ANNEX-2

REQUIREMENTS FOR THE COMPILATION OF SAFETY DATA SHEETS

PART A

0.1. Introduction

0.1.1. This Annex sets out the requirements that the supplier shall fulfil for the compilation of a safety data sheet that is provided for a substance or a mixture in accordance with Article 27.

0.1.2. The information provided in the safety data sheet shall be consistent with the information in the chemical safety report, where one is required. Where a chemical safety report has been completed, the relevant exposure scenario(s) shall be placed in an annex to the safety data sheet.

0.2. General requirements for compiling a safety data sheet

0.2.1. The safety data sheet shall enable users to take the necessary measures relating to protection of human health and safety at the workplace, and protection of the environment. The writer of the safety data sheet shall take into account that a safety data sheet must inform its audience of the hazards of a substance or a mixture and provide information on the safe storage, handling and disposal of the substance or the mixture.

0.2.2. The information provided by safety data sheets shall also meet the requirements set out in By-law on Health and Safety Precautions for Working with Chemical Substances. In particular, the safety data sheet shall enable employers to determine whether any hazardous chemical agents are present in the workplace and to assess any risk to the health and safety of workers arising from their use.

0.2.3. The information in the safety data sheet shall be written in a clear and concise manner. The safety data sheet shall be prepared by a competent person who shall take into account the specific needs and knowledge of the user audience, as far as they are known. Suppliers of substances and mixtures shall ensure that such competent persons have received appropriate training, including refresher training.

0.2.4. The language used in the safety data sheet shall be simple, clear and precise, avoiding jargon, acronyms and abbreviations. Statements such as ‘may be dangerous’, ‘no health effects’, ‘safe under most conditions of use’ or ‘harmless’ or any other statements indicating that the substance or mixture is not hazardous or any other statements that are inconsistent with the classification of that substance or mixture shall not be used.

0.2.5. The date of compilation of the safety data sheet shall be given on the first page. When a safety data sheet has been revised and the new, revised version is provided to recipients, the changes shall be brought to the attention of the recipients in Section 16 of the safety data sheet, unless the changes have been indicated elsewhere. For the revised safety data sheets, the date of compilation, identified as ‘Revision: (date)’, as well as a version number, revision number, supersedes date or some other indication of what version is replaced shall appear on the first page.

0.3. Safety Data Sheet Format

0.3.1. A safety data sheet is not a fixed length document. The length of the safety data sheet shall be commensurate with the hazard of the substance or mixture and the information available.

0.3.2. All pages of a safety data sheet, including any annexes, shall be numbered and shall bear either an indication of the length of the safety data sheet (such as 'page 1 of 3') or an indication whether there is a page following (such as 'Continued on next page' or 'End of safety data sheet').

0.4. Safety Data Sheet Content

The information required by this Annex shall be included in the safety data sheet, where applicable and available, in the relevant subsections set out in Part B. The safety data sheet shall not contain blank subsections.

0.5. Other information requirements

The inclusion of additional relevant and available information in the relevant subsections may be necessary in some cases in view of the wide range of properties of substances and mixtures.

0.6. Units

The units of measurements as set out in By-law on International Unit System published in Official Gazette dated 21/6/2002 and numbered 24792 shall be used.

0.7. Special cases

Safety data sheets shall also be required for the special cases listed in paragraph 1.3 of Annex I to By-law on Classification, Labelling and Packaging of Substances and Mixtures for which there are labelling derogations.

1. SECTION 1: Identification of the substance/mixture and of the company/undertaking

This section of the safety data sheet shall prescribe how the substance or mixture shall be identified and how the identified relevant uses, the name of the supplier of the substance or mixture and the contact detail information of the supplier of the substance or mixture, including an emergency contact, shall be provided in the safety data sheet.

1.1. Product identifier

The product identifier shall be provided in accordance with Article 20 of By-law on Classification, Labelling and Packaging of Substances and Mixtures, and in Turkish. For substances subject to registration, the product identifier shall be consistent with that provided in the registration and the registration number assigned under Article 20(3) of this Regulation shall also be indicated.

Without affecting the obligations of downstream users laid down in Article 35 of this Regulation, the part of the registration number referring to the individual registrant of a joint submission may be omitted by a supplier who is a distributor or a downstream user provided that:

(a) this supplier assumes the responsibility to provide the full registration number upon request for enforcement purposes or, if the full registration number is not available to him, to forward the request to his supplier, in line with point (b); and

(b) this supplier provides the full registration number to the Member State authority responsible for enforcement (the enforcement authority) within 7 days upon request, received either directly from the enforcement authority or forwarded by his recipient, or, if the full registration number is not available to him, this supplier shall forward the request to his supplier within 7 days upon request and at the same time inform the enforcement authority thereof.

A single safety data sheet may be provided to cover more than one substance or mixture where the information in that safety data sheet fulfils the requirements of this Annex for each of those substances or mixtures.

Other means of identification

Other names or synonyms by which the substance or mixture is labelled or commonly known, such as alternative names, numbers, company product codes, or other unique identifiers may be provided.

1.2. **Relevant identified uses of the substance or mixture and uses advised against**

At least the identified uses relevant for the recipient(s) of the substance or mixture shall be indicated. This shall be a brief description of what the substance or mixture is intended to do, such as ‘flame retardant’, ‘antioxidant’.

The uses which the supplier advises against and the reasons why shall, where applicable, be stated. This need not be an exhaustive list.

Where a chemical safety report is required, the information in this subsection of the safety data sheet shall be consistent with the identified uses in the chemical safety report and the exposure scenarios from the chemical safety report set out in the annex to the safety data sheet.

1.3. **Details of the supplier of the safety data sheet**

The supplier and/or only representative shall be identified. The full address and telephone number of the supplier shall be given as well as an e-mail address for a competent person responsible for the safety data sheet.

For registrants, the information shall be consistent with the information on the identity of the manufacturer or importer provided in the registration.

Where an only representative has been appointed, details of the manufacturer or formulator outside Turkey may also be provided.

1.4. Emergency telephone number

References to emergency information services shall be provided. Emergency situation telephone number of the Ministry of Health National Poison Center shall be given. If availability of such services is limited for any reasons, such as hours of operation, or if there are limits on specific types of information provided, this shall be clearly stated.

2. SECTION 2: HAZARDS IDENTIFICATION

This section of the safety data sheet shall describe the hazards of the substance or mixture and the appropriate warning information associated with those hazards.

2.1. Classification of the substance or mixture

The classification of the substance or the mixture which results from the application of the classification criteria in By-law on Classification, Labelling and Packaging of Substances and Mixtures shall be given. Where the supplier has notified information regarding the substance to the classification and labelling inventory in accordance with Article 41 of the same By-law, the classification given in the safety data sheet shall be the same as the classification provided in that notification.

Classification of the mixture shall be given according to By-law on Classification, Labelling and Packaging of Substances and Mixtures. If the mixture does not meet the criteria for classification in accordance with the By-law, this shall be clearly stated. Information on the substances in the mixture is provided under subsection 3.2.

If the classification, including the hazard statements, is not written out in full, reference shall be made to Section 16 where the full text of each classification, including each hazard statement, shall be given.

The most important adverse physical, human health and environmental effects shall be listed in accordance with Sections 9 to 12 of the safety data sheet, in such a way as to allow non-experts to identify the hazards of the substance or mixture.

2.2. Label elements

Based on the classification, at least the following elements appearing on the label in accordance with By-law on Classification, Labelling and Packaging of Substances and Mixtures shall be provided: hazard pictogram(s), signal word(s), hazard statement(s) and precautionary statement(s). A graphical reproduction of the full hazard pictogram in black and white or a graphical reproduction of the symbol only may be substituted for the colour pictogram provided in the same By-law.

The applicable label elements of the same By-law shall be provided.

2.3. Other hazards

Information shall be provided on other hazards which do not result in classification but which may contribute to the overall hazards of the substance or mixture (such as formation of air contaminants during hardening or processing, dustiness, dust explosion hazards, cross-sensitisation, suffocation, freezing, high potency for odour or taste, or environmental effects like hazards to soil-dwelling organisms, or photochemical ozone creation potential). The statement 'May form explosible dust-air mixture if dispersed' is appropriate in the case of a dust explosion hazard.

3. SECTION 3: Composition/information on ingredients

This section of the safety data sheet shall describe the chemical identity of the ingredient(s) of the substance or mixture, including impurities and stabilising additives as set out below. Appropriate and available safety information on surface chemistry shall be indicated.

3.1. Substances

The chemical identity of the main constituent of the substance shall be provided by providing at least the product identifier or one of the other means of identification given in subsection 1.1. The chemical identity of any impurity, stabilising additive, or individual constituent other than the main constituent, which is itself classified and which contributes to the classification of the substance shall be provided as follows:

(a) the product identifier in accordance with Article 20 of By-law on Classification, Labelling and Packaging of Substances and Mixtures;

(b) if the product identifier is not available, one of the other names (usual name, trade name, abbreviation) or identification numbers.

Suppliers of substances may choose to list in addition all constituents including non-classified ones. This subsection may also be used to provide information on multi- constituent substances.

3.2. Mixtures

The product identifier, the concentration or concentration ranges and the classifications shall be provided for at least all substances referred to in points 3.2.1 or 3.2.2. Suppliers of mixtures may choose to list in addition all substances in the mixture, including substances not meeting the criteria for classification. This information shall enable the recipient to identify readily the hazards of the substances in the mixture. The hazards of the mixture itself shall be given in Section 2.

The concentrations of the substances in a mixture shall be described as either of the following:

(a) exact percentages in descending order by mass or volume, if technically possible;

(b) ranges of percentages in descending order by mass or volume, if technically possible.

When using a range of percentages, the health and environmental hazards shall describe the effects of the highest concentration of each ingredient.

If the effects of the mixture as a whole are available, this information shall be included under Section 2.

Where the use of an alternative chemical name is permitted in accordance with Article 26 of By-law on Classification, Labelling and Packaging of Substances and Mixtures, that name can be used.

3.2.1. For a mixture meeting the criteria for classification in accordance with By-law on Classification, Labelling and Packaging of Substances and Mixtures, the following substances shall be indicated, together with their concentration or concentration range in the mixture:
a) substances presenting a health or environmental hazard within the meaning of By-law on Classification, Labelling and Packaging of Substances and Mixtures, if those substances are present in concentrations equal to or greater than the lowest of any of the following:
ia) the generic cut-off values set out in Table 1.1 of Annex I to By-law on Classification, Labelling and Packaging of Substances and Mixtures;
ib) the generic concentration limits given in parts 3 to 5 of Annex I to By-law on Classification, Labelling and Packaging of Substances and Mixtures, taking into account the concentrations specified in the notes to certain tables in part 3 in relation to the obligation to make available a safety data sheet for the mixture upon request, and for aspiration hazard (Section 3.10 of Annex I to same By-law) ≥ 10 %;

List of hazard classes, hazard categories and concentration limits for which a substance shall be listed as a substance in a mixture in subsection 3.2

1.1 Hazard class and category	Concentration limit (%)
Acute toxicity, category 1, 2 and 3	≥ 0,1
Acute toxicity, category 4	≥ 1
Skin corrosion/irritation, category 1, sub-categories 1A, 1B, 1C and category 2	≥ 1
Serious damage to eyes/eye irritation, category 1 and 2	≥ 1
Respiratory/skin sensitisation	≥ 0,1
Germ cell mutagenicity category 1A and 1B	≥ 0,1
Germ cell mutagenicity category 2	≥ 1
Carcinogenicity category 1A, 1B and 2	≥ 0,1
Reproductive toxicity, category 1A, 1B, 2 and effects on or via lactation	≥ 0,1
Specific target organ toxicity (STOT) — single exposure, category 1 and 2	≥ 1
Specific target organ toxicity (STOT) — repeated exposure, category 1 and 2	≥ 1
Aspiration hazard	≥ 10
Hazardous to the aquatic environment — Acute, category 1	≥ 0,1
Hazardous to the aquatic environment — Chronic, category 1	≥ 0,1
Hazardous to the aquatic environment — Chronic, category 2, 3 and 4	≥ 1
Hazardous for the ozone layer	≥ 0,1

(ii) the specific concentration limits given in Part 3 of Annex VI to By-law on Classification, Labelling and Packaging of Substances and Mixtures,
(iii) if an M-factor has been given in Part 3 of Annex VI to By-law on Classification, Labelling and Packaging of Substances and Mixtures, the generic cut-off value in Table 1.1 of Annex I to that By-law, adjusted using the calculation set out in Section 4.1 of Annex I to that By-law,
(iv) the specific concentration limits provided to the classification and labelling inventory established under By-law on Classification, Labelling and Packaging of Substances and Mixtures,
(v) the concentration limits set out in Annex II to By-law on Classification, Labelling and Packaging of Substances and Mixtures,

(vi) if an M-factor has been provided to the classification and labelling inventory established under By-law on Classification, Labelling and Packaging of Substances and Mixtures, the generic cut-off value in Table 1.1 of Annex I to that By-law, adjusted using the calculation set out in Section 4.1 of Annex I to that By-law.
b) substances for which there are Union workplace exposure limits which are not already included under point (a);
c) substances that are persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII, or substances included in the list established in accordance with Article 49(1) for reasons other than the hazards referred to in point (a), if the concentration of an individual substance is equal to or greater than 0,1 %.

3.2.2. For a mixture not meeting the criteria for classification in accordance with By-law on Classification, Labelling and Packaging of Substances and Mixtures, substances present in an individual concentration equal to or greater than the following concentrations shall be indicated, together with their concentration or concentration range:
(a) 1 % by weight in non-gaseous mixtures and 0,2 % by volume in gaseous mixtures for:

(i) substances which present a health or environmental hazard within the meaning of By-law on Classification, Labelling and Packaging of Substances and Mixtures; or

(ii) substances for which Union workplace exposure limits have been assigned;

(b) 0,1 % by weight for substances which are persistent, bioaccumulative and toxic in accordance with the criteria set out in Annex 13, very persistent and very bioaccumulative in accordance with the criteria set out in Annex 13, or included in the list established in accordance with Article 49(1) for reasons other than the hazards referred to in point (a).

3.2.3. For the substances indicated in subsection 3.2, the classification of the substance according to By-law on Classification, Labelling and Packaging of Substances and Mixtures, including the hazard class(es) and category code(s) as provided in Table 1.1 of Annex VI to that Regulation as well as the hazard statements which are assigned in accordance with their physical, human health and environmental hazards, shall be provided. The hazard statements do not need to be written out in full in this section; their codes shall be sufficient. In cases where they are not written out in full, reference shall be made to Section 16, where the full text of each relevant hazard statement shall be listed. If the substance does not meet the classification criteria, the reason for indicating the substance in subsection 3.2 shall be described, such as ‘non-classified vPvB substance’ or ‘substance with a workplace exposure limit’.

3.2.4. For the substances indicated in subsection 3.2 the name and, if available, the registration number, as assigned under Article 20(3) of this By-law, shall be given.
Without affecting the obligations of downstream users laid down in Article 35 of this By-law, the part of the registration number referring to the individual registrant of a joint submission may be omitted by the supplier of the mixture provided that:

(a) this supplier assumes the responsibility to provide the full registration number upon request for enforcement purposes or, if the full registration number is not available to him, to forward the request to his supplier, in line with point (b); and
(b) this supplier provides the full registration number to the related institution within seven days upon request, received either directly from the enforcement authority or forwarded by his recipient, or, if the full registration number is not available to him, this supplier shall forward the request to his supplier within seven days upon request and at the same time inform the enforcement authority thereof.
The EC number, if available, shall be given in accordance with By-law on Classification, Labelling and Packaging of Substances and Mixtures. The CAS number, if available, and the IUPAC name, if available, may also be given.
For substances indicated in this subsection by means of an alternative chemical name in accordance with Article 26 of By-law on Classification, Labelling and Packaging of Substances and Mixtures, the registration number, EC number and other precise chemical identifiers are not necessary.

4. SECTION 4: First aid measures

This section of the safety data sheet shall describe the initial care in such a way that an untrained responder can understand and provide it without the use of sophisticated equipment and without the availability of a wide selection of medications. If medical attention is required, the instructions shall state this, including its urgency.

4.1. Description of first aid measures

4.1.1. First aid instructions shall be provided by relevant routes of exposure. Subdivisions shall be used to indicate the procedure for each route, such as inhalation, skin, eye and ingestion.
4.1.2. Advice shall be provided as to whether:

(a) immediate medical attention is required and if delayed effects can be expected after exposure;
(b) movement of the exposed individual from the area to fresh air is recommended;
(c) removal and handling of clothing and shoes from the individual is recommended; and
(ç) personal protective equipment for first aid responders is recommended.

4.2. Most important symptoms and effects, both acute and delayed

Briefly summarised information shall be provided on the most important symptoms and effects, both acute and delayed, from exposure.

4.3. Indication of any immediate medical attention and special treatment needed

Where appropriate, information shall be provided on clinical testing and medical monitoring for delayed effects, specific details on antidotes (where they are known) and contraindications. For some substances or mixtures, it may be important to emphasise that special means to provide specific and immediate treatment shall be available at the workplace.

5. SECTION 5: Firefighting measures

This section of the safety data sheet shall describe the requirements for fighting a fire caused by the substance or mixture, or arising in its vicinity.

5.1. Extinguishing media

Suitable extinguishing media:
Information shall be provided on the appropriate extinguishing media.
Unsuitable extinguishing media:
Indications shall be given whether any extinguishing media are inappropriate for a particular situation involving the substance or mixture.

5.2. Special hazards arising from the substance or mixture

Information shall be provided on hazards that may arise from the substance or mixture, like hazardous combustion products that form when the substance or mixture burns, such as 'may produce toxic fumes of carbon monoxide if burning' or 'produces oxides of sulphur and nitrogen on combustion'.

5.3. Advice for firefighters

Advice shall be provided on any protective actions to be taken during firefighting, such as 'keep containers cool with water spray', and on special protective equipment for firefighters, such as boots, overalls, gloves, eye and face protection and breathing apparatus.

6. SECTION 6: Accidental release measures

This section of the safety data sheet shall recommend the appropriate response to spills, leaks, or releases, to prevent or minimise the adverse effects on persons, property and the environment. It shall distinguish between responses to large and small spills, in cases where the spill volume has a significant impact on the hazard. If the procedures for containment and recovery indicate that different practices are required, these shall be indicated in the safety data sheet.

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel
Advice shall be provided related to accidental spills and release of the substance or mixture such as:
(a) the wearing of suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing;
(b) removal of ignition sources, provision of sufficient ventilation, control of dust; and
(c) emergency procedures such as the need to evacuate the danger area or to consult an expert.
6.1.2. For emergency responders
Advice shall be provided related to suitable fabric for personal protective clothing (such as 'appropriate: Butylene'; 'not appropriate: PVC').

6.2. Environmental precautions

Advice shall be provided on any environmental precautions to be taken related to accidental spills and release of the substance or mixture, such as keeping away from drains, surface and ground water.

6.3. Methods and material for containment and cleaning up

6.3.1. Appropriate advice shall be provided on how to contain a spill. Appropriate containment techniques may include any of the following:
(a) bunding, covering of drains;
(b) capping procedures.
6.3.2. Appropriate advice shall be provided on how to clean-up a spill. Appropriate clean-up procedures may include any of the following:
(a) neutralisation techniques;
(b) decontamination techniques;
(c) adsorbent materials;
(d) cleaning techniques;
(e) vacuuming techniques;
(f) equipment required for containment/clean-up (include the use of non-sparking tools and equipment where applicable).
6.3.3. Any other information shall be provided relating to spills and releases, including advice on inappropriate containment or clean-up techniques, such as by indications like 'never use …'.

6.4. Reference to other sections

If appropriate Sections 8 and 13 shall ve referred to.

7. SECTION 7: Handling and storage

This section of the safety data sheet shall provide advice on safe handling practices. It shall emphasise precautions that are appropriate to the identified uses referred to under subsection 1.2 and to the unique properties of the substance or mixture.
Information in this section of the safety data sheet shall relate to the protection of human health, safety and the environment. It shall assist the employer in devising suitable working procedures and organisational measures according to Article 7 of By-law on Health and Safety Precautions for Working with Chemical Substances and Article 7 of By-law on Health and Safety Precautions for Working with Carcinogens and Mutagens.
Where a chemical safety report is required, the information in this section of the safety data sheet shall be consistent with the information given for the identified uses in the chemical safety report and the exposure scenarios showing control of risk from the chemical safety report set out in the annex to the safety data sheet.
In addition to information given in this section, relevant information may also be found in Section 8.

7.1. Precautions for safe handling

7.1.1. Recommendatiions shall ve specified to:
(a) allow safe handling of the substance or mixture, such as containment and measures to prevent fire as well as aerosol and dust generation;

(b) prevent handling of incompatible substances or mixtures;
(c) draw attention to operations and conditions which create new risks by altering the properties of the substance or mixture, and to appropriate countermeasures; and
(ç) reduce the release of the substance or mixture to the environment, such as avoiding spills or keeping away from drains.
7.1.2. Advice on general occupational hygiene shall be provided, such as:
(a) not to eat, drink and smoke in work areas;
(b) to wash hands after use; and
(c) to remove contaminated clothing and protective equipment before entering eating areas.

7.2. Conditions for safe storage, including any incompatibilities

The advice provided shall be consistent with the physical and chemical properties described in Section 9 of the safety data sheet. If relevant, advice shall be provided on specific storage requirements including:
(a) how to manage risks associated with:
(i) explosive atmospheres;
(ii) corrosive conditions;
(iii) flammability hazards;
(iv) incompatible substances or mixtures;
(v) evaporative conditions; and
(vi) potential ignition sources (including electrical equipment);
(b) how to control the effects of:
(i) weather conditions;
(ii) ambient pressure;
(iii) temperature;
(iv) sunlight;
(v) humidity; and
(vi) vibration;
(c) how to maintain the integrity of the substance or mixture by the use of:
(i) stabilisers; and
(ii) antioxidants;
(d) other advice including:
(i) ventilation requirements;
(ii) specific designs for storage rooms or vessels (including retention walls and ventilation);
(iii) quantity limits under storage conditions (if relevant); and
(iv) packaging compatibilities.

7.3. Specific end use(s)

For substances and mixtures designed for specific end use(s), recommendations shall relate to the identified use(s) referred to in subsection 1.2 and be detailed and operational. If an exposure scenario is attached, reference to it may be made or the information as required in subsections 7.1 and 7.2 shall be provided. If an actor in the supply chain has carried out a chemical safety assessment for the mixture, it is sufficient that the safety data sheet and the exposure scenarios are consistent with the chemical safety report for the mixture, rather than with the chemical

safety reports for each substance in the mixture. If industry- or sector-specific guidance is available, detailed reference to it (including source and issuing date) may be made.

8. SECTION 8: Exposure control/personal protection

This section of the safety data sheet shall describe the applicable occupational exposure limits and necessary risk management measures.

Where a chemical safety report is required, the information in this section of the safety data sheet shall be consistent with the information given for the identified uses in the chemical safety report and the exposure scenarios showing control of risk from the chemical safety report set out in the annex to the safety data sheet.

8.1. Control parameters

8.1.1. Where available, the following national limit values, including the legal basis of each of them, shall be listed for the substance or for each of the substances in the mixture. When listing occupational exposure limit values, the chemical identity as specified in Section 3 shall be used:

8.1.1.1.The occupational exposure limit values in accordance with By-law on Health and Safety Precautions for Working with Chemical Substances;

8.1.1.2. The occupational exposure limit values in accordance with By-law on Health and Safety Precautions for Working with Carcinogens and Mutagens,

8.1.1.3. If available, any other national occupational exposure limit values,

8.1.1.4. Biological limit values in accordance with By-law on Health and Safety Precautions for Working with Chemical Substances,

8.1.1.5. If available, any other biological limit values.

8.1.2. Information on currently recommended monitoring procedures shall be provided at least for the most relevant substances

8.1.3. If air contaminants are formed when using the substance or mixture as intended, applicable occupational exposure limit values and/or biological limit values for these shall also be listed.

8.1.4. Where a chemical safety report is required or where a DNEL as referred to in Section 1.4 of Annex I or a PNEC as referred to in Section 3.3 of Annex I is available, the relevant DNELs and PNECs for the substance shall be given for the exposure scenarios from the chemical safety report set out in the annex to the safety data sheet.

8.1.5. Where a control banding approach is used to decide on risk management measures in relation to specific uses, sufficient detail shall be given to enable effective management of the risk. The context and limitations of the specific control banding recommendation shall be made clear.

8.2. Exposure controls

The information required in the present subsection shall be provided, unless an exposure scenario containing that information is attached to the safety data sheet.

Where the supplier has waived a test under Section 3 of Annex XI, he shall indicate the specific conditions of use relied on to justify the waiving.

Where a substance has been registered as an isolated intermediate (on-site or transported), the supplier shall indicate that this safety data sheet is consistent with the specific conditions relied on to justify the registration in accordance with Article 17 or 18.

8.2.1. Appropriate engineering controls

The description of appropriate exposure control measures shall relate to the identified use(s) of the substance or mixture as referred to in subsection 1.2. This information shall be sufficient to enable the employer to carry out an assessment of risk to the safety and health of workers arising from the presence of the substance or mixture in accordance with By-law on Health and Safety Precautions for Working with Chemical Substances and By-law on Health and Safety Precautions for Working with Carcinogens and Mutagens, where appropriate.
This information shall complement that already given under Section 7.

8.2.2. Individual protection measures, such as personal protective equipment

8.2.2.1. The information on use of personal protective equipment shall be consistent with good occupational hygiene practices and in conjunction with other control measures, including engineering controls, ventilation and isolation. Where appropriate, Section 5 shall be referred to for specific fire/chemical personal protective equipment advice.
8.2.2.2. Taking into account By-law on Personal Protective Equipment published in the Official Gazette dated 29/11/2006 and numbered 26361 and referring to the appropriate CEN standards, detailed specifications shall be given on which equipment will provide adequate and suitable protection, including:
(a) Eye/face protection
The type of eye/face protection equipment required shall be specified based on the hazard of the substance or mixture and potential for contact, such as safety glasses, safety goggles, face-shield.
(b) Skin protection
(i) Hand protection
The type of gloves to be worn when handling the substance or mixture shall be clearly specified based on the hazard of the substance or mixture and potential for contact and with regard to the amount and duration of dermal exposure, including:
— the type of material and its thickness,
— the typical or minimum breakthrough times of the glove material,
If necessary, any additional hand protection measures shall be indicated.
(ii) Other
If it is necessary to protect a part of the body other than the hands, the type and quality of protection equipment required shall be specified, such as gauntlets, boots, bodysuit based on the hazards associated with the substance or mixture and the potential for contact.
If necessary, any additional skin protection measures and specific hygiene measures shall be indicated.
(c) Respiratory protection
For gases, vapours, mist or dust, the type of protective equipment to be used shall be specified based on the hazard and potential for exposure, including air-purifying respirators, specifying

the proper purifying element (cartridge or canister), the adequate particulate filters and the adequate masks, or self-contained breathing apparatus.
(d) Thermal hazards
When specifying protective equipment to be worn for materials that represent a thermal hazard, special consideration shall be given to the construction of the personal protective equipment.

8.2.3. Environmental exposure controls

The information required by the employer to fulfil his commitments under environmental protection legislation shall be specified.
Where a chemical safety report is required, a summary of the risk management measures that adequately control exposure of the environment to the substance shall be given for the exposure scenarios set out in the annex to the safety data sheet.

9. SECTION 9: Physical and chemical properties

This section of the safety data sheet shall describe the empirical data relating to the substance or mixture, if relevant. Article 10(2) of By-law on Classification, Labelling and Packaging of Substances and Mixtures shall apply. The information in this section shall be consistent with the information provided in the registration and/or in the chemical safety report where required, and with the classification of the substance or mixture.

9.1. Information on basic physical and chemical properties

The following properties shall be clearly identified including, where appropriate, a reference to the test methods used and specification of appropriate units of measurement and/or reference conditions. If relevant for the interpretation of the numerical value, the method of determination shall also be provided (for example, the method for flash point, the open-cup/closed-cup method):
(a) Appearance:
The physical state (solid (including appropriate and available safety information on granulometry and specific surface area if not already specified elsewhere in this safety data sheet), liquid, gas) and the colour
(b) Odour:
If odour is perceptible, a brief description of it shall be given;
(c) Odour threshold;
(ç) pH:
The pH of the substance or mixture as supplied or of an aqueous solution shall be indicated; in the case of an aqueous solution, the concentration shall also be indicated;
(d) Melting point/freezing point;
(e) Initial boiling point and boiling range;
(f) Flash point;
(g) Evaporation rate;
(ğ) Flammability (solid, gas);
(h) Upper/lower flammability or explosive limits;
(ı) Vapour pressure;
(i) Vapour density;

(j) Relative density;
(k) Solubility(ies);
(l) Partition coefficient: n-octanol/water;
(m) Auto-ignition temperature;
(n) Decomposition temperature;
(o) Viscosity;
(ö) Explosive properties;
(p) Oxidising properties.

If it is stated that a particular property does not apply or if information on a particular property is not available, the reasons shall be given.
To enable proper control measures to be taken, all relevant information on the substance or mixture shall be provided. The information in this section shall be consistent with the information provided in a registration where one is required.
In the case of a mixture, the entries shall clearly indicate to which substance in the mixture the data apply, unless it is valid for the whole mixture.

9.2. Other information

Other physical and chemical parameters shall be indicated as necessary, such as miscibility, fat solubility (solvent — oil to be specified), conductivity, or gas group. Appropriate and available safety information on redox potential, radical formation potential and photocatalytic properties shall be indicated.

10. SECTION 10: Stability and reactivity

This section of the safety data sheet shall describe the stability of the substance or mixture and the possibility of hazardous reactions occurring under certain conditions of use and also if released into the environment, including, where appropriate, a reference to the test methods used. If it is stated that a particular property does not apply or if information on a particular property is not available, the reasons shall be given.

10.1. Reactivity

10.1.1. The reactivity hazards of the substance or mixture shall be described. Specific test data shall be provided for the substance or mixture as a whole, where available. However, the information may also be based on general data for the class or family of substance or mixture if such data adequately represent the anticipated hazard of the substance or mixture.
10.1.2. If data for mixtures are not available, data on substances in the mixture shall be provided. In determining incompatibility, the substances, containers and contaminants that the substance or mixture might be exposed to during transportation, storage and use shall be considered.

10.2. Chemical stability

It shall be indicated if the substance or mixture is stable or unstable under normal ambient and anticipated storage and handling conditions of temperature and pressure. Any stabilisers which are, or may need to be, used to maintain the chemical stability of the substance or mixture shall

be described. The safety significance of any change in the physical appearance of the substance or mixture shall be indicated.

10.3. Possibility of hazardous reactions

If relevant, it shall be stated if the substance or mixture will react or polymerise, releasing excess pressure or heat, or creating other hazardous conditions. The conditions under which the hazardous reactions may occur shall be described.

10.4. Conditions to avoid

Conditions such as temperature, pressure, light, shock, static discharge, vibrations or other physical stresses that might result in a hazardous situation shall be listed and if appropriate a brief description of measures to be taken to manage risks associated with such hazards shall be given.

10.5. Incompatible materials

Families of substances or mixtures or specific substances, such as water, air, acids, bases, oxidising agents, with which the substance or mixture could react to produce a hazardous situation (like an explosion, a release of toxic or flammable materials, or a liberation of excessive heat), shall be listed and if appropriate a brief description of measures to be taken to manage risks associated with such hazards shall be given.

10.6. Hazardous decomposition products

Known and reasonably anticipated hazardous decomposition products produced as a result of use, storage, spill and heating shall be listed. Hazardous combustion products shall be included in Section 5 of the safety data sheet.

11. SECTION 11: Toxicological information

This section of the safety data sheet is meant for use primarily by medical professionals, occupational health and safety professionals and toxicologists. A concise but complete and comprehensible description of the various toxicological (health) effects and the available data used to identify those effects shall be provided, including where appropriate information on toxicokinetics, metabolism and distribution. The information in this section shall be consistent with the information provided in the registration and/or in the chemical safety report where required, and with the classification of the substance or mixture.

11.1. Information on toxicological effects

The relevant hazard classes, for which information shall be provided, are:
(a) acute toxicity;
(b) skin corrosion/irritation;
(c) serious eye damage/irritation;
(d) respiratory or skin sensitisation;
(e) germ cell mutagenicity;
(f) carcinogenicity;
(g) reproductive toxicity;

(h) STOT-single exposure;
(i) STOT-repeated exposure;
(j) aspiration hazard.

For substances subject to registration, brief summaries of the information derived from the application of Annexes VII to XI shall be given, including, where appropriate, a reference to the test methods used. For substances subject to registration, the information shall also include the result of the comparison of the available data with the criteria given in By-law on Classification, Labelling and Packaging of Substances and Mixtures for CMR, categories 1A and 1B, following point 1.3.1 of Annex I to this By-law.

11.1.1 Information shall be provided for each hazard class or differentiation. If it is stated that the substance or mixture is not classified for a particular hazard class or differentiation, the safety data sheet shall clearly state whether this is due to lack of data, technical impossibility to obtain the data, inconclusive data or data which are conclusive although insufficient for classification; in the latter case the safety data sheet shall specify 'based on available data, the classification criteria are not met'.

11.1.2 The data included in this subsection shall apply to the substance or mixture as placed on the market. In the case of a mixture, the data should describe the toxicological properties of the mixture as a whole, except if Article 8(3) of By-law on Classification, Labelling and Packaging of Substances and Mixtures applies. If available, the relevant toxicological properties of the hazardous substances in a mixture shall also be provided, such as the LD50, acute toxicity estimates or LC50.

11.1.3. Where there is a substantial amount of test data on the substance or mixture, it may be necessary to summarise results of the critical studies used, for example, by route of exposure.

11.1.4. Where the classification criteria for a particular hazard class are not met, information supporting this conclusion shall be provided.

11.1.5. Information on likely routes of exposure
Information shall be provided on likely routes of exposure and the effects of the substance or mixture via each possible route of exposure, that is, through ingestion (swallowing), inhalation or skin/eye exposure. If health effects are not known, this shall be stated.

11.1.6. Symptoms related to the physical, chemical and toxicological characteristics:
Potential adverse health effects and symptoms associated with exposure to the substance or mixture and its ingredients or known by-products shall be described. Available information shall be provided on the symptoms related to the physical, chemical, and toxicological characteristics of the substance or mixture following exposure. The first symptoms at low exposures through to the consequences of severe exposure shall be described. (For example 'headaches and dizziness may occur, proceeding to fainting or unconsciousness; large doses may result in coma and death').

11.1.7. Delayed and immediate effects as well as chronic effects from short and long-term exposure:
Information shall be provided on whether delayed or immediate effects can be expected after short- or long-term exposure. Information on acute and chronic health effects relating to human exposure to the substance or mixture shall also be provided. Where human data are not available, animal data shall be summarised and the species clearly identified. It shall be indicated whether toxicological data is based on human or animal data.

11.1.8. Interactive effects:
Information on interactions shall be included if relevant and available.

11.1.9. Absence of specific data:
It may not always be possible to obtain information on the hazards of a substance or mixture. In cases where data on the specific substance or mixture are not available, data on similar substances or mixtures, if appropriate, may be used, provided the relevant similar substance or mixture is identified. Where specific data are not used, or where data are not available, this shall be clearly stated.

11.1.10. Mixtures:
For a given health effect, if a mixture has not been tested for its health effects as a whole, relevant information on relevant substances listed under Section 3 shall be provided.

11.1.11 Mixtures versus substance information

11.1.11.1. The substances in a mixture may interact with each other in the body, resulting in different rates of absorption, metabolism and excretion. As a result, the toxic actions may be altered and the overall toxicity of the mixture may be different from that of the substances in it. This shall be taken into account when providing toxicological information in this section of the safety data sheet.

11.1.11.2. It is necessary to consider whether the concentration of each substance is sufficient to contribute to the overall health effects of the mixture. The information on toxic effects shall be presented for each substance, except for the following cases:
(a) if the information is duplicated, it shall be listed only once for the mixture overall, such as when two substances both cause vomiting and diarrhoea;
(b) if it is unlikely that these effects will occur at the concentrations present, such as when a mild irritant is diluted to below a certain concentration in a non-irritant solution;
(c) where information on interactions between substances in a mixture is not available, assumptions shall not be made and instead the health effects of each substance shall be listed separately.
11.1.12. Other information:
Other relevant information on adverse health effects shall be included even when not required by the classification criteria.

12. SECTION 12: Ecological information

This section of the safety data sheet shall provide information to enable evaluation of the environmental impact of the substance or mixture where it is released to the environment. Subsections 12.1, 12.2, 12.3, 12.4, 12.5 and 12.6 of the safety data sheet shall provide a short summary of the data including, where available, relevant test data and clearly indicating species, media, units, test duration and test conditions. This information may assist in handling spills, and evaluating waste treatment practices, control of release, accidental release measures and transport. If it is stated that a particular property does not apply or if information on a particular property is not available, the reasons shall be indicated.

Some properties are substance specific, i.e. bioaccumulation, persistence and degradability, and that information shall be given, where available and appropriate, for each relevant substance in the mixture. Information shall also be provided for hazardous transformation products arising from the degradation of substances and mixtures.

The information in this section shall be consistent with the information provided in the registration and/or in the chemical safety report where required, and with the classification of the substance or mixture.

12.1. Toxicity

Information on toxicity using data from tests performed on aquatic and/or terrestrial organisms shall be provided when available. This shall include relevant available data on aquatic toxicity, both acute and chronic for fish, crustaceans, algae and other aquatic plants. In addition, toxicity data on soil micro- and macroorganisms and other environmentally relevant organisms, such as birds, bees and plants, shall be included when available. Where the substance or mixture has inhibitory effects on the activity of microorganisms, the possible impact on sewage treatment plants shall be mentioned.

For substances subject to registration, summaries of the information derived from the application of Annexes VII to XI of this Regulation shall be included.

12.2. Persistence and degradability

Persistence and degradability is the potential for the substance or the appropriate substances in a mixture to degrade in the environment, either through biodegradation or other processes, such as oxidation or hydrolysis. Test results relevant to assess persistence and degradability shall be given where available. If degradation half-lives are quoted it must be indicated whether these half-lives refer to mineralisation or to primary degradation. The potential of the substance or certain substances in a mixture to degrade in sewage treatment plants shall also be mentioned.

This information shall be given where available and appropriate, for each individual substance in the mixture which is required to be listed in Section 3 of the safety data sheet.

12.3. Bioaccumulation potential

Bioaccumulative potential is the potential of the substance or certain substances in a mixture to accumulate in biota and, eventually, to pass through the food chain. Test results relevant to assess the bioaccumulative potential shall be given. This shall include reference to the octanol-water partition coefficient (Kow) and bioconcentration factor (BCF), if available.

This information shall be given where available and appropriate, for each individual substance in the mixture which is required to be listed in Section 3 of the safety data sheet.

12.4. Mobility in soil

Mobility in soil is the potential of the substance or the components of a mixture, if released to the environment, to move under natural forces to the groundwater or to a distance from the site of release. The potential for mobility in soil shall be given where available. Information on mobility in soil can be determined from relevant mobility data such as adsorption studies or leaching studies, known or predicted distribution to environmental compartments, or surface tension. For example, Koc values can be predicted from octanol/water partition coefficients (Kow). Leaching and mobility can be predicted from models.
This information shall be given where available and appropriate, for each individual substance in the mixture which is required to be listed in Section 3 of the safety data sheet.
Where experimental data is available, that data shall, in general, take precedence over models and predictions.

12.5. Results of PBT ve vPvB assessment

Where a chemical safety report is required, the results of the PBT and vPvB assessment as set out in the chemical safety report shall be given.

12.6. Other adverse effects

Information on any other adverse effects on the environment shall be included where available, such as environmental fate (exposure), photochemical ozone creation potential, ozone depletion potential, endocrine-disrupting potential and/or global warming potential.

13. SECTION 13: Disposal considerations

This section of the safety data sheet shall provide information for proper waste management of the substance or mixture and/or its container to assist in the determination of safe and environmentally preferred waste management options, consistent with the requirements of waste management legislation. Information relevant for the safety of persons conducting waste management activities shall complement the information given in Section 8.
Where a chemical safety report is required and where a waste stage analysis has been performed, the information on the waste management measures shall be consistent with the identified uses in the chemical safety report and the exposure scenarios from the chemical safety report set out in the annex to the safety data sheet.

13.1. Waste treatment methods

This subsection of the safety data sheet shall:
(a) specify waste treatment containers and methods including the appropriate methods of waste treatment of both the substance or mixture and any contaminated packaging (for example, incineration, recycling, landfilling);
(b) specify the physical/chemical properties that may affect waste treatment options;
(c) discourage sewage disposal;

(ç) Iidentify, where appropriate, any special precautions for any recommended waste treatment option.
Any relevant waste management legislation in force shall be referred to.

14. SECTION 14: Transport Information

This section of the safety data sheet shall provide basic classification information for the transport/shipment of substances or mixtures mentioned in Section 1 by road, rail, sea, inland waterways or air. Where such information is not available or relevant this shall be stated.
Where relevant, this section shall provide information on the transport classification for each of the UN Model Regulations: the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR), the Regulations concerning the International Carriage of Dangerous Goods by Rail (RID) and the European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (ADN), the International Maritime Dangerous Goods (IMDG) Code (sea) and the Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO)(air).

14.1. UN number

The UN number (i.e. the four-figure identification number of the substance, mixture or article preceded by the letters 'UN') from the UN Model Regulations shall be provided.

14.2. UN proper shipping name

The UN proper shipping name from the UN Model Regulations shall be provided, unless it was used as the product identifier in subsection 1.1.

14.3. Transport hazard class(es)

The transport hazard class (and subsidiary risks) assigned to the substances or mixtures on the basis of the predominant hazard that they present according to the UN Model Regulations shall be provided.

14.4. Packing group

The packing group number from the UN Model Regulations shall be provided, if applicable. The packing group number is assigned to certain substances in accordance with their degree of hazard.

14.5. Environmental hazards

It shall be indicated whether the substance or mixture is environmentally hazardous according to the criteria of the UN Model Regulations (as reflected in the IMDG Code, ADR, RID and ADN) and/or a marine pollutant according to the IMDG Code. If the substance or mixture is authorised or intended for carriage by inland waterways in tank-vessels, it shall be indicated whether the substance or mixture is environmentally hazardous in tank-vessels only according to the ADN.

14.6. Special precautions for user

Information shall be provided on any special precautions which a user should or must take or be aware of in connection with transport or conveyance either within or outside his premises.

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

This subsection only applies when cargoes are intended to be carried in bulk according to the following IMO instruments: Annex II of International Convention for the Prevention of Pollution from Ships (MARPOL 73/78) and the International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk (IBC Code).

The product name shall be provided (if different from that given in subsection 1.1) as required by the shipment document and in accordance with the name used in the lists of product names given in chapters 17 or 18 of the IBC Code or the latest edition of the IMO's Maritime Environment Protection Committee (MEPC).2/Circular. Ship type required and pollution category shall be indicated.

15. SECTION 15: Regulatory information

This section of the safety data sheet shall describe the other regulatory information on the substance or mixture that is not already provided in the safety data sheet (such as whether the substance or mixture is subject to by-law on substances that deplete the ozone layer , legislation on persistent organic pollutants or legislation concerning the export and import of dangerous chemicals).

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Information shall be provided regarding relevant safety, health and environmental provisions (for example, By-law on Prevention of Major Industrial Accidents and Reduction of Their Impact published in the Officical Gazette dated 31/12/2013 and numbered 28867), including advice on action that should be taken by the recipient as a result of these provisions.

If the substance or mixture covered by this safety data sheet is the subject of specific provisions in relation to the protection of human health or the environment (such as authorisations or restrictions) these provisions shall be mentioned.

15.2. Chemical Safety Assessment

This subsection of the safety data sheet shall indicate whether the supplier has carried out a chemical safety assessment for the substance or the mixture.

16. SECTION 16: Other information

This section of the safety data sheet shall contain other information that is not included in Sections 1 to 15, including information on the revision of the safety data sheet such as:
(a) in the case of a revised safety data sheet, a clear indication of where changes have been made to the previous version of the safety data sheet, unless such indication is given elsewhere in the safety data sheet, with an explanation of the changes, if appropriate. A supplier of a substance or mixture shall be able to provide an explanation of the changes upon request;

(b) a key or legend to abbreviations and acronyms used in the safety data sheet;
(c) key literature references and sources for data;
(ç) in the case of mixtures, an indication of which of the methods of evaluating information referred to in Article 11 of By-law on Classification, Labelling and Packaging of Substances and Mixtures was used for the purpose of classification;
(d) a list of relevant hazard statements and/or precautionary statements. Write out the full text of any statements which are not written out in full under Sections 2 to 15;
(e) advice on any training appropriate for workers to ensure protection of human health and the environment.

PART B

The safety data sheet shall include the following 16 headings in accordance with Article 27(5) and in addition the subheadings also listed except Section 3, where only subsections 3.1 or 3.2 need to be included as appropriate:

SECTION 1: Identification of the substcnes/mixture and of the company/undertaking
- 1.1. Product identifier
- 1.2. Relevant identified uses of the substances or mixture and uses advised against
- 1.3. Details of the supplier of the safety data sheet
- 1.4. Emergency telephone number

SECTION 2: Hazards identification
- 2.1. Classification of the substance or mixture
- 2.2. Label elements
- 2.3. Other hazards

SECTION 3: Composition/information on ingredients
- 3.1. Substances
- 3.2. Mixtures

SECTION 4: First aid measures
- 4.1. Description of first aid measures
- 4.2. Most important symptoms and effects, both acute and delayed
- 4.3. Indication of any immediate medical attention and special treatment needed

SECTION 5: Firefighting measures
- 5.1. Extinguishing media
- 5.2. Special hazards arising from the substance or mixture
- 5.3. Advice for firefighters

SECTION 6: Accidental release measures
- 6.1. Personal precautions, protective equipment and emergency procedures
- 6.2. Environmental precautions
- 6.3. Methods and material for containment and cleaning up
- 6.4. Reference to other sections

SECTION 7: Handling and storage
- 7.1. Precautions for safe handling
- 7.2. Conditions for safe storage, including any incompatibilities