

Translation. Only the Danish document has legal validity.

Order no. 1508 of 15 December 2010 issued by the Danish Ministry of Climate and Energy

Order on special obligations for manufacturers, suppliers and importers, etc. of substances and materials for use on offshore installations, etc.¹

In pursuance of section 4a, section 18(6) and section 72(1) of act no. 1424 of 21 December 2005 on the safety, etc. of offshore installations for the exploration, production and transportation of hydrocarbons (the offshore safety act) (*offshoresikkerhedsloven*), as amended by act no. 287 of 15 April 2009, the following provisions are laid down by authority and following negotiations with the Danish Working Environment Authority:

Chapter 1 *Scope and definitions*

Section 1. This order shall cover the importation, manufacturing, transfer or handing over of substances and materials for use:

- 1) on offshore installations as stipulated in section 2 of the offshore safety act (*offshoresikkerhedsloven*); and
- 2) in connection with activities carried out from ships and arrangements covered by section 3(5) of the offshore safety act (*offshoresikkerhedsloven*) (special purpose vessels) to the extent that the substances and materials affect the safety and health conditions on associated offshore installations.

Subsection 2. For the purposes of this order, substances and materials that may present a danger to or otherwise decrease safety or health (dangerous substances and materials) shall mean:

- 1) Substances and materials complying with the criteria for classification as dangerous under the regulations laid down in the act on chemical substances and products (*lov om kemiske stoffer og produkter*) or in regulations issued pursuant hereto on classification or in Regulation of the European Parliament and of the Council (EC) no. 1272/2008 on classification, labelling and packaging of substances and mixtures, etc. (the CLP regulation).
- 2) Substances and materials included with a limit value in the list of limit values for air pollution by substances and materials issued by the Danish Working Environment Authority.
- 3) Materials containing 1 per cent or more (for gaseous materials 0.2 per cent) of a substance included with a limit value in the list of limit values for air pollution by substances and materials issued by the Danish Working Environment Authority.
- 4) Other substances and materials covered by requirements for safety data sheets under article 31 of Regulation of the European Parliament and of the Council (EC) no. 1907/2006 of 18 December 2006 on the registration, evaluation, authorisation and restriction of chemicals (REACH), etc., as amended (the REACH Regulation).
- 5) Substances and materials that the Director-General of the Danish Working Environment Authority decides are to be considered dangerous to or as decreasing safety or health.
- 6) Substances and materials covered by chapter 10 on the risk of cancer when using, etc. substances and materials of the order on the use of substances and materials (chemical agents) on offshore installations, etc.

¹ This order contains provisions implementing Commission Directive 2001/58/EC of 27 July 2001, Official Journal 2001 L 212, p. 24.

Subsection 3. Special requirements on the marketing and use of chromate in concrete are stipulated in article 67 of the REACH Regulation, cf. annex XVII, item 47.

Subsection 4. The order shall not apply to the below-mentioned substances and materials covered by other legislation:

- 1) Foods and stimulants ready for consumption.
- 2) Medicaments ready for consumption.
- 3) Feedstuffs.
- 4) Cosmetic products.
- 5) Waste.
- 6) Materials containing radioactive substances.
- 7) Medical equipment intended for being placed in or used directly in contact with the human body, provided that regulations have been laid down pursuant to other legislation on the basis of EC directives on classification, labelling and marking of dangerous substances and materials ensuring the same level of information and protecting as this order.

Section 2. When using the provisions of this order, the following definitions shall be used:

- 1) Substances: Elements and their compounds.
- 2) Materials: Compositions of two or more substances, including biological materials.

Chapter 2 *Code numbered products*

Section 3. Before a substance or material is delivered for work covered by sections 20-23 of the order on the use of substances and materials on offshore installations, the importer, manufacturer or distributor determine a code number. The code number shall be determined according to the guidelines hereon stipulated in the order on the determination of code number pursuant to the act on occupational health (*lov om arbejdsmiljø*).

Section 4. The code number of a substance or material shall be given clearly on the packaging or in any other way be given in writing to the recipient. The year of the entry into force of the order according to which the code number is determined, cf. section 3, shall be given together with the code number. The code number shall be given in technical data sheets and safety data sheets made according to chapters 6 and 7.

Section 5. For a substance or material where a mixture of more components or the addition of diluents is prescribed a code number shall be determined for both the substance or material alone and for the mixture when ready for use.

Subsection 2. For a substance or material where use is prescribed at a specific temperature a code number shall be determined for both the substance or material at room temperature and for the substance or material at the prescribed temperature.

Section 5. If a substance or material contains liquids that boil at low temperatures and if breathing masks are to be used when working with the substance or the material to protect against the breathing risk, the packaging or the notice about the code number shall also contain information that the breathing mask shall be air-supplied.

Chapter 3 *Marking*

Section 7. Packaging shall be marked with an assigned product registration number (PR no.), if relevant, cf. section 16.

Section 8. Concrete and non-hardened concrete-containing products shall be marked in accordance with annex 1.

Chapter 4 *Notification*

Section 9. Anyone who annually manufactures or imports 100 kg or more of a substance or material covered by section 1(2)(i)-(iv) and (vi) shall notify the Danish Working Environment Authority hereof with the information given in annex 1. This shall, however, not apply to materials given in annex 2.

Subsection 2. The notification shall be given no later than one month after the manufacturing or the importation.

Subsection 3. Subsection 1 shall not apply to substances and materials manufactured or imported for research purposes in a quantity of less than 100 kg when the use is limited to a few persons.

Section 10. The obligation to notify shall, furthermore, rest with manufacturers and importers of dangerous substances and materials if the substance or material gets a new trade name.

Section 11. The Danish Working Environment Authority may, in order to prevent health and accident damages, in individual cases require additional information than that mentioned in annex 1 for substances and materials for special uses.

Section 12. A manufacturer or importer who has notified under section 9(1) or section 10 shall, in addition, notify the Danish Working Environment Authority about important changes compared to that notified, including whether the substance or the material is used for or assumed used for other purposes, whether new toxicological knowledge and the like is available.

Subsection 2. The manufacturer or the importer shall, in addition to what is stipulated in subsection 1, also every second year report quantity information about the previous year's manufacture and importation of the substance and the material, cf. annex 1, item 5.

Section 13. A manufacturer or an importer who has notified under section 9(1) or section 10 shall, with a view to acquiring additional information upon the request of the Danish Working Environment Authority carry out examinations or have examinations carried out in accordance with section 17.

Section 14. Notification pursuant to section 9 shall be made electronically or in paper form on special forms available from the Danish Environmental Protection Agency may meet his obligation under section 9(1) by referring to this notification.

Section 15. Notified substances and materials shall be assigned a product registration number (PR no.) by the Danish Working Environment Authority when the necessary information has been received. The number shall be given on the packaging of the substance or material no later than one year after having been assigned.

Chapter 5 *Examination methods*

Section 17. Examination of the physical-chemical properties of the substances and materials as well as their toxicity shall be made according to methods that can be recognised by the Danish Working Environment Authority to the extent that it is compatible with Commission Regulation (EC) no. 440/2008 of 30 May 2008 on laying down test methods pursuant to Regulation (EC) no. 1907/2006 of the European Parliament and of the Council on the registration, evaluation, authorisation and restriction of chemicals (REACH) and the CLP Regulation.

Subsection 2. The Danish Energy Agency may, following consultations with the Danish Working Environment Authority, order that analyses and examinations of substances and materials are to be carried out according to specific methods at laboratories accredited by DANAK or by a similar accrediting body that is a co-signatory to the EA multilateral agreement on mutual recognition to the extent that it is compatible with the REACH Regulation and the CLP Regulation.

Chapter 6 *Technical data sheets*

Section 18. Technical data sheets and the like on dangerous substances and materials shall contain all important information on the effect of the substance or material on health and safety in the working environment.

Chapter 7 *Safety data sheets*

Section 19. The supplier shall, for the substances and materials stipulated in section 1(2)(ii) and (iii) that are not covered by article 31 of the REACH Regulation, draw up safety data sheets and provide the recipient of these substances and materials with them in accordance with article 31 and annex II of the REACH Regulation, with the exception of item 12 on environmental information and item 13 on conditions relating to removal.

Subsection 2. The safety data sheet shall be in Danish or English.

Chapter 8 *Insulation materials containing synthetic mineral fibres*

Section 20. Anyone manufacturing insulation materials shall ensure that, when delivered, they are provided with:

- 1) trade name and type designation;
- 2) relevant regulations on the safe handling of the products; and

- 3) a reference to user instructions, which shall contain information about health risks and safety measures to be taken in connection herewith, including any health properties of hardening products and impregnation oils.

Subsection 2. Anyone delivering the insulation materials shall ensure that user instructions are available, cf. subsection 1(iii).

Section 21. Upon delivery, the packaging of the final insulation materials shall have been made so as to avoid the liberation of dust from the materials.

Chapter 9 *Monitoring*

Section 22. The Danish Energy Agency shall not monitor article 33(2) and article 38(4) of the REACH Regulation, cf. section 2(5) of the order on the transfer of tasks and inspection concerning Regulation of the European Parliament and of the Council (EC) no. 1907/2006 on the registration, evaluation, authorisation and restriction of chemicals (REACH) to the Danish Environmental Protection Agency, the Danish Working Environment Authority, the Danish Energy Agency and the Danish Maritime Authority.

Chapter 10 *Exemptions and access to complain*

Section 23. The Danish Energy Agency may, in case of special conditions, permit deviations from the provisions of this order when it is assessed to be fully reasonable and proper and to the extent that it is compatible with the directives implemented by this order as well as any EU Regulations applicable to the scope of the order.

Subsection 2. The permit under subsection 1 may be conditional upon certain conditions.

Section 24. Complaints about decisions made by the Danish Energy Agency under this order may be brought before the Energy Board of Appeal.

Subsection 2. The complaint shall be made in writing to the Energy Board of Appeal within four weeks from the date when the person concerned was informed about the decision.

Chapter 11 *Penalty provisions*

Section 25. Unless stricter penalty is liable under other legislation, anyone shall be liable to punishment by fine who:

- 1) contravenes section 9(1) and (2), section 10, sections 12-13, section 16, second clause, section 17(1) and sections 18-21;
- 2) does not observe orders or prohibitions given pursuant to the provisions of this order; or
- 3) disregards the conditions of permits granted pursuant to the provisions of this order.

Subsection 2. Companies, etc. (legal entities) may be liable to punishment under the provisions of chapter 5 of the penal code.

Chapter 12
Entry into force

Section 26. This order shall enter into force on 1 January 2011.

Danish Energy Agency, 15 December 2010

Ib Larsen / Dewi Dylander

Information for use when notifying substances and materials, cf. section 9

In items 1-8, the information to be given in a notification is stipulated. The information shall be exact and topical. There shall be a signature of the notifying person.

Information about the composition shall be exact, unambiguous and complete. The information about the composition given in the safety data sheet of the supplier will normally not suffice. Information about the use and quantities and other information shall also be exact. All information shall be of such a quality that it may serve for assessing the classification and risks of using the notified substance or material and be used for assessing, among other things, the spread of chemical substances and materials and the possibilities of substitutions.

As regards item 3, it shall be remarked that the substances contained shall be given with an unambiguous name and CAS no. when contained by at least:

- a) 0.1 per cent for substances classified under the act on chemical substances and products or regulations issued pursuant hereto as
 - “very toxic”;
 - “toxic”;
 - “carcinogens, categories 1 and 2”;
 - “mutagens, categories 1 and 2”;
 - “reproductive toxins, categories 1 and 2”;or according to the regulations of the CLP Regulation as
 - “acute toxicity, categories 1, 2 and 3”;
 - “carcinogenicity, categories 1A and 1B”;
 - “cell mutagenicity, categories 1A and 1B”;
 - “reproductive toxicity, categories 1A and 1B”;
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- b) 1 per cent for all other substances.

Irrespective of items a and b, the following shall however always apply:

- Substances added due to their preserving effect shall be notified irrespective of their concentration.
- If the publication by the Danish Ministry of the Environment of the list of dangerous substances or annex VI of the CLP Regulation indicates lower limits than the above for the relevant substance contained or if the material is covered by the special marking regulations in annex 2 of the classification order issued by the Danish Ministry of the Environment or by annex II of the CLP Regulation with a lower percentage limit, these limits shall apply as regards when the substance contained shall be notified.
- If a substance may, at a lower limit than the above, effect requirements for a safety data sheet under article 31 of the REACH Regulation, these limits shall apply as regards when the substances contained shall be notified.

Materials manufactured through simple mixtures or through dilution for internal use in the company shall not be covered by the notification obligation.

For each substance and material for which notification is due, the following information shall be provided:

- 1. Information about the notifying company**
 - 1.1. Company name and address
 - 1.2. Company registration (CVR) number
 - 1.3. Contact person
 - 1.4. Whether the notifying person is himself a manufacturer of the substance or material, whether the notifying person has given the substance or material a new trade name or whether it concerns importation from the European Customs Union or importation from third countries.
 - 1.5. The supplier's and, possibly, the manufacturer's name and address in case of importation or change of trade name.
- 2. Information about the substance or material**
 - 2.1. Trade name
 - 2.2. Other designations (such as synonyms or trade name for individual goods in framework notifications)
 - 2.3. Original trade name in case of change of trade name
- 3. Information about the composition of the substance or material**
 - 3.1. Unambiguous chemical name and CAS no. for included substances
 - 3.2. Trade name, possibly PR no., composition and manufacturer of included substances (raw materials)
 - 3.3. Percentage content of included substances and materials

A connected group of materials may be notified as one in a framework notification if the individual materials only differ from one another through alternative content components. The percentage content may, possibly, be given with small variations reasoned in production technical conditions. Framework notification may be made only if the individual materials in the frame have the same danger marking, application area, code number, if relevant, and the same chemical-toxicological properties.

- 4. Information about the use of the substance or material**
 - 4.1. The technical function (preferably function codes) of the substance or material
 - 4.2. Industries where the substance/material is intended used (preferably industrial codes)
- 5. Quantity information for the substance or material**
 - 5.1. Manufactured or imported quantity per year
 - 5.2. This quantity distributed on the Danish market, exports or use in own business
- 6. Information about the classification/markings of the substance or material**
 - 6.1. Risk symbols, risk and safety sentences under the act on chemical substances and products (*lov om kemiske stoffer og produkter*) or in regulations issued pursuant hereto or risk classes, risk categories, signal words, risk sentences and safety sentences under the CLP Regulation.
- 7. Other information about the substance or the material**
 - 7.1. State at 20°C
 - 7.2. Customs tariff (for use in statistical contexts)
- 8. Information about confidentiality**
 - 8.1. Information that is requested to be treated as confidential, including a reason for this

The information will be handled confidentially according to the regulations in force.

Materials for which notification is not obligatory

Materials in liquid form covered by section 1(2)(iii) due to the content of:

- 1) titanium dioxide, CAS no. 13463-67-7;
 - 2) ferric oxide, CAS no. 13463-40-6;
 - 3) kaolin, respirable, CAS no. 1332-58-7;
 - 4) silicic acid, SiO₂, amorphous, CAS no. 1343-98-2; or
 - 5) silicic acid, SiO₂, amorphous, respirable, CAS no. 1343-98-2
- shall be exempted from section 9.