

NB: Unofficial translation; legally binding texts are those in Finnish and Swedish

**Ministry of Social Affairs and Health Decree
on submitting information concerning chemicals**

374/2002

Section 1 - Duties of undertakings

- (1) Undertakings responsible for placing chemicals on the market or supplying them for use in Finland must submit the information set out in Appendix 1 of this Decree on chemicals that are referred to in section 17(3) of the Chemicals Act (744/1989) to the National Product Control Agency for Welfare and Health.
- (2) The information (notification) must be submitted as instructed in Appendix 1 for chemicals intended for professional use and for those intended to the general public. Forms that comply with Appendix 2 may be used to submit the information.

Section 2 - Information to be submitted

- (1) Adequately detailed information must be submitted so that instructions for treatment of acute poisoning and preventive instructions can be issued and occupational diseases and accidents investigated.
- (2) Information must be provided on the following items used professionally or intended to the general public:
 - 1) chemical (substance and preparation) classified as dangerous under the Ministry of Social Affairs and Health Decree on the Bases of

Classification of Chemicals and Labelling (807/2001), hereinafter the classification decree, referred to in section 19 of the Chemicals Act (744/1989); and

- 2) preparation that is not classified as dangerous under the classification decree but contain at least one substance that is dangerous to health or the environment or a substance for which an occupational exposure limit value has been determined; the concentration of the substance in the preparation must be at least 1% by mass in the case of a solid or liquid substances, or at least 0.2% by volume in the case of gaseous substances.
- (3) If needed for the purpose provided in subsection 1, the undertaking must provide the National Product Control Agency for Welfare and Health with additional information on the composition of a preparation.
- (4) If information on a preparation's composition or other information on a preparation is confidential, this must be clearly identified and so indicated in the notification.

Section 3 - Maintaining trade or professional secrecy for chemical names identifying substances contained in preparations

- (1) An undertaking may request from the National Product Control Agency for Welfare and Health that the chemical name by which a substance contained in a preparation classified as dangerous be kept a trade or professional secret if the substance has been classified simply as harmful (Xn, R20, R21, R22) or irritating (Xi, R36, R37, R38), or as irritating or harmful but also explosive,

oxidising, extremely flammable, highly flammable, flammable or dangerous to the environment. Such a request may not be made in the case of substances for which an occupational exposure limit value has been determined.

- (2) If justified cause exists, an undertaking may maintain trade or professional secrecy for a chemical name identifying a substance contained in a non-classified preparation if the substance has been classified simply as harmful (Xn, R20, R21, R22) or irritating (Xi, R36, R37, R38), or as irritating or harmful but also explosive, oxidising, extremely flammable, highly flammable, flammable or dangerous to the environment.
- (3) In cases referred to in subsections 1 and 2, the common name may be used instead of the chemical name identifying the substance given on the labelling and in the safety data sheet, as laid down in Appendix 3.

Section 4 - Procedure for maintaining trade or professional secrecy for chemical names that identify substances

- (1) In cases referred to in section 3(1), the provisions laid down in Appendix 3, part A.I, must be observed when submitting a justified request (application) to the National Product Control Agency for Welfare and Health for maintaining trade or professional secrecy for a chemical name identifying a substance contained in a preparation classified as dangerous, where the preparation is first placed on the European Community market in Finland. The undertaking in question must supply the competent authorities of other Member States of the European Community for information purposes the

details of any decision to maintain trade or professional secrecy for the name of a substance that they receive from a competent authority if the preparation is also to be placed on the market in other Member States of the European Community.

- (2) An undertaking which places on the Finnish market a preparation containing a substance whose identifying chemical name can be kept a trade or professional secret under a decision made in some other Member State of the European Community must provide the National Product Control Agency for Welfare and Health with the information required by Appendix 3, part A.II.1.
- (3) In the cases referred to in section 3(2), the identifying name of a substance contained in a non-classified preparation must be submitted (notification) to the National Product Control Agency for Welfare and Health as laid down in Appendix 3, part A.II.2.
- (4) The National Product Control Agency for Welfare and Health may request the undertaking to submit further information for the purpose of assessing the justifications given in an application or notification for maintaining trade or professional secrecy for the name of a substance.

Section 5 - *Exemptions from the duty to submit information*

Information need not be submitted on chemicals:

- 1) that are used in process-oriented research and development; process-oriented research and development means product development activities in which the applicability of the Chemicals Act

is assessed through production trials or at a testing facility;

- 2) that are used in scientific research and development; scientific research and development means scientific experiments, analyses and chemical studies conducted in controlled circumstances, including the assessment of the properties, behaviour and efficacy of a chemical, and scientific studies related to product development; this exemption does not, however, include chemicals used in ordinary laboratory activities, unless otherwise provided in paragraph 3;
- 3) that are dangerous but their total annual deliveries per undertaking are so small in volume that the chemical cannot be considered to constitute a danger.

Section 6 - *Notifying changes*

- (1) When substantial changes occur in the information submitted on a chemical, the undertaking must provide the National Product Control Agency for Welfare and Health with an updated notification.
- (2) The information referred to above in subsection 1 is as follows:
 - 1) a change in the trade name of a preparation;
 - 2) a change in the information regarding the undertaking;
 - 3) a change in the composition of a preparation as provided in section 6 of the classification decree;
 - 4) new or changed information on the properties of a chemical referred to in section 17(3) of the Chemicals Act;
 - 5) other factors that have an essential bearing on the information content or on the registration of

information referred to in section 20 of the Chemicals Decree (675/1993).

Section 7 - *Entry into force*

- (1) This Decree enters into force on April 1, 2003. The provisions referred to in sections 3 and 4 on maintaining trade or professional secrecy for a chemical name identifying a substance enter into force on August 1, 2002. With regard to plant protection products referred to in the Pesticides Act (327/1969) and biocidal products referred to in the Chemicals Act, the Decree enters into force on August 1, 2004.
- (2) This Decree repeals the Ministry of Social Affairs and Health Decision on providing information on dangerous chemicals (377/1998) issued on May 29, 1998. The repealed Decision applies to plant protection products and biocidal products until August 1, 2004.
- (3) Before its entry into force, this Decree may be applied as of June 1, 2002 instead of the Decision referred to in subsection 2.