

Siemens Gamesa Renewable Energy

List of substance regulations in chemicals, materials and articles.

At Siemens Gamesa Renewable Energy we are committed to improve the protection of human health and the environment through limiting the use of hazardous substances in chemicals, materials and articles and substituting to less hazardous substances where it is technically possible.

In countries around the world substance regulations have been implemented to restrict and prohibit use of harmful substances and here below you will find a list of some of the legal requirements that products supplied to Siemens Gamesa shall comply with.

The list is **not a complete list of all global legislations**. As an example, substances and chemical products are regulated in national legislations all over the world.

As a supplier of components and chemicals to Siemens Gamesa you will see below a list the legal requirements with a short description.

The legal list is divided into 3 Chapters:

Chapter 1: Regulation of mixture and articles

Chapter 2: Regulation of Products/Articles

Chapter 3: Siemens Gamesa Prohibited and Restricted list (global)

You will in Chapter 2 find a list of EU legal requirements for articles and sub-articles, which shall be complied with for products to be allowed on the EU market.

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1 Regulation of mixtures and articles

1.1 EU REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals)

1.1.1 REACH Annex XVII Restriction List

Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles.

- Example Asbestos: The manufacture, placing on the market and use of these fibers and of articles and mixtures containing these fibers added intentionally is prohibited.

The list is available on ECHA website: <https://echa.europa.eu/substances-restricted-under-reach>

1.1.2 Candidate List of substances of very high concern for Authorisation

The Candidate list contain Substances of very high concern (SVHC) and is updated every ½ year with additional substances. Substances on the candidate list contained in mixtures and articles shall be informed to downstream users and there is requirement for notification by import to EU. The substances are candidates for the REACH Authorisation list

The REACH Candidate list: <https://echa.europa.eu/candidate-list-table>

1.1.3 Authorisation list Annex XIV

Authorisation is required for the use of a substance included in Annex XIV of REACH, either on its own or in a mixture.

Link to REACH Authorisation list Annex XIV <https://echa.europa.eu/authorisation-list>

1.1.4 REACH registration of substance when manufactured or imported into EU

Potential manufacturers and importers of substances must submit an inquiry to ECHA and register the substance before they can manufacture or import the substance.

More information here: <https://echa.europa.eu/en/regulations/reach/registration>

And exemptions from registration here:

https://echa.europa.eu/documents/10162/13655/reach_factsheet_on_communication_obligation_en.pdf

1.2 Great Britain – UK REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals)

1.2.1 Restriction in mixtures and in articles under UK REACH.

Limitation, ban or set conditions on the manufacture, placing on the market or use of a substance or group of substances

Link here: <https://www.hse.gov.uk/reach/restrictions.htm>

1.2.2 Registration of substances manufactured or imported into Great Britain

Any GB-based legal entity intending to manufacture or import a substance into GB at or above 1 tonne per year is required to submit a registration to the Agency for that substance. Registration is per substance, per legal entity.

<https://www.hse.gov.uk/reach/new-registration.htm>

1.3 USA Chemical regulations

— 1.3.1 Toxic Substances Control Act (TSCA)

Chemical Substance Inventory contains all existing chemical substances manufactured, processed, or imported in the United States that do not qualify for an exemption or exclusion under TSCA.

More information on TSCA: <https://www.epa.gov/tsca-inventory>

1.3.2 Proposition 65 (California, USA)

The list contains a wide range of naturally occurring and synthetic chemicals that are known to cause cancer or birth defects or other reproductive harm.

More information here: <https://oehha.ca.gov/proposition-65/proposition-65-list>

1.4 Global legal requirement

1.4.1 Fluorinated gas (greenhouse gas)

Fluorinated gases (F-gases) are powerful greenhouse gases, with a global warming effect up to 23000 times greater than carbon dioxide (CO₂). To limit emission there are global regulatory actions to control F-gases as part of policies to combat climate change.

Countries have regulations to limit use and import of Fluorinated gases in bulk and inside equipment, which also include reporting of imported quantities of fluorinated and other greenhouse gases.

EU List of the F-gases

Limitation and prohibition is available in the F-gas regulation: https://ec.europa.eu/clima/policies/f-gas/legislation_en

In the EU F-gas regulation there are reporting requirements for different kind of F-gases listed in the regulation. Reporting of F-gas (bulk and in equipment) are required when importing F-gas in bulk or inside equipment:

- Into EU from non-EU countries also from Great Britain
- Into Great Britain countries outside Great Britain also import from EU

USA legal requirement on Greenhouse gases

Limitation and report requirements to producers, suppliers and importers of greenhouse gas also inside equipment into USA.

Find more on EPA USA website: <https://www.epa.gov/ghgreporting/fluorinated-greenhouse-gas-emissions-and-supplies-reported-ghgrp>

1.4.2 Ozone depleting gas

World governments agreed in the late 1980s to protect the Earth's ozone layer by phasing out ozone-depleting substances emitted by human activities, under the Montreal Protocol.

Global action taken under the Montreal Protocol has halted the depletion of the ozone layer and allowed it to start recovering, but much remains to be done to ensure a steady recovery.

In general, ozone-depleting substances are banned altogether, but there are some exemptions that allow and control the use of such substances in certain specific applications where there are no feasible alternatives.

EU Ozone regulation

- In Europe, the Protocol is implemented in the EU 'Ozone Regulation' – [Regulation \(EC\) 1005/2009 on substances that deplete the ozone layer](#).

Link to find more information of the EU Ozone regulation:

https://ec.europa.eu/clima/policies/ozone/regulation_en

2 Regulation of Products/Articles

Legal requirements on articles – and sub-articles, this include components, spareparts, single parts.

REACH: "An article is an object which during production is given a special shape surface or design which determines its function to a larger degree than does its chemical composition"

More information here: <https://echa.europa.eu/-/guidance-on-requirements-for-substances-in-articles>

2.1 REACH Candidate List Substances in Articles (components)

Producers, distributors and importers of products (articles), placed on the EU marked, containing SVHC substances (Substances of very high Concern) listed in the Candidate list have according to REACH Art. 33 a duty to inform of the SVHC to customers and downstream users.

The information must as a minimum contain the information:

CAS no. and Substances name > 0,1 w/w %

Directive [REACH Art. 33 "Duty to communicate information on SVHC in articles"](#) (obligation since 2007)

Substances of very high concern is listed in the [REACH Candidate list](#) the list is updated with new substances every ½ year, in July and January (more than 200 substances on the list).

2.2 SCIP database (Substances of Concern in Products)

Producers, distributors and importers of products (articles), placed on the EU marked, containing SVHC substances (Substances of very high Concern) listed in the Candidate list have according to the Waste Directive (2018) an obligation to register products in the SCIP database when placed on the EU market. The legal requirement is applicable from 5 January 2021 and forward for products containing SVHC.

SCIP (Substances of Concern in Products) registration must be done per legal entity.

The SCIP number of a registered product, if there will be no changes to the product, can be forwarded and used by downstream users of complex articles.

Suppliers from outside of EU cannot register in the SCIP database and the obligation must be taken over by “only representative” in EU or the importer.

More information SCIP database: <https://echa.europa.eu/da/scip>

2.3 Batteries also inside equipment

Producers and importers of all batteries have producer responsibility when placing batteries, also inside equipment, on the EU/EEA market.

Some of the requirements in the Battery Directive 2006/66/EC (and amendments):

- Restriction of substances in batteries – Mercury, Lead and Cadmium
- Labelling with cross over bin and info of substances in the battery e.g. Pb
- Designs easy to remove and replace batteries
- Report quantities of batteries placed yearly on the market and pay per kg (finance the waste handling)
- Take-back obligation of batteries

The legal obligations of batteries and the directive is available in this link:

https://ec.europa.eu/environment/topics/waste-and-recycling/batteries-and-accumulators_en

Substances maximum concentration in the battery:

- Cadmium/cadmium compounds 0.001 % by weight (10 ppm) of battery
- Mercury/mercury compounds 0.0001% by weight (1 ppm) of battery
- Lead/lead compounds 0.004% by weight (40 ppm) of battery
- Perchlorates 0.0000006% by weight (6 ppb) of battery

2.4 Electrical Electronic Equipment (EEE)

Restriction of Certain Hazardous Substances in electrical electronic equipment (RoHS). The scope of RoHS is to restrict certain hazardous substances in electrical electronic equipment. Many countries have implemented their own RoHS regulation and please find a list here to ensure compliance with the regulation:

<https://www.rohsguide.com/rohs-future.htm>

REACH Candidate Substances in Articles is also applicable for electrical electronic equipment and therefore also the REACH Art. 33 Duty to inform – please see section 2.1

2.4.1 RoHS 3 (EU 2015/863) – EU RoHS

The EU RoHS:

- Restriction of Certain Hazardous Substances (RoHS) Directive 2011/65/EU as amended by Directive (EU) 2015/863 of March 2015)
- The European RoHS 3 (EU Directive 2015/863)

EU RoHS specifies maximum levels for 10 restricted substances. The first six applied to the original RoHS while the last four were added under RoHS 3, which took effect July 22, 2019. Many of the substances listed in RoHS 3 are also listed in:

- [REACH list of SVHC \(Substances of Very High Concern\)](#) and therefore also included in the “REACH Art. 33 Duty to inform customer” requirement and,
- [REACH restriction list XVII](#) and therefore may have further restrictions.

Electrical Electronic Equipment in the scope of the EU RoHS are prohibited in the EU market, if the product contains substances listed in the RoHS 3 exceeding the thresholds. If there is no exemption in the RoHS directive for the specific product.

EU RoHS list of restricted substances:

- Cadmium (Cd): < 100 ppm
- Lead (Pb): < 1000 ppm
- Mercury (Hg): < 1000 ppm
- Hexavalent Chromium: (Cr VI) < 1000 ppm
- Polybrominated Biphenyls (PBB): < 1000 ppm
- Polybrominated Diphenyl Ethers (PBDE): < 1000 ppm
- Bis(2-Ethylhexyl) phthalate (DEHP): < 1000 ppm
- Benzyl butyl phthalate (BBP): < 1000 ppm
- Dibutyl phthalate (DBP): < 1000 ppm
- Diisobutyl phthalate (DIBP): < 1000 ppm

2.4.2 WEEE Waste of electrical and electronic equipment

The Producer, importer and distributor of electrical and electronic equipment (EEE) has a legal obligation to finance, organize the collection, waste management and recycling of the products it places on the market (Producer responsibility).

The producer responsibility includes registration and reporting categories and quantities to competent authorities in the countries the EEE is placed on the market. In most EU countries the reporting will be yearly.

The WEEE directive has divided the EEE in 6 categories, implementation in the EU countries could include more categories.

More information on the WEEE directive: https://ec.europa.eu/environment/topics/waste-and-recycling/waste-electrical-and-electronic-equipment-weee_en

3 Siemens Gamesa Prohibited and Restricted list (global)

For products supplied to SGRE, this is detailing the list of products that are Prohibited or Restricted in SGRE. The lists are founded in the classification of the chemical products based on the [Globally Harmonized System](#) under United Nations.

The Prohibited and Restricted Lists are developed based on the following.

| Selection Principles | |
|-------------------------------------|--|
| Prohibited List | Classifications as Fatal or Toxic to health Classifications with irreversible effects Classifications as carcinogenic, mutagenic or reproductive toxic as these are internationally recognized to raise significant concern regarding human health ¹ Significant health classifications where the exposure risk is related to inhalation |
| Restricted List | Classifications to health one level down compared to the prohibited list Most severe environmental classifications |
| General Preventive Principle | For all other products a general preventive principle is followed, which also corresponds to the legal requirements in many countries. This means that the less hazardous product has to be chosen for the task and rejection of products is accepted if there is a less hazardous product with the applicable properties available – also if it is not on the Prohibited or the Restricted list. |

3.1 Prohibited list

Classification refer to the product classification

| Hazard Class | Category | | GHS pictogram | Hazard Statement | Hazard Code |
|--------------------------------|-----------|-------------------|---|--|-------------------|
| Acute Toxicity | 1,2 | Oral |  | Fatal if swallowed | H300 |
| | 3 | Oral | | Toxic if swallowed | H301 |
| | 1,2 | Dermal | | Fatal in contact with skin | H310 |
| | 3 | Dermal | | Toxic in contact with skin | H311 |
| | 1,2 | Inhalation | | Fatal if inhaled | H330 |
| | 3 | Inhalation | | Toxic if inhaled | H331 |
| Respiratory Sensitisation | 1, 1A, 1B | Inhalation |  | May cause allergy or asthma symptoms or breathing difficulties if inhaled | H334 |
| Germ Cell Mutagenicity | 1A, 1B | - |  | May cause genetic defects | H340 |
| Carcinogenicity | 1A, 1B | - | | May cause cancer | H350 ² |
| Reproductive toxicity | 1A, 1B | - | | May damage fertility or the unborn child | H360 ² |
| Specific target organ toxicity | 1 | Single exposure |  | Causes damage to organs | H370 |
| | 1 | Repeated exposure | | Causes damage to organs through prolonged or repeated exposure (inhalation only) | H372 |

¹ See e.g. [ECHA Substances of Very High Concern](#) (EU), [IARC](#), (USA)

² Including any sub-category; e.g. by the letters d, f, i, F, D and combinations hereof.

Any additional national or regional classifications that corresponds to the selection principles above, but in another classification system are also to be considered as prohibited.

Currently this applies:

| GHS pictogram | Hazard Statement | Hazard Code |
|---------------|---|-------------|
| - | Toxic by eye contact | EUH070 |
| - | Contact with acids liberates very toxic gas | EUH032 |

3.2 Restricted list

Classification refer to the product classification

| Hazard Class | Category | GHS pictogram | Hazard Statement | Hazard Code |
|--|-----------|---------------|--|-------------------|
| Germ Cell Mutagenicity | 2 | | Suspected of causing genetic defects | H341 |
| Carcinogenicity | 2 | | Suspected of causing cancer | H351 |
| Reproductive toxicity | 2 | | Suspected of damaging fertility or the unborn child | H361 ² |
| Skin Sensitisation | 1, 1A, 1B | | May cause an allergic skin reaction | H317 |
| Specific target organ toxicity | 1 | | Causes damage to organs through prolonged or repeated exposure (other exposures than inhalation) | H372 |
| Hazardous to the aquatic environment (acute) | Acute 1 | | Very toxic to aquatic life | H400 |
| Hazardous to the aquatic environment (chronic) | Chronic 1 | | Very toxic to aquatic life with long lasting effects | H410 |
| Hazardous to the ozone layer | 1 | | Harms public health and the environment by destroying ozone in the upper atmosphere | H420 |

Products are also considered Restricted if they contain substances of the following:

| Involved substance | Explanation |
|--|---|
| Chemical products with substances on the REACH Candidate List | <p>Applicable for EU.</p> <p>This list contains specific substances with names and CAS numbers.</p> <p>The list is regularly updated and announced at http://echa.europa.eu/web/guest/candidate-list-table</p> |