Commission Regulation (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (Text with EEA relevance)

COMMISSION REGULATION (EU) 2020/878

of 18 June 2020

amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC[(1)], and in particular Article 131 thereof,

Whereas:

(1) Annex II to Regulation (EC) No 1907/2006 lays down requirements for the compilation of safety data sheets, used to provide information on chemical substances and mixtures in the Union.

(2) As of 1 January 2020, Commission Regulation (EU) 2018/1881[(2)] amending Annexes I, III and VI to XII to Regulation (EC) No 1907/2006 shall apply. Regulation (EU) 2018/1881 introduces specific requirements for nanoforms of substances. As information related to those requirements is to be included in the safety data sheets, Annex II to Regulation (EC) No 1907/2006 should be modified accordingly.

(3) The Globally Harmonised System of Classification and Labelling of Chemicals (GHS) developed in the framework of the United Nations, sets out internationally harmonised criteria for the classification and labelling of chemicals and rules on safety data sheets. The Union confirmed its intention to incorporate the GHS criteria into Union law.

(4) The instruments foreseen by GHS to communicate the hazards of substances and mixtures are labels and safety data sheets. The GHS provisions on safety data sheets are included in Regulation (EC) No 1907/2006. Therefore, the requirements for safety data sheets laid down in Annex II to Regulation (EC) No 1907/2006 should be adapted to the rules for safety data sheets of the sixth and seventh revision of the GHS.

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2020/878. (See end of Document for details)*

(5) Annex VIII to Regulation (EC) No 1272/2008 of the European Parliament and of the Council[3] will allow, inter alia, the possibility that the unique formula identifier be indicated only in the safety data sheet as regards hazardous mixtures supplied for use at industrial sites. It will also require for certain mixtures which are not packaged that the unique formula identifier be indicated in the safety data sheet. For reasons of consistency, Annex II to Regulation (EC) No 1907/2006 should reflect those changes and indicate where the unique formula identifier should appear in the safety data sheet.

(6) The Commission Communication of 7 November 2018'Towards a comprehensive European Union framework on endocrine disruptors'[4] indicates that the Commission is assessing how to improve the communication through the supply chain for endocrine disruptors under Regulation (EC) No 1907/2006 in the context of the work on safety data sheets. A number of specific requirements for safety data sheets have been identified as relevant for substances and mixtures with endocrine disrupting properties and Annex II of this Regulation should therefore be modified accordingly.

(7) Specific concentration limits, multiplying factors and acute toxicity estimates set in accordance with Regulation (EC) No 1272/2008, are relevant for the safe use of substances and mixtures, and should therefore be provided in safety data sheets, if available.

(8) Requiring economic operators who have already compiled safety data sheets, to update them immediately in accordance with the provisions of this Regulation would impose a disproportionate burden on them. Operators should rather be allowed to continue providing safety data sheets in accordance with Regulation (EC) No 1907/2006, as amended by Commission Regulation (EU) 2015/830[5] for a certain period. This is without prejudice to the obligation to update the safety data sheets in accordance with Article 31(9) of Regulation (EC) No 1907/2006, and to the cases where the unique formula identifier is added to safety data sheets as provided for in section 5 of Part A of Annex VIII to Regulation (EC) No 1272/2008.

(9) The measures provided for in this Regulation are in accordance with the opinion of the Committee established under Article 133 of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS REGULATION:

Article 1

Annex II to Regulation (EC) No 1907/2006 is replaced by the text in the Annex to this Regulation.

Article 2

By way of derogation from Article 3, safety data sheets not complying with the Annex to this Regulation may continue to be provided until 31 December 2022.

Article 3

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 January 2021.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 18 June 2020.

For the Commission

The President

Ursula VON DER LEYEN

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2020/878. (See end of Document for details)*

ANNEX

ANNEX II

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 31.

0.1.2. The information on substances provided in the safety data sheet shall be consistent with the information in the registration and in the chemical safety report, where 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.

0.1.3. The safety data sheet shall mention in each relevant section whether and which different nanoforms it covers and link the relevant safety information to each of those nanoforms. As provided for in Annex VI, the term "nanoform" in this Annex refers to a nanoform or a set of similar nanoforms.

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 Directive 98/24/EC. 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)", shall appear on the first page, as well as one

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or more indications of which version is replaced, such as version number, revision number, or supersedes date.

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.

Additional safety and environmental information is required to address the needs of seafarers and other transport workers in the bulk transport of dangerous goods in sea-going or inland navigation bulk carriers or tank-vessels subject to International Maritime Organisation (IMO) or national regulations. Subsection 14.7 recommends the inclusion of basic classification information when such cargoes are transported in bulk according to the relevant IMO instruments. In addition, ships carrying oil or oil fuel, as defined in Annex I of MARPOL[(6)], in bulk or bunkering oil fuel are required, before loading, to be provided with a "material safety data sheet" in accordance with the IMO's Maritime Safety Committee (MSC) resolution "Recommendations for Material Safety Data Sheets (MSDS) for MARPOL Annex I Oil Cargo and Oil Fuel" (MSC.286(86)). Therefore, in order to have one harmonised safety data sheet for maritime and non-maritime use, the additional provisions of Resolution MSC.286(86) may be included in the safety data sheets, where appropriate, for marine transport of MARPOL Annex I cargoes and marine fuel oils.

0.6. **Units**

The units of measurement as set out in Council Directive 80/181/EEC[(7)] 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 Regulation (EC) No 1272/2008 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**