

Regulations on REACH and CLP, SVHC substances

Principal procedures

TRIBOTECC GmbH focusses on meeting the requirements contained in the REACH and CLP regulations. Thus, TRIBOTECC has established a Chemical Regulatory Compliance group a few years ago.

TRIBOTECC will comply with the REACH and CLP regulations as for all other chemical legislations relevant to TRIBOTECC's business. TRIBOTECC will not use any non-compliant substances within its products.

Some information like the exact chemical identity and composition of our substances and preparations is confidential business information and therefore must not be published.

Pre-Registration

TRIBOTECC has (pre) registered all relevant substances requiring registration at the European Chemical Agency (ECHA), including both substances produced within the EU and substances or mixtures imported into the EU.

There is no obligation according to the REACH regulation to communicate pre-registration numbers and registration deadlines along the supply chain.

The pre-registration process entitles TRIBOTECC to use the transitional periods stipulated in the REACH regulation (latest 31 May 2018). The transitional period depends on manufactured/imported volume band. Through this pre-registration, TRIBOTECC has ensured continuity of delivery to its customers.

Substances are only to be (pre)registered if they are produced and/or imported in quantities of ≥ 1 t/year. Many TRIBOTECC products contain substances which are exempt from the REACH regulation, like natural substances, polymers, articles, reaction products, neutralisation products etc. Mixtures do not need to be (pre)registered. Therefore, not each substance produced or sold has been (pre)registered.

For substances which TRIBOTECC does not produce or import, but purchases, TRIBOTECC is a downstream user. Tribotecc's up-stream suppliers are responsible for the pre-registration and registration of the supplied raw materials. Even in the case that suppliers have given their intention to register, this is not legally binding.

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Registration

Building on pre-registration, TRIBOTECC intends to register all relevant substances by 2018.

TRIBOTECC has successfully registered all substances which have been identified for registration by 30 November 2010 and 31 May 2013.

The registration numbers of TRIBOTECC substances are listed in chapter 3 of the updated Material Safety Data Sheet of the respective TRIBOTECC product. No additional communication of the registration number is legally required.

Registration of a substance by TRIBOTECC will generally result in a revised Material Safety Data Sheet. The REACH registration number is listed in chapter 1 and/or 3 of the MSDS.

For substances which TRIBOTECC does not produce or import, but purchases, TRIBOTECC will receive the registration numbers from its suppliers. These registration numbers are also listed in the updated Material Safety Data Sheet of the respective TRIBOTECC product. Lower volume producers or importers have an extended registration deadline (2018, at the latest). Hence, these companies are still legitimate suppliers even if their substances do not have a registration number yet.

The availability of the registration number of purchased raw materials is not considered a major change and will therefore not necessarily trigger an immediate update of the Material Safety Data Sheet. In addition, there may be several steps in the supply chain between registrant and all downstream users resulting in unavoidable delays for the according information to be listed within the updated Material Safety Data Sheet.

The Chemical Regulatory Compliance Group of Tribotecc has started to compile registration dossiers for substances requiring registration by 31 May 2018, at the latest.

SVHC substances – Substances of very high concern

The European Chemicals Agency (ECHA) publishes regular proposals to identify chemicals as Substances of Very High Concern (SVHC). The outcome of this process is a list of identified substances which are candidates for prioritisation (the “Candidate List”). Substances included in the Candidate List are possible candidates for authorisation.

http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp

The listing of a substance on the Candidate List does not automatically lead to authorisation and gives no indication of the risks which might result from the use of the substance within the supply chain. Only if a candidate substance is then officially listed in Annex XIV of the REACH regulation, the use of the substance becomes liable to authorisation after a certain transitional period.

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As soon as the ECHA decision on new candidate substances is officially published, TRIBOTECC will check its products as to whether or not they contain these substances. If TRIBOTECC products contain substances from the Candidate List, they will be listed in section 3 of the MSDS as hazardous ingredients, including information on the concentration in the mixture. These substances need only be listed in the MSDS where the concentration is above 0.1%. In addition the substance is named in chapter 15 as a substance of the Candidate List. This addition to chapter 15 is not a significant change of the MSDS and will be done within the next update.

There is no additional requirement for further communication on SVHC substances.

Authorisation

Any decision concerning the inclusion of a substance from the Candidate List in the Authorisation List (Annex XIV) will be published on the ECHA homepage.

<http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/authorisation-list>

Safe Use within the lifecycle (CSA/CSR)

A Chemical Safety Report (CSR) has to be created for substances which require registration and are manufactured or imported above 10 tonnes per year.

Main elements of the CSR are exposure scenarios for identified uses. Within the exposure scenarios, the manufacturer or importer recommends risk reduction measures to down-stream users. Any identified usages have been collected in close co-operation with our customers and associations. The Use Descriptors according to ECHA Guidance R12 are being used.

For substances which have already been registered with ECHA, any relevant exposure scenario is taken into consideration.

The communication of exposure scenarios in the annex of the extended Safety Data Sheet (eSDS) applies currently mostly for single substances. For mixtures, the applicable risk reduction measures are communicated within the 16 sections of the Safety Data Sheet. This is currently necessary because exposure scenarios are not always available for all substances in mixtures and any contradictory or inappropriate information on the mixture from exposure scenarios of single substances is to be avoided.

If customer usages are not sufficiently included within these standard exposure scenarios, it is strongly recommended that missing usages are reported to Tribotecc by referring to the listed ECHA Use Descriptors. This will help Tribotecc to include missing usages into Tribotecc's usage communication along the supply chain.

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Some specific Use Descriptors may be included in more generic ones.

Non-hazardous substances do not require a quantified detailed CSR, therefore, a qualitative exposure assessment is sufficient.

CLP Regulation (Regulation on Classification, Labelling and Packaging of Substances and Mixtures)

The CLP Regulation will ultimately replace the current rules on Classification, Labelling and Packaging of Substances (Directive 67/548/EEC) and Preparations (Directive 1999/45/EC) after the transitional periods given in the regulation.

TRIBOTECC will meet the deadlines for classification and labelling described in the CLP Regulation.

Substances have been classified according to the CLP Regulation since 1 December 2010. The transitional period for mixtures ended on 1 June 2015.

Extended transitional periods are valid for re-labelling and new packaging of substances or mixtures which are placed on the market before expiration of the respective deadline. This means that products manufactured before expiration of the deadlines are allowed to be placed on the market with the current labels for the period of two years after expiration of the deadline. The postponed deadline for mixtures is 1 June 2017.

C&L Inventory

Manufacturers and importers who place a hazardous substance on the market will also have to notify certain information to ECHA, in particular the identity, classification and labelling of that substance, according to Article 40 of the CLP Regulation, which will be included in the Classification and Labelling Inventory.

TRIBOTECC has already notified all relevant substances to the C&L Inventory by December 1st, 2010 and has, ever since, been performing notifications for any substances that have been manufactured/imported and placed on the market.

Changes in classification and labelling of notified substances trigger an update of the C&L Inventory notification.

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