The obligation is applicable to importation from countries within the EU as well as from countries outside the EU. Whoever professionally manufactures or imports chemical products as may be assigned to any of the product categories specified in the Appendix to the Ordinance shall report his operations to the Products Register.

The obligation to notify the Products Register also applies to whoever, in his own name, packs, repacks or changes the name of a chemical product or a biotechnical organism, without having manufactured or imported the product or the organism to Sweden.

### **What is to be notified**

**Section 2** A notifiable chemical product is characterised by:

1. the product name, e.g. trade name, product name or product designation;
2. components included;
3. content of each component.

Products differing in any of these respects shall be notified separately unless the difference is due to unintentional variations between different production batches.

In accordance with Annex 1, certain products may be notified under a common designation.

Whoever manufactures or imports several products with different product names, but with the same function and chemical composition, may notify these under a common designation.

All product names intended to be used on the Swedish market shall, however, be accounted for in the notification.

Products manufactured or imported for an explicit testing purpose in quantities smaller than 1,000 kg need not be notified unless they are supplied to more than a small number of users.

The obligation to notify the Products Register does not apply to chemical products and biotechnical organisms falling under the Medical Products Act (1992:859), the Food Act (2006:804) or the Feeding Stuffs and Animal By-products Act (2006:805). Nor does this obligation apply to cosmetic and hygienic products intended for end-users falling under the Cosmetic and Hygienic Products Ordinance (1993:1283). (*KIFS 2009:2*)

## **When is notification to be submitted?**

**Section 3** A notification of operations, containing the information referred to in Section 4, points 1 and 2, shall be submitted as soon as possible and not later than when the operation starts.

For notifiable products, the information referred to in Section 4, points 3–16 shall be submitted not later than on 28 February of the calendar year after the product became notifiable. (*KIFS 2009:2*)

## **Information in the notification**

**Section 4** The notification shall contain:

1. the name of the person obliged to notify or the company name, including the national registration or organisation number;
  2. the address and telephone number of the person obliged to notify;
  3. the product name and, where applicable, common designation;
  4. the statistical number of the product. This consists of the first six digits of the Combined Nomenclature (CN) under Council Regulation (EEC) No 2658/87 of 23 July 1987 on (customs and statistical nomenclature and the common customs tariff);
  5. a statement on whether the person obliged to notify is a manufacturer or importer of the product from the common market or from a third country;
  6. whether the product has been given a new trade name, a new product name or a new product designation;
  7. whether the person obliged to notify is a commercial agent who has obtained the permission of the Swedish Chemicals Agency to fulfil the obligation to notify instead of an importer;
  8. whether the product is intended to be available to consumers for their private use;
  9. for products under customs tariff numbers 28 and 29 in the Appendix to the Chemical Products and Biotechnical Organisms Ordinance (2008:245) that are used as a starting product in manufacture: estimated percentage distribution of the use of the product between various business sectors, not more than three. For other products: information on primary use. In addition, for products exported by the person obliged to notify: information on the approximate percentage of exports;
  10. function;
  11. information on classification, specifying either the hazard code and the product's risk phrase(s) under the Swedish Chemicals Agency's Classification and Labelling Regulations (2005:7) or information on the product's hazard class, hazard category and indication of danger according to Regulation (EC) No 1272/2008.
  12. information on product name and concentration of all included components, such as:
    - a) have been classified according to the Swedish Chemical Agency's Regulations (KIFS 2005:7) in one or more of the hazard classes
      - carcinogenic category 1 or 2,
      - mutagenic category 1 or 2,
      - toxic to reproduction category 1 or 2
      - allergenic, or
    - b) have been classified according to Regulation (EC) No 1272/2008 in one or more of the hazard classes
      - carcinogenic category 1A or 1B,
      - germ cell mutagenic category 1A or 1B,
      - toxic for reproduction category 1A or 1B
      - skin or respiratory sensitisation category 1.
- Other substances that are hazardous to human health or the environment and the concentration of each such substance shall be stated if the substance is included in a product in a concentration that requires a statement in a Safety Data Sheet according to Annex II, Heading 3 of Regulation (EC) No 1907/2006 (REACH).
- Any other name of substances and concentrations of each such substance shall be stated if the concentration amounts to more than five per cent by weight of the product.
13. for products under customs tariff numbers 22, 28 and 29 in the Appendix to the Chemical Products and Biotechnical Organisms Ordinance (2008:245): information on the chemical

composition of the rest of the product and on any impurities amounting to at least one per cent of the product's weight;

14. in the case of certain paints and varnishes as well as vehicle refinishing products as defined in Directive 2004/42/EC containing volatile organic compounds (VOC), information on the sub-category to which the substance belongs and the concentration of volatile organic compounds in g/l in the form the product is in when it is ready for use.

15. information on which substances in the product are preservatives for the same, and the concentration of every such substance. If the preservative has been notified, its trade name may be used.

16. for such chemical products where the notifier has stated the function as being a biocidal or odour agent: information on which substance or substances constitute an active ingredient.

Names of substances shall be given with an unambiguous chemical name. The unambiguous chemical name is the "preferred name" according to CAS or IUPAC nomenclature, chemically unequivocal synonyms according to the IUPAC nomenclature and generally accepted substance names, known as ISO names or trivial names. CAS numbers and EC numbers may also be used. (*KIFS 2009:2*).

**Section 4 a** Concentrations referred to in points 12 or 15 within the interval 0–1% shall be stated as accurately as possible. Otherwise, figures for concentrations may be rounded up to the nearest whole percent. If the composition of the product varies, the concentration may be stated with the interval defining the limits of variation in whole percent. For paint and lacquer products, it is sufficient to specify the interval within which the concentration lies. Accordingly, permitted intervals are 0–1%, freely chosen 5% intervals within the 1-10% range and otherwise freely chosen 10% intervals. (*KIFS 2009:2*).

**Section 5** The report shall be submitted on the form provided by the Swedish Chemicals Agency or in another way agreed upon.

**Section 6** The Swedish Chemicals Agency assigns notification numbers to the registered products.

### **Change of address**

**Section 7** The person obliged to notify shall, as soon as possible, notify the Agency of any change of address and telephone number.

### **Information on quantity**

**Section 8** Supplementary information shall be submitted not later than 28 February each year. This should include:

1. product name, report number or common designation;
2. data on the quantity manufactured or imported during the immediately preceding calendar year;
3. changes in information submitted previously.

Figures for quantities may be rounded up, in the interval 0.1–9.9 tonnes to the nearest tenth of a tonne, in the interval 10–999 to the nearest whole tonne, and for concentrations above to the nearest 10-tonne figure.

### **Respite**

**Section 9** A person obliged to notify who, through no fault of his own, is prevented from submitting information in time may, after a written application, be granted a respite by the Swedish Chemicals Agency. This respite is not defined as a period exceeding one month unless particular reasons exist.

## Permission to a commercial agent

**Section 10** A commercial agent may receive such permission as referred to in the second paragraph of Section 16 point 3 of the Chemical Products and Biotechnical Organisms Ordinance (2008:245), after written application to the Swedish Chemicals Agency. A copy of the current registration certificate for the applicant should be enclosed with the application or equivalent information for companies registered outside Sweden. The application shall be signed by a person authorised to sign for the company, or by the person designated by the authorised signatory.

Permission for a particular calendar year is granted only if the application has been received by the Swedish Chemicals Agency not later than 1 November in the same year or, for operations commenced subsequently, before the end of the calendar year.

## Chapter 4. Permit requirements

### Products deemed particularly hazardous

**Section 1** *Particularly hazardous chemical products* are such products considered

- a) when, in accordance with the Swedish Chemicals Agency's Classification and Labelling Regulations (KIFS 2005:7), are classified
  - as *Very toxic* and are to be labelled with the symbol Skull and Cross-bones and the indication of danger Very toxic
  - as *Toxic* and are to be labelled with the symbol Skull and Cross-bones and the indication of danger Toxic,
  - in one of the categories of danger *Carcinogenic*, *Mutagenic* or *Toxic to Reproduction* and are to be labelled with the symbol Skull and Cross-bones, or
  - as *Corrosive* and are to be labelled with the indication of danger Corrosive and the risk phrase Causes severe burns.
- b) when classified and labelled in accordance with Regulation (EC) No 1272/2008 belong to
  - the hazard class *Acute toxicity* in hazard categories 1, 2 and 3 and are to be labelled with the hazard pictogram Skull and Cross bones (GHS06) and the signal word Danger,
  - any of the hazard classes *Carcinogenicity*, *Germ cell mutagenicity* or *Reproductive toxicity* in hazard category 1A or 1B and to be labelled with the hazard pictogram Health hazard (GHS08) and the signal word Danger, or
  - the hazard class *Skin Corrosion* in hazard category 1A and to be labelled with the hazard pictogram Corrosion (GHS05) and the signal word Danger.
  - one of the hazard classes *Specific target organ toxicity – single exposure* or *Specific target organ toxicity – repeated exposure* in hazard category 1 and to be labelled with the hazard pictogram Health hazard (GHS08) and the signal word Danger. (KIFS 2012:2)

### Exemptions

**Section 2** The provisions of Sections 7 and 9-14 of the Chemical Products and Biotechnical Organisms Ordinance (2008:245) shall not apply to sodium hydroxide, potassium hydroxide, chromates, coal tar, explosives, fluxing agents, artists' colours in paste form, diesel fuel oils, fuel oils or ammonium gas intended as coolants in cooling systems for pleasure boats. Nor shall the provisions apply to fuels intended for motor drive.

In the case of methanol products, the exemption in the second sentence of the first paragraph does not apply to professional transfer under Section 7, point 2 of the Chemical Products and Biotechnical Organisms Ordinance (2008:245). Methanol products may be acquired and handled in other respects without a permit of the kind referred to in Section 7, point 1 of the Ordinance.

With regard to such methanol products as require a permit under Section 7, first paragraph, point 2 of the Chemical Products and Biotechnical Organisms Ordinance (2008:245), special provisions are contained in Section 11 of the Swedish Chemicals Agency's Regulations on the Classification and Labelling of Chemical Products (KIFS 2005:7). (KIFS 2012:3).

## **Duty of recording**

**Section 3** Anyone professionally supplying particularly hazardous or very hazardous chemical products shall record particulars concerning:

1. the date of sale;
2. the name and quantity of the product;
3. the name and address of the purchaser or his business;
4. whether the product has been supplied for professional handling or for such handling (private use) as requires permission under Section 7, point 1 of the Chemical Products and Biotechnical Organisms Ordinance (2008:245). In the latter case, a note shall be made of the manner in which the purchaser has shown his authorisation.

**Section 4** Records need not be kept regarding the supply of

1. chemical products exempted under Section 2, first paragraph;
2. chemical products which cause severe burns and which are regarded as very hazardous products solely on account of their corrosive properties and supplied for professional handling.

**Section 5** The particulars referred to in Section 3 shall be entered in a special book or kept together in some other way so that they can easily be inspected.

**Section 6** The particulars shall be kept for at least three years.

## **Chapter 5. Particular provisions on certain chemical products and articles**

**Section 1.** *Has ceased to apply (KIFS 2009:6).*

**Section 2** *Has ceased to apply (KIFS 2009:6).*

**Section 3** *Has ceased to apply (KIFS 2009:6).*

**Section 4** *Has ceased to apply (KIFS 2009:6).*

**Section 5** *Has ceased to apply (KIFS 2009:6).*

### **Certain chlorinated solvents**

#### *Scope of the prohibition concerning methylene chloride*

**Section 6** It follows from the third paragraph of Section 5 and the second paragraph of Section 6 of the Chemical Products (Handling, Import and Export Prohibitions) Ordinance (1998:944) that the prohibitions on handling methylene chloride in these sections do not apply to such paint strippers containing methylene chloride as are regulated by Entry 59 Annex XVII to Regulation (EC) No 1907/2006 of 18 December 2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). The designation dichloromethane is used instead of methylene chloride in the EC Regulation.

The exemptions from the prohibitions contained in Ordinance (1998:944) apply irrespective of the concentration in which methylene chloride is present in the paint stripper. (*KIFS 2010:7*).

**Section 7** In derogation of the prohibition in Section 6 of the Chemical Products (Handling, Import and Export Prohibitions) Ordinance (1998:944), chemical products consisting wholly or partly of methylene chloride or trichloroethylene are allowed for professional use for research and development and in analytical work.

**Section 8** According to the provisions in Section 7 of the Chemical Products (Handling, Import and Export Prohibitions) Ordinance (1998:944), the Swedish Chemicals Agency may in the individual case grant exemption from the prohibition if there are exceptional reasons for doing so.

Normally, exceptional reasons are considered to exist if a company applying for exemption to use a solvent can verify that:

1. the company continually investigates possible alternatives;
2. a usable alternative to satisfy the need of the undertaking has not yet become available, and
3. the use by the undertaking does not entail unacceptable exposure.

#### *Fees*

**Section 9** An applicant for an exemption shall pay an application fee of 2,500 SEK to the Swedish Chemicals Agency. The application fee is payable when the application is made.

The Swedish Chemicals Agency may reduce or waive the application fee if there are particular reasons for doing so.

#### *Products may be sold for allowed uses*

**Section 10** Chemical products consisting wholly or partly of methylene chloride or trichloroethylene, notwithstanding the prohibition in Section 6 of the Chemical Products (Handling, Import and Export Prohibitions) Ordinance, may be supplied for such professional use as is allowed under Section 7 in this Chapter or pursuant to a decision made by the Swedish Chemicals Agency in the individual case.

### **Volatile organic compounds in paints and varnishes and vehicle refinishing products**

**Section 11** In Sections 12-15

a) *volatile organic compound* (VOC) means any organic compound having an initial boiling point less than or equal to 250°C measured at a standard pressure of 101.3 kPa

b) *content of volatile organic compounds* (VOC content) means the quantity of volatile organic compounds, expressed in g/l, in the formulation of the product in the form it is in when it is ready for use. The mass of volatile organic compounds in a given product which react chemically during drying to form part of the coating shall not be considered part of the VOC content.

c) *organic solvent* means any volatile organic compound which is used alone or in combination with other agents to dissolve or dilute raw materials, products, or waste materials, or is used as a cleaning agent to dissolve contaminants, or as a dispersion medium, or as a viscosity adjuster, or as a surface tension adjuster, or as a plasticiser, or as a preservative

d) *coating* means any preparation, including all the organic solvents or preparations containing organic solvents necessary for its proper application, which is used to provide a film with decorative, protective or other functional effect on a surface

e) *film* means a continuous layer resulting from the application of one or more coats to a substrate.

**Section 12** The paints and varnishes and vehicle refinishing products which are listed in Annex 2, part 1. may only be placed on the market if they have a content of volatile organic compounds which does not exceed the limit values stated in Annex 2, part 2.

In cases where solvents or components which contain solvents must be added for the products to be ready for use, the limit values in Annex 2, part 2 shall be applied to the content of volatile organic compounds in the form the product is in when it is ready for use.

The analytical methods stated in Annex 2, part 3 shall be used to establish compliance with the limit values in Annex 2, part 2.

**Section 13** The paints and varnishes and vehicle refinishing products listed in Annex 2, part 1 may only be placed on the market if they are labelled with

1. the subcategory of the product and the applicable limit value for volatile organic compounds in g/l in accordance with Annex 2, part 2 and
2. the maximum content of volatile organic compounds, expressed in g/l, in the form the product is in when it is ready for use.

**Section 14** The requirements of Sections 12 and 13 do not apply to paints and varnishes and vehicle refinishing products which are placed on the market to be used solely in activities which are covered by the Swedish Environmental Protection Agency's Regulations (NFS 2001:11) limiting emissions of volatile organic compounds caused by the use of organic solvents in certain activities and installations and which are covered by an obligation to obtain a permit or to provide notification in accordance with the Ordinance concerning Environmentally Hazardous Activities and Protection of Public Health (1998:899). (*KIFS 2009:2*).

**Section 15** The Swedish Chemicals Agency may in an individual case grant dispensation from the requirements of Section 12 in respect of very limited quantities of paints and varnishes and vehicle refinishing products for the restoration and maintenance of buildings and veteran vehicles which have been deemed to be of particular historical and cultural value.

### **1,4-Dichlorobenzene**

**Section 16** Chemical products which contain 1,4-dichlorobenzene (para-dichlorobenzene) and which are intended to disguise odours may not be professionally marketed, supplied or used.

### **Mercury and Mercury-Containing Products**

#### *Exempted products*

**Section 17** In derogation of the prohibitions in Section 9 of the Chemical Products (Handling, Import and Export Prohibitions) Ordinance (1998:944), mercury and articles containing mercury may be placed on the Swedish market or used in accordance with what follows from Annex 4.

The prohibition in Section 9 of the Ordinance does not apply to the following articles intended for sale to the general public

- a) measuring instruments more than 50 years old on 3 October 2007, or
- b) barometers not falling within a) up to and including 3 October 2009. (*KIFS 2009:2*).

**Section 18** Anyone who professionally imports, exports, manufactures, sells or uses mercury or articles containing mercury in accordance with what follows from Annex 4, shall record the following:

1. date of import or export, manufacture or sale,
2. when used, the date of mercury use,
3. number of entities,
4. amount of mercury,
5. area of use, and
6. if the entities have been sold, name and address of the buyer or, if the entities have not been sold, information on what happened to them.

The obligation to record notes according to this Section does not apply to nursing staff, who are covered by Sections 18 b-c. (*KIFS 2009:2*).

**Section 18 a** Particulars recorded in accordance with Section 17 shall on request be submitted to the Swedish Chemicals Agency. (*KIFS 2009:2*).

**Section 18 b** Nursing staff may use dental amalgam under the conditions given in Annex 4, point 10.

When such treatment is considered by a nursing team, this activity shall be notified to the National Board of Health and Welfare before the first treatment of a patient. Subsequent treatment of other patients at the same clinic need not be notified again. (*KIFS 2009:2*).

**Section 18 c** When dental amalgam is used, the nursing staff are responsible for the attending dentist recording for each patient the following:

1. Patient data (social security number and current address).
2. Dental status and proposed treatment (document diagnosis/condition).

3. It there are particular medical reasons.
4. The amount of amalgam used.
5. Date of use.

The nursing staff shall for control and follow-up reasons keep information available on how many and which patients have been treated with dental amalgam in the treatment activity. (KIFS 2009:2).

### **Formaldehyde in Wood-based Boards**

#### *Area of application*

**Section 19** The provisions in Sections 20-25 apply to wood-based boards (particle boards, plywood, wood-fibre boards, block board and similar wood-based boards) containing additives with formaldehyde as an ingredient.

The provisions shall not apply to phenol-glued boards, where the added formaldehyde occurs only as a co-polymer with phenol.

#### *Quality assurance for production and import*

**Section 20** Anyone who manufactures or imports to Sweden wood-based boards must ensure that the untreated boards do not give off more formaldehyde than

1. 0.124 mg/m<sup>3</sup> of air when tested according to Swedish Standard SSEN 717-1:2004, or
2. that which can definitely be ensured not to exceed this emission limit value in an equivalent harmonised standard for emission testing on wood-based boards.

The testing shall be performed by a laboratory that is accredited for the task by SWEDAC under the Technical Control Act (1992:1119) or by a laboratory in another country within the European Union, the European Economic Area (EEA) or Turkey, if the laboratory

1. Is accredited for the task according to the requirements of Swedish Standard SS- EN ISO/IEC17025:2005 by a certification body which fulfils and applies the requirements of SS-EN ISO/IEC 17011:2005, or
2. In some other way offers equivalent guarantees in terms of technical and professional competence and assurance of independence.

Wood-based board labelled CE in accordance with Class E1 shall be considered to fulfil the requirements of the first paragraph. (KIFS 2008:6).

**Section 21** Has ceased to apply. (KIFS 2008:6).

#### *Other quality assurance*

**Section 22** Whoever professionally markets wood-based boards, shall ensure that the boards fulfil the requirements in these Regulations and, on request, give evidence of their so doing.

**Section 23** Whoever professionally manufactures, imports or markets interior fixtures or similar fittings made of wood-based boards, shall ensure that the boards fulfil the requirements in these Regulations and, on request, be able to demonstrate that they do so. (KIFS 2008:6).

#### *Prohibition of sale etc.*

**Section 24** Boards not fulfilling the requirements of Section 20 may not be marketed, supplied or used professionally.

#### *Other testing methods*

**Section 25** For in-house inspection and supervisory inspection such testing methods as correlate satisfactorily with the method referred to in Section 20 may be applied.

### *Exemptions*

**Section 26** The Swedish Chemicals Agency may grant exemption from the provisions of Sections 20–25 if there are particular reasons for doing so.

### **Preservative-treated Wood**

#### *Area of application*

**Section 27** The provisions of Sections 28–37 apply to wood and other wood-based materials which have been treated with preservatives to protect them against attack by fungi, bacteria, insects or marine organisms (preservative-treated wood).

The regulations also apply to imported preservative-treated wood. The provisions of Sections 30–37 do not apply to preservative-treated wood that is exported.

#### *Requirements on fixation etc.*

**Section 28** Whoever is engaged in professional wood treatment using preservatives shall take the measures needed to ensure that the wood is not supplied contrary to the provisions of Section 29. Corresponding obligations are incumbent on anyone professionally importing preservative-treated wood.

**Section 29** Preservative-treated wood may not be supplied from a treatment plant unless the wood is dry on the surface and in all essentials not sticky, or before fixation of the preservative, if any, is completed.

**Section 30** Professional use of preservative-treated wood is not allowed unless the wood is dry on the surface and in all essentials not sticky, or before fixation of the preservative, if any, is completed.

#### *Restrictions on use*

**Section 31** Anyone using preservative-treated wood must carefully consider the need and, in considering design and choice of wood, ensure that the use will have a minimum of impact on human health and the environment.

**Section 32** Wood treated with preservatives containing compounds of chromium may be used only when long-term protection is required, as for example:

1. when the wood is buried in, or otherwise in permanent contact with, damp soil or water;
2. when the wood is used for the construction of jetties or other marine facilities;
3. when the wood is permanently installed as a safety device for protection against accidents;
4. when it is difficult to replace following incorporation in a moisture-prone environment, for example ground plates on plinths and concrete slabs, ground-floor joists, etc and similar in-built parts.

All other use of such treated wood is prohibited.

**Section 33** *Has ceased to apply. (KIFS 2010:6).*

**Section 34** Professional marketing or supply of preservative-treated wood is not allowed for purposes prohibited by these Regulations.

#### *Information in cases of supply*

**Section 35** Whoever professionally supplies preservative-treated wood shall provide written information on:

1. the restrictions on use applicable to the wood under Sections 31–33;
2. the name of the plant where the treatment was carried out;
3. the active ingredients of the preservative;
4. woodworking applications for which the timber is suitable and unsuitable;

5. health hazards associated with woodworking or other handling of the wood;
6. suitable safety precautions;
7. measures for treatment of waste from the wood.

Special provisions on the labelling of arsenic-treated wood are contained in Chapter 8, Section 40.

The information requirement under point 2 of the first paragraph does not apply to wood that is offered for sale on the second-hand market for re-use.

**Section 36** The information referred to in Section 35 shall be attached to every bundle of wood.

**Section 37** Where preservative-treated wood is marketed to be collected not in bundles, the information stated in Section 35 shall be displayed in a notice beside the wood. In addition, a product information sheet shall be available free of charge for anyone collecting the wood.

### **Heavy metals in packaging materials**

**Section 38** Boxes, crates and pallets of plastics and glass packagings may exceed the limit for the sum of the concentrations of lead, cadmium, mercury and hexavalent chromium of 100 µg/g laid down in Section 12 of the Chemical Products (Handling, Import and Export Prohibitions) Ordinance (1998:944) on condition that the requirements of the second and third paragraphs are fulfilled.

Boxes, crates and pallets of plastics shall fulfil the requirements of Articles 4 and 5 of Commission Decision 1999/177/EC of 8 February 1999 establishing the conditions for a derogation for plastic crates and plastic pallets in relation to the heavy metal concentration levels established in Directive 94/62/EC on packaging and packaging waste.

The glass packaging must fulfil the requirements in Articles 4 and 5 of Commission Decision of 19 February 2001 establishing the conditions for a derogation for glass packaging in relation to the heavy metal concentration levels established in Directive 94/62/EC on packaging and packaging waste.

### **Electrical and electronic products**

**Section 39** The prohibition in Section 11 b of the Chemical Products (Handling, Import and Export Prohibitions) Ordinance (1998:944) shall not be applied with respect to uses of lead, mercury, cadmium, hexavalent chromium and polybrominated diphenyl ethers listed in Annex 3. (*KIFS 2010:7*).

**Section 40** The prohibition contained in Section 11 b of the Chemical Products (Handling, Import and Export Prohibitions) Ordinance (1998:944) applies only if the concentration exceeds 0.1 per cent by weight for lead, mercury, hexavalent chromium, polybrominated biphenyls (PBBs) and polybrominated diphenylethers (PBDEs) in homogeneous materials and 0.01 per cent by weight for cadmium in homogeneous materials. (*KIFS 2009:2*).

## **Chapter 6. Gas containers according to Directive 90/396/EEC**

### **Area of application**

**Section 1** The provisions in this Chapter apply to such appliances etc., hereafter referred to as gas containers, which are covered by the regulations (SÄIFS 2000:6) on gas containers of the National Inspectorate of Explosives and Flammables.

### **Design and construction**

**Section 2** Gas containers shall be designed and constructed considering these Regulations and the provisions of Chapter 2, Sections 3-4 of the Environmental Code.

**Section 3** Gas containers containing toxic gas as a propellant must be equipped with a particular device preventing the collection of unburned gases in areas where the containers are used.

**Section 4** Gas containers must be so constructed that, when used normally, combustion products do not contain unacceptable concentrations of substances harmful to health.

**Section 5** Materials and components used for the manufacture of gas containers and which may come into contact with food or water used for sanitary purposes, must not impair the quality of the food or water.

## **Chapter 7. Genetically modified organisms**

### **Area of application**

**Section 1** The scope of provisions under this Chapter is evident from Chapter 13 of the Environmental Code and the Ordinance (2002:1086) on Deliberate Release into the Environment of Genetically Modified Organisms.

### **Permit application**

**Section 2** The application summary (Summary Notification Information Format, SNIF) referred to in Chapter 2 Section 3 of the Ordinance (2002:1086) on Deliberate Release into the Environment of Genetically Modified Organisms shall contain the information specified in Council Decision 2002/813/EC.

### **Fees**

**Section 3** Fees shall be used for such genetically modified organisms to which these regulations are applicable as follows.

	Application fee Swedish kronor
1. On application for consent to deliberate release	112,000
2. On application for consent to placing on the market,	
a) for each product	5,000
b) for each organism where the permit for deliberate release has not been issued by the Swedish Chemicals Agency	112,000

The application fee shall be paid when the application is made.

**Section 4** Fees for control samples referred to in Article 19(d) of Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC shall be charged according to the principle of true price plus 15% supplement for the administrative expenses of the Swedish Chemicals Agency.

**Section 5** A fee for supervision shall be charged at 400 Swedish kronor per hour plus any travel expenses.

**Section 6** If there are special reasons for doing so, the Swedish Chemicals Agency may decide to reduce or waive the fee in accordance with Section 3.

## **Chapter 8. Flammability and chemical properties of toys**

**Section 1** The provisions of this chapter with regard to flammability and chemical properties supplement the Swedish Consumer Agency's Safety of Toys Regulations (KOVFS 2011:3).

**Section 2** The provisions are applicable to toys placed on the market and in public activity under the Safety of Toys Act (2011:579).

The exemptions from the scope of the Act for certain toys or articles set out in the Swedish Consumer Agency's Safety of Toys' Regulations have the same meaning in application of this chapter.

**Section 3** Terms and expressions in the Safety of Toys Act, in the Safety of Toys Ordinance and in the Swedish Consumer Agency's Safety of Toys Regulations have the same meaning in application of this chapter and Annex 5.

**Section 4** Toys shall fulfil the particular safety requirements with regard to flammability and chemical properties set out in Annex 5. (*KIFS 2011:3*).

**Transitional provisions to KIFS 2008:2**

1. These Regulations come into effect on 1 January 2009 with respect to Chapter 3 and otherwise on 1 June 2008, when the Swedish Chemicals Agency Regulations on Chemical Products and Biotechnical Organisms (KIFS 1998:8) cease to apply. The Swedish Chemicals Agency Regulations on Chemical Products and Biotechnical Organisms (KIFS 1998:8) shall, however, continue to apply until 1 July 2008 with respect to Chapter 9 Section 40 point 9 a and until 31 December with respect to permits for the importation of products of very high concern from a country outside the European Economic Area and with respect to notification to the Products Register.

2. Decisions notified pursuant to the Swedish Chemicals Agency Regulations (KIFS 1998:8) on Chemical Products and Biotechnical Organisms shall be deemed to be notified pursuant to the corresponding provision in these Regulations.

3. Older provisions apply with respect to articles covered by the prohibitions in Chapter 8 Section 17 and Section 19 and placed on the market, sold or in some other way supplied to the end-user prior to 1 September 2005.

4. The provisions of Chapter 8 Section 27 do not apply to such installations or machines as were used for the first time prior to 24 March 1994. They may in such cases be used until they are disposed of.

5. If there are special reasons in the individual case, the Swedish Chemicals Agency may grant dispensation from the prohibition in Chapter 8 Section 47 for diaphragms in existing electrolyte installations and issue orders on labelling.

6. The limit values relating to paints and varnishes in phase 2 in Annex 2 (2)(A) shall be applied with effect from 1 January 2010. Paints and varnishes in phase 2 in Annex 2 (1)(A) which are produced prior to 1 January 2010 may be placed on the market up to including 1 January 2011 despite not fulfilling the requirements of Annex 2(2).

7. Articles which contain mercury and have been imported, manufactured and sold pursuant to Chapter 9 Section 15 of the Swedish Chemicals Agency Regulations (KIFS 1998:8) on Chemical Products and Biotechnical Organisms may continue to be used. Older provisions on obligation to record apply with respect to these articles.

**Transitional provisions to regulations amending KIFS 2008:2**

**KIFS 2008:5**

These Regulations come into force the day after the day they were printed as marked on them in the Code of Statutes of the Swedish Chemicals Agency.

**KIFS 2008:6**

These Regulations come into force in the case of Chapter 5, Section 17 on 3 April 2009 and in other cases on 15 December 2008.

**KIFS 2009:2**

These Regulations come into force on 1 June 2009.

*Change of the transitional provisions of KIFS 2008:2*

6. The limit values for paints and varnishes in phase 2 of Annex 2, part 2 A, shall apply from 1 January 2010. Paints and varnishes in phase 2, Annex 2, part 2 A, produced before 1 January 2010 may be placed on the market until 1 January 2011, notwithstanding that they do not meet the requirements of Annex 2, part

**KIFS 2009:6**

These Regulations come into force on 1 July 2009.

**KIFS 2009:9**

These Regulations come into force the day after the day they were printed as marked on them in the Code of Statutes of the Swedish Chemicals Agency.

**KIFS 2010:4**

These Regulations come into force on 1 August 2010.

**KIFS 2010:7**

These Regulations come into force on 1 January 2011.

**KIFS 2011:3**

1. These Regulations come into force on 20 July 2011.
2. The Regulations do not apply to toys which were placed on the EU market before the date the Regulations came into force.

**KIFS 2012:1**

These Regulations come into force on 10 June 2012 in the case of Annex 2, and in other cases on 1 March 2012.

**KIFS 2012:3**

These Regulations come into force on 1 August 2012.

## Chemical products that may be reported to the Products Register under a common designation, Chapter 3, Section 2

### A. Finished paint and lacquer products

The terms paint family and lacquer family are used here to mean paints/lacquers which have most of their commercial name in common. Variants mean products belonging to the same paint/lacquer family but differing in colour, shade, degree of delustring, structure or rheological properties.

Several variants within a single paint/lacquer family may be reported under *one* common designation with *one* product report.

The following regulations apply to such a report:

1. The common designation shall be a name that forms part of the product name of all variants reported.
2. The number of variants shall be specified.
3. Variants not considered hazardous to health or the environment may not be reported in combination with variants that are hazardous to health or the environment.
4. If the variants are hazardous to health or the environment, the components considered capable of giving the product properties hazardous to health or the environment shall be the same and lie within the same concentration range in all variants, pursuant to Section 4, last subsection.

### B. Polymer products

The term polymer is used here to mean a chemical compound whose average molecular weight exceeds 1,000. The term polymer products is used here to mean products mainly comprising one or more polymers and intended to be used as raw materials.

The term variants means polymer products in which the polymers are formulated from the same basic chemical components but differ in their degree of polymerisation or molecular structure. Besides monomers, basic components may be reactive compounds that form part of polymer molecules after the polymerisation stage.

Several variants of a polymer product may be reported under *one* common designation with *one* product report.

The following regulations apply to such a report:

1. All product names intended to be used on the Swedish market shall be specified.
2. The number of variants shall be specified.
3. Variants not considered hazardous to health or the environment may not be reported in combination with variants that are hazardous to health or the environment.
4. If the variants are hazardous to health or the environment, the concentrations and components considered capable of giving the polymer product properties hazardous to health or the environment shall be the same in all variants.

### C. Kits

The term kit is used here to mean composite packaging delivered to consumers and containing modified quantities of products intended to be used together, for example composite packages of base and hardener and composite packages of certain photochemicals.

Several products included in a kit may be reported under *one* common designation.

The following applies to such a report:

1. All products included in a kit shall be reported individually, stating in which kit or kits the product is contained.
2. When the product charge is determined, each reported kit is regarded as one product, whereas no charge is made for products reported as only included in a kit.

#### *D. Distillates/fractions*

The term distillates/fractions here means base oil products which can be described by a CAS number. The term variants means distillates with the same CAS number but with differing viscosity or other physical properties. Several variants within a distillate/fraction may be notified under a single common designation with a single product notification. The following is applicable to such a notification:

1. The common designation shall be a name which describes the distillate/fraction or forms part of the product name.

2. The number of variants shall be stated.

3. Variants which have not been assessed as hazardous to health or the environment shall not be notified together with variants that are hazardous to health or the environment.

4. If the variants are hazardous to health or the environment, the components which have been assessed as being capable of giving the product properties that are hazardous to health or the environment must be the same and be within the same concentration interval in accordance with Chapter 3 Section 4 a in all variants. (*KIFS 2009:2*).

## Paints and varnishes and vehicle refinishing products, Chapter 5, Sections 11-15

### 1. Paints and varnishes and vehicle refinishing products

#### A. Paints and varnishes

For the purposes of these Regulations, paints and varnishes means products listed in the sub-categories below, excluding aerosols. Paints and varnishes are coatings applied to buildings, their trim and fittings, and associated structures for decorative, functional and protective purposes.

#### Subcategories:

- a) *matt coatings for interior walls and ceilings* means coatings intended for application to interior walls and ceilings with a degree of gloss of  $< 25$  at  $60^\circ$  angle.
- b) *glossy coatings for interior walls and ceilings* means coatings intended for application to interior walls and ceilings with a degree of gloss of  $> 25$  at  $60^\circ$  angle.
- c) *coatings for exterior walls of mineral substrate* means coatings designed for application to outdoor walls of masonry, brick or stucco.
- d) *interior/exterior trim and cladding paints for wood, metal or plastic* means coatings designed for application to trim and cladding which produce an opaque coat. These coatings are designed for either a wood, metal or plastic substrate. This subcategory includes undercoats and intermediate coatings.
- e) *interior/exterior trim varnishes and woodstains* means coatings intended for application to trim which produce a transparent or semi-transparent film for decoration and protection of wood, metal and plastic. This category includes opaque woodstains. Opaque woodstain means coatings producing an opaque film for the decoration and protection of wood, against weathering, as defined in EN 927-1, within the semi-stable category.
- f) *minimal build woodstains* means woodstains which, in accordance with EN 927-1:1996, have a mean thickness of less than  $5\mu\text{m}$  when tested according to ISO 2808:1997, method 5A.
- g) *primers*: means coatings with sealing and/or blocking properties designed for use on wood or walls and ceilings.
- h) *binding primers* means coatings designed to stabilise loose substrate parties or impart hydrophobic properties and/or to protect wood against blue stain.
- i) *one-pack performance coatings* means performance coatings based on film-forming material. They are designed for applications requiring a special performance, such as primer and topcoats for plastics, primer coat for ferrous substrates, primer coat for reactive metals such as zinc and aluminium, anticorrosion finishes, floor coatings, including for wood and cement floors, graffiti resistance, flame retardant, and hygiene standards in the food or drink industry or health services.
- j) *two-pack performance coatings* means coatings with the same use as one-performance coatings, but with a second component (e.g. tertiary amines) added prior to application.
- k) *multicoloured coatings*: means coatings designed to give a two-tone or multiple-colour effect, directly from the primary application.
- l) *decorative effect coatings*: means coatings designed to give special aesthetic effects over specially prepared pre-painted substrates or base coats and subsequently treated with various tools during the drying period.

## B. Vehicle refinishing products

For the purposes of these Regulations, vehicle refinishing products means products listed in the subcategories below. They are used for the coating of road vehicles as defined in Council Directive 70/156/EEC of 6 February 1970, on the approximation of the laws of the Member States on type-approval of motor vehicles and their trailers, or part of them, carried out as part of vehicle repair, conservation or decoration outside of manufacturing installations.

### Subcategories

- a) *preparation and cleaning* means products designed to remove old coatings and rust, either mechanically or chemically, or to provide a key for new coatings.
  - *preparatory products* includes gunwash (a product designed for cleaning spray-guns and other equipment), paint strippers, degreasers (including anti-static types for plastic) and silicone removers.
  - *precleaner* means a cleaning product designed for the removal of surface contamination during preparation for and prior to the application of coating materials.
- b) *bodyfiller/stopper* means heavy-bodied compounds designed to be applied to fill deep surface imperfections prior to the application of the surfacer/filler.
- c) *primer* means any coating that is designed for application to bare metal or existing finishes to provide corrosion protection prior to application of a primer surfacer.
  - *surfacer/filler* means a coating designed for application immediately prior to the application of topcoat for the purpose of corrosion resistance, to ensure adhesion of the topcoat, and to promote the formation of a uniform surface finish by filling in minor surface imperfections
  - *general metal primer* means a coating designed for application as primers, such as adhesion promoters, sealers, surfacers, undercoats, plastic primers, wet-on-wet, non-sand fillers and spray fillers
  - *wash primer* means coatings containing at least 0.5 % by weight of phosphoric acid designed to be applied directly to bare metal surfaces to provide corrosion resistance and adhesion; coatings used as weldable primers; and mordant solutions for galvanised and zinc surfaces
- d) *topcoat* means any pigmented coating that is designed to be applied either as a single-layer or as a multiple-layer base to provide gloss and durability. It includes all products involved such as base coatings and clear coatings.
  - *base coatings* means pigmented coatings designed to provide colour and any desired optical effects, but not the gloss or surface resistance of the coating system.
  - *clear coating* means a transparent coating designed to provide the final gloss and resistance properties of the coating system.
- e) *special finishes*: means coatings designed for application as topcoats requiring special properties, such as metallic or pearl effect, in a single layer, high-performance solid-colour and clear coats, (e.g. anti-scratch and fluorinated clear-coat), reflective base coat, texture finishes (e.g. hammer), anti-slip, under-body sealers, anti-chip coatings, interior finishes; and aerosols.

## 2. Limit values for the content of volatile organic compounds

### A. Limit values for the content of volatile organic compounds (VOCs) in paints and varnishes

WB = water-based coating (coatings the viscosity of which is adjusted by the use of water)

SB = solvent-based coating (coatings the viscosity of which is adjusted by the use of organic solvent)

	<b>Product sub-category</b>	<b>Type</b>	<b>Phase 1 (g/l)</b>	<b>Phase 2 (g/l)</b>
a.	Matt coatings for interior walls and ceilings: <25 at 60° angle)	WB	75	30
		SB	400	30
b.	Glossy coatings for interior walls and ceilings: >25 at 60° angle)	WB	150	100
		SB	400	100
c.	Coatings for exterior walls of mineral substrate	WB	75	40
		SB	450	430
d.	Interior/exterior trim and cladding paints for wood, metal or plastic	WB	150	130
		SB	400	300
e.	Interior/exterior trim varnishes and woodstains	WB	150	130
		SB	500	400
f.	Minimal build woodstains for indoor and outdoor use	WB	150	130
		SB	700	700
g.	Primers	WB	50	30
		SB	450	350
h.	Binding primers	WB	50	30
		SB	750	750
i.	One-pack performance coatings	WB	140	140
		SB	600	500
j.	Two-pack performance coatings for special applications, e.g. floors	WB	140	140
		SB	550	500
k.	Multicoloured coatings	WB	150	100
		SB	400	100
l.	Decorative effect coatings	WB	300	200
		SB	500	200

## B. Limit values for the content of volatile organic solvents (VOC) in vehicle refinishing products

	Product subcategory	Lack	VOC g/l
a.	Preparation and cleaning	Preparatory products	850
		Precleaner	200
b.	Bodyfiller/stopper	All types	250
c.	Primers	Surfacer/general metal primer	540
		Washprimer	780
d.	Topcoat	All types	420
e.	Special finishes	All types	840

### 3. Analysis methods

Parameter	Entity	Test Method	Publication date
Content of volatile organic compounds	g/l	ISO 11890-2	2002
Content of volatile organic compounds in occurrence of reactive diluents	g/l	ASTMID 2369	2003

Allowed method for products with a VOC concentration below 15 percentage by weight without occurrence of reactive solvents

Parameter	Entity	Test	
		Method	Publication date
VOC concentration	g/l	ISO 11890-2 <sup>1</sup>	2006

Allowed method for products with a VOC of at least 15 percentage by weight without occurrence of reactive solvents

Parameter	Entity	Test	
		Method	Publication date
VOC concentration	g/l	ISO 11890-1 <sup>2</sup>	2007
VOC concentration	g/l	ISO 11890-2	2006

Allowed method for products with VOC concentration when reactive solvents emerge.

Parameter	Entity	Test	
		Method	Publication date
VOC concentration	g/l	ASTMD 2369	2003

<sup>1</sup> Swedish denomination of the standard is SS-EN ISO 11890-2:2006, Färg och lack – Bestämning av halt flyktiga komponenter (VOC) – Del 2: Gaskromatografisk metod (ISO 11890-2:2006). Paints and varnishes -- Determination of volatile organic compound (VOC) content

<sup>2</sup> Swedish denomination of the standard is SS-EN 11890-1:2007, Färg och lack – Bestämning av halt flyktiga komponenter (VOC) – Del 1: Differensmetod (ISO 11890-1:2007.)

## Uses exempted from the prohibition in Section 11b of the Chemical Products (Handling, Import and Export Prohibitions) Ordinance (1998:944)

Exemption	Use and date of application
1 Mercury in single capped (compact) fluorescent lamps not exceeding (per burner):	
1.a For general lighting purposes < 30 W: 5 mg	Expires on 31 December 2011. 3.5 mg may be used per burner after 31 December 2011 and up to 31 December 2012; 2.5 mg per burner may be used after 31 December 2012
1.b For general lighting purposes $\geq 30$ W and < 50 W: 5 mg	Expires on 31 December 2011. 3.5 mg per burner may be used after 31 December 2011
1.c For general lighting purposes $\geq 50$ W and < 150 W: 5 mg	
1.d For general lighting purposes $\geq 150$ W: 15 mg	
1.e For general lighting purposes with circular or square structural shape and a tube diameter of $\leq 17$ mm	No limitation of use up to 31 December 2011. 7 mg per burner may be used after 31 December 2011
1.f For special purposes: 5 mg	
2.a Mercury in double-capped linear fluorescent lamps for general lighting purposes not exceeding (per lamp):	
2.a.1 Tri-band phosphor with normal lifetime and a tube diameter of < 9 mm (e.g. T2): 5 mg	Expires on 31 December 2011; 4 mg may be used per lamp after 31 December 2011
2.a.2 Tri-band phosphor with normal lifetime and a tube diameter of $\geq 9$ mm and $\leq 17$ mm (e.g. T5): 5 mg	Expires on 31 December 2011; 3 mg may be used per lamp after 31 December 2011
2.a.3 Tri-band phosphor with normal lifetime and a tube diameter of > 17 mm and $\leq 28$ mm (e.g. T8): 5 mg	Expires on 31 December 2011; 3.5 mg may be used per lamp after 31 December 2011
2.a.4 Tri-band phosphor with normal lifetime and a tube diameter of > 28 mm (e.g. T12): 5 mg	Expires on 31 December 2012. 3.5 mg may be used per lamp after 31 December 2012
2.a.5 Tri-band phosphor with long lifetime ( $\geq 25\ 000$ hours): 8 mg	Expires on 31 December 2011. 5 mg may be used per lamp after 31 December 2011

<b>Exemption</b>	<b>Use and date of application</b>
2.b Mercury in other fluorescent lamps not exceeding (per lamp):	
2.b.1 Linear halophosphate lamps with tube > 28 mm (e.g. T10 and T12): 10 mg	Expires on 13 April 2012
2.b.2 Non-linear halophosphate lamps (all diameters): 15 mg	Expires on 13 April 2016
2.b.3 Non-linear tri-band phosphor lamps with tube diameter > 17 mm (e.g. T9)	No limitation of use until 31 December 2011; 15 mg may be used per lamp after 31 December 2011
2.b.4 Lamps for other general lighting and special purposes (e.g. induction lamps)	No limitation of use until 31 December 2011; 15 mg may be used per lamp after 31 December 2011
3 Mercury in cold cathode fluorescent lamps and external electrode fluorescent lamps (CCFL and EEFL) for special purposes not exceeding (per lamp):	
3.a Short length ( $\leq 500$ mm)	No limitation of use until 31 December 2011; 3.5 mg may be used per lamp after 31 December 2011
3.b Medium length (> 500 mm and $\leq 1\ 500$ mm)	No limitation of use until 31 December 2011; 5 mg may be used per lamp after 31 December 2011
3.c Long length (> 1 500 mm)	No limitation of use until 31 December 2011; 13 mg may be used per lamp after 31 December 2011
4.a Mercury in other low pressure discharge lamps (per lamp)	No limitation of use until 31 December 2011; 15 mg may be used per lamp after 31 December 2011
4.b Mercury in High Pressure Sodium (vapour) lamps for general lighting purposes not exceeding (per burner) in lamps with improved colour rendering index $R_a > 60$	
4.b.I $P \leq 155$ W	No limitation of use up to 31 December 2011. 30 mg per burner may be used after 31 December 2011

<b>Exemption</b>	<b>Use and date of application</b>
4.b.II 155 W < P ≤ 405 W	No limitation of use up to 31 December 2011. 40 mg per burner may be used after 31 December 2011
4.b.III P > 405 W	No limitation of use up to 31 December 2011. 40 mg per burner may be used after 31 December 2011
4.c Mercury in other High Pressure Sodium (vapour) lamps for general lighting purposes, not exceeding (per burner):	
4.c.I P ≤ 155 W	No limitation of use up to 31 December 2011. 25 mg per burner may be used after 31 December 2011
4.c.II 155 W < P ≤ 405 W	No limitation of use up to 31 December 2011. 30 mg per burner may be used after 31 December 2011
4.c.III P > 405 W	No limitation of use up to 31 December 2011. 40 mg per burner may be used after 31 December 2011
4.d Mercury in High Pressure Mercury (vapour) Lamps (HPMV)	Expires on 13 April 2015
4.e Mercury in metal halide lamps (MH)	
4.f Mercury in other discharge lamps for special purposes not specifically mentioned in this Annex	
5a Lead in glass of cathode ray tubes	
5.b Lead in glass of fluorescent tubes not exceeding 0.2% by weight	
6.a Lead as an alloying element in steel for machining purposes and in galvanised steel containing up to 0.35% lead by weight	
6.b Lead as an alloying element in aluminium containing up to 0.4% lead by weight	
6.c Copper alloys containing up to 4% lead by weight	

<b>Exemption</b>	<b>Use and date of application</b>
7.a Lead in high melting temperature type solders (i.e. lead-based alloys containing 85% by weight or more lead)	
7.b Lead in solders for servers, storage and storage array systems, network infrastructure equipment for switching, signalling, transmission as well as network management for telecommunications	
7.c.I Electrical and electronic components containing lead in a glass or ceramic other than dielectric ceramic in capacitors, e.g. piezoelectric devices, or lead in a glass or ceramic matrix compound	
7.c.II Lead in dielectric ceramic in capacitors for a rated voltage of 125 V AC or 250 V DC or higher	
7.c.III Lead in dielectric ceramic in capacitors for a rated voltage of less than 125 V AC or 250 V DC	Expires on 1 January 2013 and after that date may be used in spare parts for electrical and electronic equipment placed on the market before 1 January 2013
7.c.IV Lead in PZT-based dielectric ceramic in capacitors contained in integrated circuits or discrete semiconductors	
8.a Cadmium and its compounds in one shot pellet type thermal cut-offs	Expires on 1 January 2012 and after that date may be used in spare parts for electrical and electronic equipment placed on the market before 1 January 2012
8.b Cadmium and its compounds in electrical contacts	
9 Hexavalent chromium as an anticorrosion agent of the carbon steel cooling system in absorption refrigerators up to 0.75% by weight in the cooling solution	
9.b Lead in bearing shells and bushes for refrigerant-containing compressors for heating, ventilation, air conditioning and refrigeration (HVACR) applications	

<b>Exemption</b>	<b>Use and date of application</b>
11.a Lead used in C-press compliant pin connector systems	May be used in spare parts for electrical and electronic equipment placed on the market before 24 September 2010
11.b Lead used in other than C-press compliant pin connector systems	Expires on 1 January 2013 and after that date may be used in spare parts for electrical and electronic equipment placed on the market before 1 January 2013
12 Lead as a coating material for the thermal conduction module C-ring	May be used in spare parts for electrical and electronic equipment placed on the market before 24 September 2010
13.a Lead in white glasses used for optical applications	
13.b Cadmium and lead in filter glasses and glasses used for reflectance standards	
14 Lead in solders consisting of more than two elements for the connection between the pins and the package of microprocessors with a lead content of more than 80% and less than 85% by weight	Expires on 1 January 2011 and after that date may be used in spare parts for electrical and electronic equipment placed on the market before 1 January 2011
15 Lead in solders to complete a viable electrical connection between semiconductor die and carrier within integrated circuit flip chip packages	
16 Lead in linear incandescent lamps with silicate coated tubes	Expires on 1 September 2013
17 Lead halide as radiant agent in high-intensity discharge (HID) lamps used for professional reprography applications	
18.a Lead as activator in the fluorescent powder (1% lead by weight or less) of discharge lamps when used as speciality lamps for diazoprinting reprography, lithography, insect traps, photochemical and curing processes containing phosphors such as SMS ((Sr,Ba) <sub>2</sub> MgSi <sub>2</sub> O <sub>7</sub> :Pb)	Expires on 1 January 2011
18.b Lead as activator in the fluorescent powder (1% lead by weight or less) of discharge lamps when used as sun tanning lamps containing phosphors such as BSP (BaSi <sub>2</sub> O <sub>5</sub> :Pb)	

Exemption	Use and date of application
19 Lead with PbBiSn-Hg and PbInSn-Hg in specific compositions as main amalgam and with PbSn-Hg as auxiliary amalgam in very compact energy-saving lamps (ESL).	Expires on 1 June 2011
20 Lead oxide in glass used for binding front and rear substrates of flat fluorescent lamps used for liquid crystal displays (LCDs).	Expires on 1 June 2011
21 Lead and cadmium in printing inks for the application of enamels on glasses, such as borosilicate and soda lime glasses	
23 Lead in finishes of fine pitch components other than connectors with a pitch of 0.65 mm and less	May be used in spare parts for electrical and electronic equipment placed on the market before 24 September 2010
24 Lead in solders for the soldering to machined through hole discoidal and planar array ceramic multilayer capacitors	
25 Lead oxide in surface conduction electron emitter displays (SED) used in structural elements, notably in the seal frit and frit ring	
26 Lead oxide in the glass envelope of black light blue lamps	Expires on 1 June 2011
27 Lead alloys as solder for transducers used in high-powered (designated to operate for several hours at acoustic power levels of 125 dB SPL and above) loudspeakers	Expires on 24 September 2010
29 Lead bound in crystal glass as defined in Annex I (categories 1, 2, 3 and 4) of Council Directive 69/493/EEC <sup>3</sup>	
30 Cadmium alloys as electrical/mechanical solder joints to electrical conductors located directly on the voice coil in transducers used in high-powered loudspeakers with sound pressure levels of 110 dB (A) and more	
31 Lead in soldering materials in mercury free flat fluorescent lamps (which e.g. are used for liquid crystal displays, design or industrial lighting)	

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<sup>3</sup> OJ L 326, 39.12.1969, p. 36.

Exemption	Use and date of application
32 Lead oxide in seal frit used for making window assemblies for argon and krypton laser tubes	
33 Lead in solders for the soldering of thin copper wires of 100 µm diameter and less in power transformers	
34 Lead in cermet-based trimmer potentiometer elements	
36 Mercury used as a cathode sputtering inhibitor in DC plasma displays with a content more than 30 mg per display	Expires on 01 July 2010
37 Lead in the plating layer of high voltage diodes on the basis of a zinc borate glass body	
38 Cadmium and cadmium oxide in thick film pastes used on aluminium bonded beryllium oxide	
39 Cadmium in colour converting II-VI LEDs (< 10 µg Cd per mm <sup>2</sup> of light-emitting area) for use in solid state illumination or display systems	Expires on 01 July 2014
40 Cadmium in photoresistors for analog optocouplers in professional audio equipment	Expires on 31 December 2013

*(KIFS 2012:1)*

## Mercury and certain articles containing mercury, Chapter 5, Section 17

### 1. Mercury

Mercury for use in certain areas	May be placed on the Swedish market until	May be used for stated application until
<b>Analytical chemicals</b>		
1. Mercury compounds for analysis of mercury and development of such analytical methods.	until further notice	until further notice
2. Mercury compounds for analysis according to international standard methods in the pharmaceutical field.	31.12.2014	31.12.2015
3. Mercury compounds for analysis of COD and in ampoules for COD analysis.	31.12.2011	31.12.2012
4. Mercury compounds for analysis and research and development in medical diagnostics.	31.12.2011	31.12.2012
5. Mercury compounds for analysis other than in accordance with 1-4.	31.12.2011	31.12.2012
<b>Research and development</b>		
6. Mercury compounds for research and development in industry and higher education.	31.12.2011	31.12.2012
<b>Disinfection of medical equipment</b>		
7. Thiomersal for disinfection of transfusion and dialysis equipment	31.12.2011	41.12.2012
<b>Dental amalgam</b>		
8. Dental amalgam for emission measurements of mercury at crematoria.	until further notice	until further notice
9. Mercury for manufacturing of dental amalgam intended for use in accordance with 10.	31.12.2011	31.12.2011
10. Dental amalgam for the following use and if the following conditions are met:	31.12.2011	30.06.2012

Mercury for use in certain areas	May be placed on the Swedish market until	May be used for stated application until
<p>dental amalgam may only be used on adults in hospital dental care or equivalent function if</p> <ol style="list-style-type: none"> <li>there are special medical reasons,</li> <li>other methods of treatment do not provide a sufficiently good result in an individual case, and</li> <li>the clinic is specially arranged from the environmental point of view for the use of dental amalgam.</li> </ol>		

## 2. Articles containing mercury

Articles containing mercury for use within certain areas	May be placed on the Swedish market until	May be released on to the Swedish market as spare parts for the indicated use until
<b>Measuring instruments</b>		
1. Thermometers for flashpoint determination as provided in Directive 67/548/EEC.	31.12.2013	31.12.2013
<b>Seam welding</b>		
2. Welding wheels and metallic mercury for the refilling thereof for the welding of		31.12.2013 31.12.2017
– straight sections		
– curved sections		
<b>Tracking devices</b>		
3. Tracking devices for wildlife research	31.12.2010	31.12.2010
<b>Medical devices and monitoring and control equipment</b>		
4. Electrical and electronic medical devices and monitoring and control instruments covered by product category 8-9 in Annex 1 to the Ordinance (2005:09) on Producer Responsibility for Electrical and Electronic Products.	until further notice	until further notice

(KIFS 2009:2).

## Particular safety requirements concerning flammability and chemical properties

### II Flammability

1. Toys must not constitute a hazardous flammable element in the child's environment. They must therefore be composed of materials which fulfil one or more of the following conditions:
  - a) they do not burn if directly exposed to a flame or spark or other potential source of fire;
  - b) they are not readily flammable (the flame goes out as soon as the fire cause disappears);
  - c) if they do ignite, they burn slowly and present a low rate of spread of the flame;
  - d) irrespective of the toy's chemical composition, they are designed so as to mechanically delay the combustion process.

Such combustible materials must not constitute a risk of ignition for other materials used in the toy.

2. Toys which, for reasons essential to their functioning, contain substances or mixtures that meet the classification criteria laid down in *Section 1 of Appendix B*, in particular materials and equipment for chemistry experiments, model assembly, plastic or ceramic moulding, enamelling, photography or similar activities, must not contain, as such, substances or mixtures which may become flammable due to the loss of non-flammable volatile components.
3. Toys other than percussion caps must not be explosive or contain elements or substances likely to explode when used as specified in Section 9(1) of the Safety of Toys Act (2011:579).
4. Toys and, in particular, chemical games and toys, must not contain as such substances or mixtures:
  - a) which, when mixed together, may explode through chemical reaction or through heating;
  - b) which may explode when mixed with oxidising substances; or
  - c) which contain volatile components which are flammable in air and liable to form a flammable or explosive vapour/air mixture.

### III Chemical properties

1. Toys shall be designed and manufactured in such a way that there are no risks of adverse effects on human health due to exposure to the chemical substances or mixtures of which the toys are composed or which they contain when the toys are used as specified in the first paragraph of Section 9 of the Safety of Toys Act.

Toys shall comply with the relevant Community legislation relating to certain categories of products or to restrictions for certain substances and mixtures.

2. Toys that are themselves substances or mixtures must also comply with the Swedish Chemicals Agency Regulations (KIFS 2005:7) on the classification and labelling of chemical products or Regulation (EC) No 1272/2008 of 16 December 2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures<sup>4</sup>, as applicable, relating to the classification, packaging and labelling of certain substances and mixtures.
3. Without prejudice to the restrictions referred to in the second paragraph of point 1, substances that are classified as carcinogenic, mutagenic or toxic for reproduction (CMR) of category 1A, 1B or 2 under Regulation (EC) No 1272/2008 shall not be used in toys, in components of toys or in micro-structurally distinct parts of toys.
4. By way of derogation from point 3, substances or mixtures classified as CMR of the categories laid down in *Section 3 of Appendix B* may be used in toys, in components of toys or micro-structurally distinct parts of toys provided that one or more of the following conditions is met:

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<sup>4</sup>OJ L 353, 31.12.2008, p.1 (Celex 32008R1272).

- a) these substances and mixtures are contained in individual concentrations equal to or smaller than the relevant concentrations established in the Community legal acts referred to in *Section 2 of Appendix B* for the classification of mixtures containing these substances;
- b) these substances and mixtures are inaccessible to children in any form, including inhalation, when the toy is used as specified in the first paragraph of Section 9 of the Safety of Toys Act;
- c) a decision has been taken by the Commission to permit certain use of the substance or mixture and this has been listed in *Appendix A*.

That decision may be taken if the following conditions are met:

- i) the use of the substance or mixture has been evaluated by the relevant scientific committee and found to be safe, in particular in view of exposure;
- ii) there are no suitable alternative substances or mixtures available, as documented in an analysis of alternatives;
- iii) the substance or mixture is not prohibited for use in consumer articles under Regulation (EC) No 1907/2006<sup>5</sup>.

The Commission shall mandate the relevant scientific committee to re-evaluate these substances or mixtures as soon as new concerns arise on the safety and at the latest every five years from the date that a decision has been taken by the Commission on inclusion in the list in *Appendix A*.

5. By way of derogation from point 3, substances or mixtures classified as CMR of the categories laid down in *Section 4 of Appendix B* may be used in toys, in components of toys or micro-structurally distinct parts of toys provided that:
  - a) these substances and mixtures are contained in individual concentrations equal to or smaller than the relevant concentrations established in the Community legal acts referred to in *Section 2 of Appendix B* for the classification of mixtures containing these substances;
  - b) these substances and mixtures are inaccessible to children in any form, including inhalation, when the toy is used as specified in the first paragraph of Section 9 of the Safety of Toys Act (2011:579), or
  - c) a decision has been taken by the Commission to permit the substance or mixture and its use, and the substance or mixture and its permitted uses have been listed in *Appendix A*.

The decision described in point c may be taken if the following conditions are met:

- i) the use of the substance or mixture has been evaluated by the relevant scientific committee and found to be safe, in particular in view of exposure;
- ii) the substance or mixture is not prohibited for use in consumer articles under Regulation (EC) No 1907/2006.

The Commission shall mandate the relevant scientific committee to re-evaluate these substances or mixtures as soon as new concerns arise on the safety and at the latest every five years from the date that a decision has been taken by the Commission on inclusion in the list in *Appendix A*.

6. Points 3, 4 and 5 shall not apply to nickel in stainless steel.
7. Points 3, 4 and 5 shall not apply to materials that comply with the specific limit values set out in Appendix C, or, until such provisions have been laid down, but not later than 20 July 2017, to materials covered by and complying with the provisions for food contact materials set out in Regulation (EC) No 1935/2004 and the related specific measures for particular materials.
8. Without prejudice to the application of points 3 and 4, nitrosamines and nitrosable substances shall be prohibited for use in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth if the migration of the substances is equal to or higher than 0.05 mg/kg for nitrosamines and 1 mg/kg for nitrosable substances.
9. The Commission shall systematically and regularly evaluate the occurrence of hazardous substances of materials in toys. These evaluations shall take into account reports of market surveillance bodies and concerns expressed by Member States and stakeholders.

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<sup>5</sup>OJ L 396, p. 1, 30.12.2006 (Celex 32006R1907)

10. Cosmetic toys, such as play cosmetics for dolls, shall comply with the compositional and labelling requirements laid down in the Ordinance (1993:1283) on cosmetic and hygiene products and associated regulations issued by the Swedish Medical Products Agency.

11. Toys shall not contain the following allergenic fragrances:

No	Name of the allergenic fragrance	CAS number
1.	Alanroot oil ( <i>Inula helenium</i> )	97676-35-2
2.	Allylisothiocyanate	57-06-7
3.	Benzyl cyanide	140-29-4
4.	4 tert-Butylphenol	98-54-4
5.	Chenopodium oil	8006-99-3
6.	Cyclamen alcohol	4756-19-8
7.	Diethyl maleate	141-05-9
8.	Dihydrocoumarin	119-84-6
9.	2,4-Dihydroxy-3-methylbenzaldehyde	6248-20-0
10.	3,7-Dimethyl-2-octen-1-ol (6,7-Dihydrogeraniol)	40607-48-5
11.	4,6- Dimetyl-8-tert-butylkumarin	17874-34-9
13.	7,11-Dimethyl-4.6,10-dodecatrien-3-one	26651-96-7
14.	6,10-Dimethyl-3.5,9-undecatrien-2-one	141-10-6
15.	Diphenylamine	122-39-4
16.	Ethyl acrylate	140-88-5
17.	Fig leaf, fresh and preparations	68916-52-9
18.	trans-2-Heptenal	18829-55-5
19.	trans-2-Hexenal diethyl acetal	67746-30-9
20.	trans-2-Hexenal dimethyl acetal	18318-83-7
21.	Hydroabietyl alcohol	13393-93-6
22.	4-Ethoxy-phenol	622-62-8

No	Name of the allergenic fragrance	CAS number
23.	6-Isopropyl-2-decahydronaphthalenol	34131-99-2
24.	7-Methoxycoumarin	531-59-9
25.	4-Methoxyphenol	150-76-5
26.	4-(p-Methoxyphenyl)-3-butene-2-one	943-88-4
27.	1-(p-Methoxyphenyl)-1-penten-3-one	104-27-8
28.	Methyl trans-2-butenolate	623-43-8
29.	6-Methylcoumarin	92-48-8
30.	7-Methylcoumarin	2445-83-2
31.	5-Metyl-2,3-hexanedione	13706-86-0
32.	Costus root oil ( <i>Saussurea lappa</i> Clarke)	8023-88-9
33.	7-Ethoxy-4-methylcoumarin	87-05-8
34.	Hexahydrocoumarin	700-82-3
35.	Peru balsam, crude (Exudation of <i>Myroxylon pereirae</i> (Royle) Klotzsch)	8007-00-9
36.	2-Pentylidene-cyclohexanone	25677-40-1
37.	3,6,10-Trimethyl-3,5,9-undecatrien-2-one	1117-41-5
38.	Verbena oil ( <i>Lippia citriodora</i> Kunth)	8024-12-2
39.	Musk ambrette (4-tert-Butyl-3-methoxy-2,6-dinitrotoluene)	83-66-9
40.	4-Phenyl-3-buten-2-one	122-57-6
41.	Amyl cinnamal	122-40-7
42.	Amylcinnamyl alcohol	101-85-9
43.	Benzyl alcohol	100-51-6
44.	Benzyl salicylate	118-58-1
45.	Cinnamyl alcohol	104-54-1
46.	Cinnamal	104-55-2
47.	Citral	5392-40-5

No	Name of the allergenic fragrance	CAS number
48.	Coumarin	91-64-5
49.	Eugenol	97-53-0
50.	Geraniol	106-24-1
51.	Hydroxy-citronellal	107-75-5
52.	Hydroxy-methylpentylcyclohexenecarboxaldehyde	31906-04-4
53.	Isoeugenol	97-54-1
54.	Oakmoss extracts	90028-68-5
55.	Treemoss extracts	90028-67-4

However, the presence of traces of these fragrances shall be allowed provided that such presence is technically unavoidable under good manufacturing practice and does not exceed 100 mg/kg.

In addition, the names of the following allergenic fragrances shall be listed on the toy, on an affixed label, on the packaging or in an accompanying leaflet, if added to a toy, as such, at concentrations exceeding 100 mg/kg in the toy or components thereof.

No	Name of the allergenic fragrance	CAS number
1.	Anisyl alcohol	105-13-5
2.	Benzyl benzoate	120-51-4
3.	Benzyl cinnamate	103-41-3
4.	Citronellol	106-22-9
5.	Farnesol	4602-84-0
6.	Hexyl cinnamaldehyde	101-86-0
7.	Lilial	80-54-6
8.	d-Limonene	5989-27-5
9.	Linalool	78-70-6
10.	Methyl heptine carbonate	111-12-6
11.	3-methyl-4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-one	127-51-5

12. The use of the fragrances set out in points 41 to 55 of the list set out in point 11 and of the fragrances set out in points 1 to 11 of the list set out in the third paragraph of that point shall be allowed in olfactory board games, cosmetic kits and gustative games, provided that:

- i) these fragrances are clearly labelled on the packaging, and the packaging contains the warning set out in point 10 of Part B of Annex 5 to the Swedish Consumer Agency's Safety of Toys Regulations;
- ii) if applicable, the resulting products made by the child in accordance with the instructions comply with the requirements of the Cosmetic and Hygiene Products Ordinance and associated regulations issued by the Swedish Medical Products Agency; and
- iii) if applicable, these fragrances comply with the relevant legislation on food.

Such olfactory board games, cosmetic kits and gustative games shall not be used by children under 36 months and shall comply with point 1 of Part B of Annex 5 to the Swedish Consumer Agency's Safety of Toys Regulations.

13. Without prejudice to points 3, 4 and 5, the following migration limits, from toys or components of toys, shall not be exceeded:

Element	mg/kg in dry, brittle, powder-like or pliable toy material	mg/kg in liquid or sticky toy material	mg/kg in scraped-off toy material
Aluminium	5 625	1 406	70 000
Antimony	45	11,3	560
Arsenic	3,8	0,9	47
Barium	4 500	1 125	56 000
Boron	1 200	300	15 000
Cadmium	1,9	0,5	23
Chromium (III)	37,5	9,4	460
Chromium (VI)	0,02	0,005	0,2
Cobalt	10,5	2,6	130
Copper	622,5	156	7 700
Lead	13,5	3,4	160
Manganese	1 200	300	15 000
Mercury	7,5	1,9	94
Nickel	75	18,8	930
Selenium	37,5	9,4	460
Strontium	4 500	1 125	56 000
Tin	15 000	3 750	180 000
Organic tin	0,9	0,2	12
Zinc	3 750	938	46 000

These limit values shall not apply to toys or components of toys which, due to their accessibility, function, volume or mass, clearly exclude any hazard due to sucking, licking, swallowing or prolonged contact with skin when used as specified in the first paragraph of Section 9 of the Safety of Toys Act.

#### Appendix A

#### List of CMR substances and their permitted uses in accordance with points 4, 5 and 6 of Part III

Substance	Classification	Permitted use
Nickel	CMR 2	In stainless steel

#### Appendix B

#### Classification of substances and mixtures

As a result of the timing of the application of Regulation (EC) No 1272/2008, there are equivalent ways of referring to a given classification that should be used at different points in time.

#### 1. Criteria for classifying substances and mixtures for the purposes of point 2 of Part II

A. Criteria to be applied from 20 July 2011 until 31 May 2015:

##### Substances

The substance fulfils the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008:

- hazard classes 2.1 to 2.4, 2.6 and 2.7 and 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F;
- hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10;
- hazard class 4.1;
- hazard class 5.1,

### *Mixtures*

The mixture is dangerous within the meaning of the Swedish Chemicals Agency Regulations (KIFS 2005:7) on classification and labelling.

B. Criteria to be applied from 1 June 2015:

The substance or mixture fulfils the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008:

- a) hazard classes 2.1 to 2.4, 2.6 and 2.7 and 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F;
- b) hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10;
- c) hazard class 4.1;
- d) hazard class 5.1,

### **2. Community legal acts governing the use of certain substances for the purposes of points 4(a) and 5(a) of Part III**

From 20 July 2011 until 31 May 2015, the relevant concentrations for the classification of mixtures containing the substances shall be those established in accordance with Directive 1999/45/EC.

From 1 June 2015, the relevant concentrations for the classification of mixtures containing the substances shall be those established in accordance with Regulation (EC) No 1272/2008.

### **3. Categories of substances and mixtures classified as carcinogenic, mutagenic or toxic for reproduction (CMR) for the purposes of point 4 of Part III**

#### *Substances*

Point 4 of Part III concerns substances classified as CMR category 1A and 1B under Regulation (EC) No 1272/2008.

#### *Mixtures*

From 20 July 2011 until 31 May 2015, point 4 of Part III concerns mixtures classified as CMR category 1 and 2 under the Swedish Chemicals Agency's Regulations (2005:7) on classification and labelling.

From 1 June 2015, point 4 of Part III concerns mixtures classified as CMR category 1A and 1B under Regulation (EC) No 1272/2008.

### **4. Categories of substances and mixtures classified as carcinogenic, mutagenic or toxic for reproduction (CMR) for the purposes of point 5 of Part III**

#### *Substances*

Point 5 of Part III concerns substances classified as CMR category 2 under Regulation (EC) No 1272/2008.

#### *Mixtures*

From 20 July 2011 until 31 May 2015, point 5 of Part III concerns mixtures classified as CMR category 3 under the Swedish Chemicals Agency's Regulations (2005:7) on classification and labelling.

From 1 June 2015, point 5 of Part III concerns mixtures classified as CMR category 2 under Regulation (EC) No 1272/2008.

**5. Categories of substances and mixtures classified as carcinogenic, mutagenic or toxic for reproduction (CMR) for the purposes of the power of the Commission to take decisions to list CMR substances in *Appendix A***

*Substances*

The power to take decisions concerns substances classified as CMR category 1A, 1B and 2 under Regulation (EC) No 1272/2008.

*Mixtures*

From 20 July 2011 until 31 May 2015, this power concerns mixtures classified as CMR category 1, 2 and 3 under the Swedish Chemicals Agency's Regulations on classification and labelling.

From 1 July 2015 this power concerns mixtures classified as CMR category 1A, 1B and 2 under Regulation (EC) No 1272/2008.

*Appendix C*

**Specific limit values for chemicals used in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth adopted by the Commission.**

*(KIFS 2011:3)*