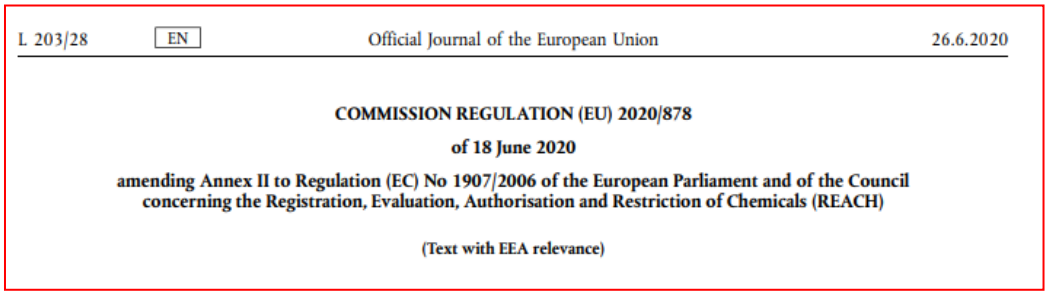
NEWSLETTER JULY 2020

REACH

NEW REGULATION (EU) n. 2020/878: ANNEX II AMENDMENT



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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 Regulation (EU) n. 2020/878, amending the Annex II of the Regulation (EC) n. 1907/2006 (REACH) about the Safety Data Sheet editing, has been published. The Regulation will replace the **Regulation (EU) n. 2015/830**, still in force, until the 1st January 2021.

However, the Regulation establishes a transitional period since 31th December 2022: until this date, SDSs that do not comply with the new Annex II may continue to be provided; beyond this date, all SDSs have to be updated.

The latest version of the text in all the official languages of the Union can be consulted at the link below:
https://eur-lex.europa.eu/legal-content/IT/TXT/?qid=1594197520400&uri=CELEX:32020R0878

SAFETY DATA SHEET MODIFICATIONS

In brief, the main modifications of the content of SDS as per the new regulation are here reported. This is not an exhaustive list of all modifications. In order to update your SDS at the best, we suggest to read carefully the content of the new regulation or call our experts for consultancy.

Section 1: identification of the substance / mixture and of the company / undertaking- Product identifier

The supplier has the right to provide UFI in the SDS; if it does the code must be entered in this section.
However, it is mandatory to provide the Unique Formula Identifier (UFI) in cases where the supplier is authorized to waive the obligation to print or place the UFI on the label of a dangerous mixture (industrial use and for mixtures which are not packaged).
More information about UFI code can be consulted at the link below:
https://poisoncentres.echa.europa.eu/ufi-generator

NEWSLETTER JULY 2020

Section 2: Hazards Identification - Other Hazards

You are asked to indicate whether the substance has been included in the REACH Candidate List (substances so-called SVHC) according to Art. 59.1 of REACH due to properties of interference with the endocrine system (ED), as well as whether the substance is a substance identified as having properties of interference with the endocrine system in accordance with the criteria established in the Commission Delegated Regulation (EU) 2017/2100 or in the Commission Regulation (EU) 2018/605.

For a mixture it is necessary to provide information for each of the substances present in the mixture in concentrations equal to or greater than 0.1% by weight.

Section 3: Composition / information on ingredients - substances

If available, it is necessary to indicate the specific concentration limit, the M factor and the estimate of acute toxicity for the substances included in Part 3 of Annex VI of Regulation (EC) 1272/2008 (CLP) or determined in accordance with Annex I of this Regulation.

If the substance is registered and concerns a nano-form, the characteristics of the particles that specify the nano-form must be indicated, as described in Annex VI of REACH. If the substance is not registered, but the SDS concerns nano-forms whose particle characteristics affect the safety of the substance, these characteristics must be indicated.

Section 3: Composition / information on ingredients - mixtures

Some limits for the insertion among the mixture components have been explicated. The aspiration toxicity limit has been **lowered from 10% to 1%**

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

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, categories 1A, 1B, 1C and category 2	≥ 1
Serious damage to eyes/eye irritation, category 1 and 2	≥ 1
Respiratory sensitiser category 1 or category 1B	≥ 0,1
Respiratory sensitiser category 1A	≥ 0,01
Skin sensitiser category 1 or category 1B	≥ 0,1
Skin sensitiser category 1A	≥ 0,01
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, 2 and 3	≥ 1
Specific target organ toxicity (STOT) – repeated exposure, category 1 and 2	≥ 1
Aspiration toxicity	≥ 1
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

Section 9: Physical and Chemical Properties

Information to be provided regarding the physical and chemical properties of the substance or mixture has to be reviewed.

The Regulation provides a better explanation of the physical and chemical entries. Moreover, section 9.2 “other information” has been expanded. Please find here a table summarizing such end-points.

9.1. Information on basic physical and chemical properties

(a) Physical state
(b) Colour
(c) Odour
(d) Melting point/freezing point
(e) Boiling point or initial boiling point and boiling range
(f) Flammability
(g) Lower and upper explosion limit
(h) Flash point
(i) Auto-ignition temperature
(j) Decomposition temperature
(k) pH
(l) Kinematic viscosity
(m) Solubility
(n) Partition coefficient n-octanol/water (log value)
(o) Vapour pressure
(p) Density and/or relative density
(q) Relative vapour density
(r) Particle characteristics

9.2. Other information

9.2.1. Information with regard to physical hazard classes
(a) Explosives
(b) Flammable gases
(c) Aerosols
(d) Oxidizing gases
(e) Gases under pressure
(f) Flammable liquids
(g) Flammable solids
(h) Self-reactive substances and mixtures
(i) Pyrophoric liquids
(j) Pyrophoric solids
(k) Self-heating substances and mixtures
(l) Substances and mixtures, which emit flammable gases in contact with water
(m) Oxidizing liquids
(n) Oxidizing solids
(o) Organic peroxides
(p) Corrosive to metals
(q) Desensitized explosives

9.2.2. Other safety characteristics

(a) mechanical sensitivity;
(b) self-accelerating polymerization temperature;
(c) formation of explosive dust/air mixtures;
(d) acid/alkaline reserve;
(e) evaporation rate;
(f) miscibility;
(g) conductivity;
(h) corrosiveness;
(i) gas group;
(j) redox potential;
(k) radical formation potential;
(l) photocatalytic properties.

Section 10: Stability and Reactivity - Chemical Stability / Conditions to Avoid

New information requirements are added for desensitized explosives.

Section 11: Toxicological Information - Information on Other Hazards

Information on adverse health effects caused by substances identified as having **endocrine disrupting properties** should be provided.

11.2	**Information on other hazards**
11.2.1.	*Endocrine disrupting properties* Information on adverse health effects caused by endocrine disrupting properties shall be provided, where available, for the substances identified as having endocrine disrupting properties in Subsection 2.3. This information shall consist of brief summaries of the information derived from application of the assessment criteria laid down in the corresponding Regulations ((EC) No 1907/2006, (EU) 2017/2100, (EU) 2018/605), that is relevant to assess endocrine disrupting properties for human health.

Section 12: Ecological Information

The conditions for generating data relevant to ecological information are changed. In addition, suppliers are required to provide information on the negative environmental effects caused by substances identified as having **endocrine disrupting properties**.

12.6.	**Endocrine disrupting properties** Information on adverse effects on the environment caused by endocrine disrupting properties shall be provided where available, for the substances identified as having endocrine disrupting properties in subsection 2.3. This information shall consist of brief summaries of the information derived from application of the assessment criteria laid down in the corresponding Regulations ((EC) No 1907/2006, (EU) 2017/2100, (EU) 2018/605), that is relevant to assess endocrine disrupting properties for the environment.

Section 14: Transport information

Various information requirements are introduced regarding the transport / shipping of mixtures.

Section 15: Regulatory information - Specific health, safety and environmental laws and regulations for the substance or mixture

In cases where the substance or mixture is subject to authorization pursuant to Title VII of REACH, information must be provided on the possible conditions and monitoring provisions imposed on the downstream user.

15.1.	**Safety, health and environmental regulations/legislation specific for the substance or mixture**
	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 at Union level (such as authorisations given under Title VII or restrictions under Title VIII) these provisions shall be mentioned. Where an authorisation granted under Title VII imposes conditions or monitoring arrangements to a downstream user of the substance or mixture, they shall be provided.

General comment and advices

The process of updating regularly the SDS content and preparation criteria is still progressing with this last regulation related to the REACH Annex II content. Safety Data Sheets (**SDSs**) were first regulated by Directive EEC n. 91/155 (March 5, 1991) which defines, in application of EC Directive EEC 88/379 (Council Directive 88/379/EEC of 7 June 1988 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labeling of dangerous preparations), the criteria of specific safety information regarding the dangerous preparations (now mixtures). Such pieces of regulation were strictly correlated with and consequence of the "*mother*" European Directive EEC n. 67/548 (June 27, 1967) regarding the safety of chemical substances and preparation. From that period lots of directives included criteria and requirements to study and classify the chemical substances and chemical preparations as well as to make the Risk Assessment during use. All these Directive have been incorporated in the last three pillars of the actual system (REACH, CLP. Reg. and regulation concerning SDS – REACH Annex II and following amendments). After the REACH Regulation application (2007), three new "SDS" regulations were delivered to update REACH Annex II: Reg. EU 453/2010 (May 20, 2010); EU Reg. n. 830/2015 (May 28, 2015) and this last. Within 10 years……. 3 regulations!

All along these last 30 years of SDS and SDS related regulations, the content of SDS became progressively more demanding in terms of data/information to be provided along the supply chain. This is due to the fact that Reach regulation imposes, generally speaking, the registration of the substances following their experimental evaluation and data production. The driven concept of the legislators is the following: a substance undergoes experimental testing and therefore all these data must be reported on the related SDS. BUT, as we all know, an SDS is requested also for substances (or mixtures) that does not go to experimental testing or not full experimental testing. Let's make three cases:

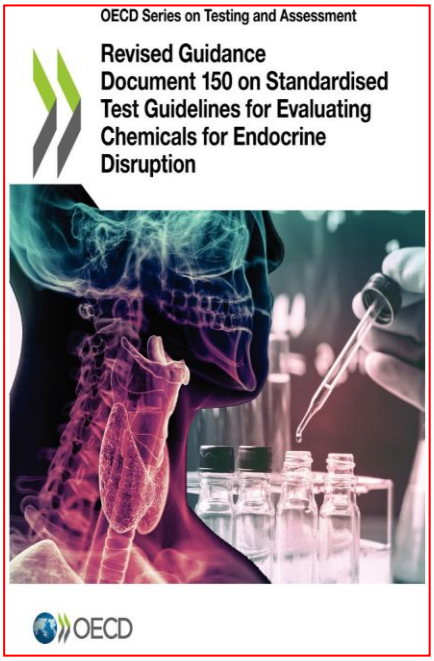
ACTIVE PHARMACEUTICAL INGREDIENTS (APIs) (bulk ingredients). They are not covered by registration requirements as already covered by the pharmaceutical regulations but, when marketed, they need to have the related SDS (Title IV of Reach Regulation: Information along the supply chain). In this case, no experimental testing is done to comply with Reach registration; safety data can be found with robust data search but in many cases such data are not published as confidential or not available in particular for the environmental effects. The SDS will be lacking for such information.

ISOLATED INTERMEDIATE SUBSTANCES (registered under SCC). These substances can be registered as for Art. 17 or 18 (on site or transported) with "*available data*". The focal point of the registration is the containment by technical means under SCC. Such substances very often (always) do not have any data. Also in this case the SDS will be lacking of such information.

MIXTURES. Mixtures are, in most cases, not directly tested for their own specific toxicological of environmental properties with the exception of agrochemical and biocide products. Classification can be done by the calculation method based on safety profile of each component. It's normal to report in the various sections a huge list of studies for each component supporting the calculation method approach. Are we sure this is the most robust scientific approach?

The crucial issue is that of standardizing the information to be included in the Safety Data Sheet and consequently, the quality of the information transmitted along the supply chain to the end-user. Last but not least, the approach that a REACH Inspector will adopt when inspecting a SDS is not harmonized. We had experience of different approaches; from a very formal "check the list" approach: the SDS is available and updated regularly up to a very precise check of all information written in the document. We expect that REACH Inspector will evaluate the content of SDS considering correctly the type of substance and its use. A SDS of an intermediate substance will never by similar in terms of content with that of a substance with dispersive use.

Last consideration is related to the scientific content of the SDS. As you realize from this Newsletter, a utmost attention is given to the ED (Endocrine Disrupting) properties of the substance especially and correctly under Section 2 (Hazard identification), Section 11 (Toxicological Information) and Section 12 (Ecological information). The evaluation of the ED properties is a huge scientific activity including specific testing methods addressed to understand the mechanism of action of the substance both for human health and for environmental species (vertebrate and invertebrate animals). Such evaluation must be done in accordance with the criteria established in the Commission Delegated Regulation (EU) 2017/2100 (Biocides) or in the Commission Regulation (EU) 2018/605 (Pesticide) as well as other specific guidance such as **OECD 150** framework guideline on *Standardized test Guidelines for evaluating Chemical for Endocrine Disruption* (see following figure).



Understanding if a substance or a component of a mixture can have ED properties represents an important burden to industry. Furthermore, substances like intermediates will not have any data concerning this end-point. API (Active Pharmaceutical Ingredients), again, will not have any data or few data regarding the environmental impact as this is not typical research approach in the pharmaceutical industry. A "*liason*" will be possible with the so called ERA (Environmental Risk Assessment) of Medicine Product as already requested by a EMA guidance since 2006. A new guidance is now expected by the end of 2020.

We can conclude that the preparation of a SDS will increasingly be a multidisciplinary work and scientifically sound work. Not a single person will be able to cover all requirements but a team of experts including toxicologists, eco-toxicologists, risk assessors, chemists, HSE managers and occupational doctors.

End of the newsletter