COMPLIANCE

Frequently asked questions

The European biotrade regulatory framework

GUIDE

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Questions and answers

This FAQ is part of a series of knowledge products produced by ABioSA. These knowledge products and other biotrade resources can be found at www.abs-biotrade.info/projects/abiosa/resources

A glossary of biotrade terms can be found at www.abs-biotrade.info/resources

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CLP - EC Regulation 1907/2006 – Classification, Labelling and Packaging

Does CLP apply to me?

CLP applies to you if you manufacture, import, use or distribute chemical substances or mixtures. You must classify, label and package any substance or mixture - regardless of its annual tonnage - in accordance with the CLP regulation. This must be done before you place it on the EU market. Placing a substance or mixture on the market means making it physically available to third parties, whether in return for payment or free of charge.

If you are a manufacturer or importer, you are required under CLP to classify substances that are subject to registration or notification in line with Article 7 or 9 of REACH. This must be done even if you do not place them on the market, and includes steps such as the classification of substances that are used for product and process-orientated research and development (PPORD).

If you are a manufacturer or importer, you must notify the Classification and Labelling Inventory (established by the European Chemicals Agency (ECHA)) of hazardous substances above certain applicable concentration limits that you place on the market, whether on their own or contained in hazardous mixtures. This must be done regardless of the annual tonnage manufactured or imported, as well as for substances you place on the market subject to registration under REACH. However, the duty to notify does not apply where you have already submitted the information which is relevant for a notification under CLP as part of a registration.

What is GHS?

GHS is the Globally Harmonized System of classification and labelling of chemicals. It provides a basis for uniform physical, environmental, health and safety information on hazardous chemicals at a global level through the harmonisation of the classification criteria, labelling rules and guidance on the preparation of Safety Data Sheets.

The GHS is developed and maintained by the United Nations, with the aim of avoiding different information requirements on hazards for the same chemicals around the world. In addition, it also aims to facilitate trade; by applying GHS across different countries, it is no longer necessary for an exported chemical to be reclassified and relabelled in order to comply with different classification criteria, labelling rules and Safety Data Sheet requirements of the importing country.

For further information on the development of the UN GHS, please visit the United Nations Economic Commission for Europe's **website**. (ECHA, n.d.)

What is the difference between GHS and CLP?

The GHS was implemented through European Economic Community legislation in the form of EC Regulation 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP Regulation). This regulation is legally binding and directly applicable in the Member States of the EU, whereas GHS is not legally binding.

GHS and CLP are not identical, as CLP is also based on the old EU legislation on classification and labelling, i.e. the Dangerous Substances Directive 67/548/EEC (DSD) and the Dangerous Preparations Directive 1999/45/EC (DPD).

Additionally, based on the so-called UN GHS "building block approach", CLP does not include all the hazard categories included for a hazard class because they were not part of DSD, e.g. category 4 of the hazard class 'flammable liquids', or category 3 of the hazard class 'skin corrosion/irritation'. CLP includes special labelling and packaging rules that are not part of the UN GHS, but which were brought over from the DSD and DPD, e.g. the rules on small packaging (CLP Article 29), on supplemental information for certain mixtures (Part 2 of Annex II to CLP), and for the provision of child-resistant fastenings or tactile warnings. It also includes rules for the eventuality where a substance is covered both by CLP and by transport legislation (CLP Article 33).

It should be noted that in contrast to the UN GHS, CLP does not include specific rules on Safety Data Sheets, as they are already regulated by REACH through its Article 31 and Annex II (ECHA, n.d.).

Where can I find the consolidated version of the CLP regulation?

You can find the latest consolidated version of CLP via the ECHA **website**. It should be noted that the text has no legal value; for legal compliance, please refer to the texts published in the ***Official Journal of the European Union*** (ECHA, n.d.).

Do pure essential oils need to be labelled in accordance with the CLP regulation?

The obligations under CLP apply to any hazardous substance or mixture that is not regulated by product-specific EU legislation with more specific rules on classification and labelling.

Pure essential oils are placed on the market for several different uses. They may, for example, be intended for use as a cosmetic product. The intended use will determine whether a particular product is subject to product-specific legislation.

If a pure essential oil falls under the definition of a cosmetic product, the product also has to fulfil all the requirements of the Cosmetic Products Regulation (CPR, EC Regulation 1223/2009).

A cosmetic product is excluded from the scope of CLP if all of the following three conditions are met:

1. The product falls within the definition of a cosmetic product according to the CPR. If the CPR applies, all requirements set out in that regulation have to be fulfilled, otherwise the cosmetic product will be considered as non-compliant. This means that - among other things - the cosmetic product must have been assessed, and notification of its properties must have been provided, as outlined in Article 10 and Article 13 of the CPR respectively. It must be fully labelled in accordance with the regulation, with the appropriate label information and instructions for use.
2. At the moment of placing the product on the market, the product is intended for the end user, i.e., either a consumer or professional ultimately using the cosmetic product.
3. The product is in the finished state, i.e., its final formulation, as placed on the market and made available to the end user.

In fulfilling all of the above, the cosmetic product would be meeting the conditions for exemption provided for in Article 1(5) of CLP, i.e., being in the finished state and intended for use by the final user. The obligation to label an essential oil in accordance with CLP applies unless the product is outside the scope of CLP. To be outside the scope of CLP, the product must be covered by any of the product-specific pieces of legislation specified in Article 1(5) of CLP, must have undergone the processes defined in the relevant regulation or directive, and at the moment of placing the product on the market, it must be in its finished state and intended for use by the final user (ECHA, n.d.).

Do cosmetic products have to be classified and notified to the Classification and Labelling Inventory?

Similar to other substances and mixtures referred to in Article 1(5) of CLP which are in the finished state and intended for use by the final user, substances and mixtures in the form of cosmetic products - as defined in the Cosmetic Products Regulation (CPR, EU Regulation 1223/2009) - are not covered by the provisions of CLP. However, for substances that are manufactured or imported in volumes of at least one tonne per year, either on their own or contained in a mixture, requirements for classification (but not labelling or packaging) may still apply under REACH, as such substances may need to be registered.

Substances or mixtures intended for use in cosmetic products, but which are not yet in the finished state or intended for use by the final user, are covered by the provisions of CLP. Therefore, the suppliers of these products must classify, label and package them accordingly.

Further, these manufacturers or importers are obliged to notify the relevant substances in line with the provisions on notification to the Classification and Labelling Inventory, unless they have already registered the substance under REACH (ECHA, n.d.).

Where can I find the updated version of Table 3.1 of Annex VI to CLP?

The European Commission issues Adaptations to Technical Progress (ATPs) to the CLP regulation, which provides updates to the Harmonized Classification and Labelling in Table 3.1 of Annex VI to CLP. The updated version of this table is included in the Classification and Labelling Inventory managed by ECHA.

ECHA has prepared an unofficial **Excel table** containing all updates to the Harmonized Classification and Labelling in Table 3.1 of Annex VI to CLP. The table should be used for informative purposes only, as it may contain inconsistencies with the legally binding entries in Annex VI to CLP, as published in the ***Official Journal of the European Union*** (ECHA, n.d.).

If a substance is subject to 'Harmonized Classification', do I have to classify it for the hazards which are not covered by the entry in Part 3 of Annex VI?

Yes. A substance listed in Annex VI must be classified in accordance with the entry in Part 3 of Annex VI. Further, the manufacturer, importer or downstream user of such a substance has to carry out a self-classification - in accordance with Title II for those hazard classes or differentiations - where no 'Harmonized Classification' is contained in the entry in Part 3 of Annex VI. For example, a substance may have a 'Harmonized Classification' for acute oral toxicity, but not for acute dermal toxicity. This means that a supplier would have to explore whether the classification criteria for acute dermal toxicity are fulfilled using available information, and classify accordingly. For 'Harmonized Classifications' referring to the aquatic hazard classification (acute or chronic category 1) where no M-factor is listed on Annex VI, the classifier must set an M-factor (multiplying factor for substances that are highly toxic to the aquatic environment, i.e., LC50 or EC50 < 1mg/L). The purpose of applying the M-factor is to give an increased weight to highly toxic components when classifying a mixture.

Self-classification may entail new testing for those physical hazards where no 'Harmonized Classification' exists and where, pursuant to CLP Article 8(2), adequate and reliable information is not available (ECHA, n.d.).

REACH - EC Regulation 1272/2008 – Registration, Evaluation, Authorisation and Restriction of Chemicals

Does REACH apply to substances (either on their own, in a mixture or in articles) manufactured or imported in volumes below 1 tonne per year?

Yes. Aside from registration there are several obligations under REACH that apply irrespective of tonnage. These include restrictions, authorisation and communication in the supply chain (such as the provision of Safety Data Sheets). The one tonne per year threshold applies to registration only. To identify your obligations, we recommend you to use the ECHA **Navigator** tool (ECHA, n.d.).

What are the REACH obligations of non-EU/EEA companies?

Companies established outside of the EU/European Economic Area (EEA) do not have obligations under REACH. It is the EU importer that sources substances from the non-EU/EEA company who must comply with REACH. Non-EU/EEA manufacturers and formulators exporting substances to the EU can (but are not obliged to) appoint an 'only representative' to fulfil the obligations of importers. More guidance on 'only representatives' can be found in our **Q&A section on only representatives** and in the '**Guidance on Registration**' section 2.1.2.5 - "Only representative of a non-EU manufacturer".

For further information, see the ECHA webpage concerning the **non-EU companies** (ECHA, n.d.).

Which substances are covered by Annex V?

Annex V of REACH lists a series of broad categories of substances for which registration is deemed inappropriate or unnecessary. Substances included in Annex V are also exempted from the supply chain communication and downstream user provisions, as well as evaluation. The registration exemption applies to the substances, provided they meet the conditions for the exemption; these are provided in the relevant category of Annex V.

If you need more detailed information on any category of substances, you can find this in the '**Guidance for Annex V**', which gives explanations and background information for applying the different exemptions. It also clarifies when an exemption can be applied (ECHA, n.d.).

How do I proceed if I have concerns about confidential business information (CBI) when discussing substance sameness?

Consider taking specific measures in the Substance Information Exchange Forum (SIEF) to protect information that you consider to be CBI. However, you will still need to share your CBI with the SIEF to make a conclusion on the substance sameness. You can, for example:

1. Have confidentiality agreements that limit access to documents or other information to specific named persons, or departments.
2. Allow access to certain documents in a 'reading room' only (where copying is not allowed).

3. Agree to have certain documents reviewed and/or assessed only by a third party expert (independent consultant) or a trustee.

You can strengthen this by having additional personal confidentiality agreements for those who are granted access to the CBI documents. As a minimum, you should specify to the other SIEF members that the information is indeed CBI, and that you are only communicating it for the purposes of the verification of substance identity under REACH. For more information on CBI, see ECHA's '**Guidance on Data-sharing**', section 9 (ECHA, n.d.).

What is a letter of access (LoA) under REACH?

When a registrant does not own a study report that they require for their registration, they need to agree with its owner on the conditions of using it for REACH registration purposes. The owner of the data and the registrant are free to define the rights that will be granted. If a robust summary of a study has already been submitted to ECHA, a registrant can, for instance, refer to that study in their dossier provided that they have permission to do so. In that context, the registrant and the data owner must agree on the conditions of the right to refer. The LoA is a term often used to describe the agreement on the sharing of data and granting a right to refer. The intellectual property rights of the data owner must in any case be respected by the potential registrant (ECHA, n.d.).

How can communication within a joint submission be facilitated?

Co-registrants can agree at an early stage that one company takes over the organisation of the information exchange and the preparation of the joint submission. This is not compulsory, as REACH does not set any conditions in this respect.

Where the information for exchange is considered commercially sensitive by one or more potential registrant (e.g., because of an impurity content that can indicate a production process), they can propose a confidentiality agreement, the use of an independent third party or trustee who can handle the confidential information on behalf of the potential registrants, or a similar arrangement. Any other form of organisation is equally possible, as long as it is agreed by all existing and/or potential new co-registrants. Detailed information on how to organise and improve communication between co-registrants can be found in ECHA's '**Guidance on Data-sharing**' (ECHA, n.d.).

Do I have any data-sharing obligations after I have submitted my registration?

You may have additional duties to share data even after you have submitted your registration. This can happen in the following cases:

- When potential registrants are informed of previous and other potential registrants by ECHA following an inquiry pursuant to Article 26 of REACH.
- After the successful submission of the registration dossier, whenever new information becomes available. In such cases, according to Article 22 of REACH, registrants have to update the joint registration dossier. This may require prior data-sharing and may have an impact on decisions on classification and labelling. It can also lead to the need to change the Chemical Safety Report.

- As a consequence of dossier evaluation by ECHA (a compliance check or the assessment of a testing proposal) or substance evaluation. These processes may lead to a request to submit further information, which would need to be addressed among all registrants of the same substance. For substance evaluation cases, these are not necessarily limited to the tonnage band-related information requirements. Registrants should agree on the generation of the requested information and on the sharing of the data and costs. In certain cases, registrants who have ceased manufacturing a substance may be requested to provide additional information. Therefore, data-sharing does not only apply to existing studies, but also to studies which will be needed to ensure that the registration is compliant with REACH (ECHA, n.d.).

Who can appoint an 'only representative'?

According to Article 8(1) of REACH, a natural or legal person established outside of the EU who manufactures substances (to be used on their own, in mixtures and/or to produce articles), formulates mixtures or produces articles, can nominate an 'only representative' located within the EU to carry out the required registration of their substance (as such, in mixtures and/or in articles) imported into the EU. Distributors are not mentioned in Article 8(1) of REACH, and thus cannot appoint an 'only representative'. The reference to the EU covers both the EU countries and the European Free Trade Association countries that have adhered to the European Economic Area Agreement, being Iceland, Liechtenstein and Norway.

The 'only representative' will have to fulfil the registration obligations of importers (Title II of REACH) and comply with all other obligations of importers under the REACH regulation. More information on the role of the 'only representative' is provided in section 2.1.2.5 - 'Only representative of a "non-EU manufacturer"' of the '**Guidance on Registration**' (ECHA, n.d.).

Who can be appointed as an 'only representative'?

A non-European Economic Area company (that can appoint an 'only representative', see **here**) may, by mutual agreement, appoint a natural or legal person established in the EEA to act as their 'only representative'. According to Article 8(2) of REACH, this representative shall comply with all obligations of importers under REACH. Therefore the 'only representative' is required to have sufficient background in the practical handling of substances and information related to them. More information on the 'only representative' is also provided in section 2.1.2.5 - 'Only representative of a "non-EU manufacturer"' of the 'Guidance on Registration', available **here** (ECHA, n.d.).

Is there a special procedure to appoint an 'only representative'?

The issue of becoming an 'only representative' is a question of mutual agreement between the non-EU manufacturer and the natural or legal person established in the EU who is being appointed as an 'only representative'.

Non-EU manufacturers need to send a letter confirming this appointment to their 'only representative', who must have it available in case of inspection by the relevant member state's enforcement authority; no such letter has to be sent to ECHA. However, when compiling the registration dossier in IUCLID, the 'only representative' is advised to attach this letter of appointment to the registration dossier in the field, "Official assignment from non-EU manufacturer" in section 1.7. More information on the duties of the 'only

representative' is provided in section 2.1.2.5 - 'Only representative of a "non-EU manufacturer"' of the 'Guidance on Registration', available **here**. In addition, the non-EU manufacturer shall inform the importer/s within the same supply chain of the appointment of the 'only representative' according to Article 8(3) of the REACH regulation. These importers shall be regarded as downstream users (ECHA, n.d.).

How can non-EU manufacturers help their 'only representatives' or importers to prepare for registration?

The importer or the 'only representative' is responsible for submitting a registration dossier or a pre-registration to take advantage from the extended registration deadlines for phase-in substances. In order to assist these actors under REACH, the non-EU manufacturer may wish to make themselves aware of the information requirements laid down in REACH, and start collecting the relevant information. This may include correct identification (CAS or EINECS/ELINCS/NLP number) and naming of the substance, and information on its composition. This is explained in more detail in the 'Guidance for Identification and Naming of Substances under REACH and CLP', available **here**.

The non-EU manufacturer may also assist in providing all available information regarding the intrinsic properties of the substances (see Annex VII to XI of REACH). However, these supporting measures of the non-EU manufacturer cannot relieve the 'only representative' or the importer from the duty to comply with all relevant obligations of the REACH regulation. More information for non-EU manufacturers can be found **here** (ECHA, n.d.).

Why do I need to provide analytical data for my substance?

This information is needed to verify the composition of your substance and to ensure that the chemical identifiers, such as IUPAC name or CAS number, are appropriate.

What spectral data does ECHA require?

ECHA requires, as a minimum, ultra-violet (UV), infra-red (IR) and nuclear magnetic resonance (NMR) spectra (Annex VI section 2.3.5, REACH). You can also provide a mass spectrum in place of an NMR spectrum. For some substances, this information is not sufficient or appropriate and, in such cases, you need to provide other types of spectral data. For example, in the case of inorganic substances, X-ray diffraction (XRD), X-ray fluorescence (XRF) or atomic absorption spectroscopy (AAS) are likely to be more appropriate techniques (ECHA, n.d.).

Is it possible to get access to the analytical information of other (potential) registrants?

No. ECHA protects the confidentiality of the analytical information submitted by registrants, including potential registrants.

Does 100% of the substance composition have to be accounted for?

Yes. The sum of the typical concentrations of each constituent should add up to 100%.

Where can I find further information that would help me in complying with the requirements related to the substance identification?

When preparing your dossier to be submitted to ECHA, we recommend that you also review the following documents:

- Guidance for Identification and Naming of Substances under REACH and CLP, available **here**.
- The relevant Submission Manuals, available **here**.
- Q&A on Substance Identification, available **here**.
- Q&A on Inquiry, available **here**.

Do I need to report concentration ranges for each constituent?

Yes. You need to report concentration ranges - both minimum and maximum values - for each constituent. These should be representative of the substance as manufactured/imported, and these can be taken from sources such as the certified specification limits which often form part of a Certificate of Analysis (CoA). It is important that the concentration ranges are realistic and do not cover different substances (ECHA, n.d.).

Where can I find more information on the Substance Identity Profile (SIP)?

For more information on the SIP, please read Appendix III (Substance identification and joint submission of data) of the 'Guidance for Identification and Naming of Substances under REACH and CLP', available **here** from ECHA. You can also find technical instructions on reporting substance identity information in IUCLID format in the manual 'How to prepare PPORD and registration dossiers', available on the ECHA website (ECHA, n.d.).

Do the registrants have to submit all their data jointly?

An overview of the required and optional information for a joint submission for registration based on Article 11 of the REACH regulation is provided in Section 6.2 - 'Overview of the part of the technical dossier that may be jointly submitted for registration' of the 'Guidance on Data-sharing', available **here**.

Some information forming part of the registration has to be submitted jointly, whereas other information needs to be submitted separately. Additionally, there is information the registrant/s may elect to submit jointly or separately, according to the criteria defined in Article 11(3) of REACH. The following information must be submitted jointly:

- Information on the classification and labelling of the substance.
- Robust study summaries, and an indication as to which of these relate to classification and which relate to labelling.

- Information submitted must be reviewed by an assessor.

Under specific conditions, which should be explained in the dossier, a separate submission of the required data is allowed (see also Q&A 109).

Additionally, each registrant must submit individually:

- The identity of the manufacturer or importer.
- The identity of the substance.
- Information on the manufacture and use/s.
- Exposure information for substances in quantities of 1 to 10 tonnes.
- An indication of which of the submitted information on manufacture and use has been reviewed by an assessor.

The registrants may decide to submit the following information jointly or separately:

- Guidance on safe use of the substance.
- A Chemical Safety Report (CSR), when required.
- An indication which of the information submitted for the CSR has been reviewed by an assessor (ECHA, n.d.).

Can different classifications of a substance be included in the joint submission dossier?

According to Article 29(2) of the REACH regulation, one of the main aims of the SIEF is to agree on classification and labelling of a substance where potential registrants hold different opinions on how best these requirements should be satisfied. Nevertheless, if all member registrants agree, the Lead Registrant may include different classifications of the substance in the joint part of the registration dossier (e.g., if different impurity profiles lead to different classifications).

In this case, member registrants should leave the pertinent section of their member dossier empty to avoid being treated as an opt-out for the classification and labelling of the substance. If the member registrants cannot agree on the inclusion of all the different classifications of the substance in the joint part of the registration dossier, one or more of the member registrants may decide to provide their substance classification separately (by filling in the respective section in their member dossier). If this is the case, a justification in accordance with Article 11(3) of REACH is required. In addition, in cases where a 'Harmonized Classification & Labelling' for a substance is provided in Annex VI to the CLP Regulation, then it must be used. Further information can be found in the manual '**How to prepare registration and PPORD dossiers**' (ECHA, n.d.).

Should all available studies be included to the joint submission dossier?

Yes. According to Annex VI to the REACH regulation, any physicochemical, toxicological and ecotoxicological information that is available and relevant must be provided in the registration dossier. In practice, after gathering and assessing all existing information, the registrant has to select the information that is reliable, relevant and adequate. For key studies, robust study summaries have to be provided; for supporting studies, study summaries are sufficient. Further guidance on information gathering and evaluation is also provided in chapters R.3 and R.4 of the '**Guidance on Information Requirements and Chemical Safety Assessment**'.

How do I know which joint submission to join?

Multiple registrants of the same substance share two main obligations under the REACH regulation, data-sharing and joint submission obligations. Registrants can identify who else has registered their substance, and therefore shares common obligations under REACH.

It is the common responsibility of all (potential) registrants, yourself included, to form a single joint submission. ECHA strongly recommends that all registrants use **this** new page as a tool to ensure compliance with these obligations. For example, no role is displayed next to a registrant that has submitted a registration dossier outside of an existing joint submission. They are required to contact the Lead Registrant, as they share the same responsibilities as the other multiple registrants. Registrants of the same substance are obliged to make every effort and to ensure that they are part of the same joint registration dossier. Existing registrants outside the joint submission are required to negotiate access to the joint submission with their co-registrants – regardless of whether or not they need to share data. For further information see the 'Guidance on data-sharing' **document**, Chapter 6, "Registration: Joint Submission". Please also note the partial exceptions applicable for intermediate registrants (ECHA, n.d.).

Cosmetics - EC Regulation 1223/2009

Can I hand make cosmetic products in my workspace at home?

Yes, as long as the products are produced according to EU regulatory guidelines and comply with Good Manufacturing Practice (GMP).

What is GMP and why is it important?

Good Manufacturing Practice (GMP) is having procedures in place to ensure that products are prepared in a clean environment and do not become contaminated in production. It allows traceability and control during production.

What product testing is required before a Cosmetic Product Safety Report (CPSR) can be compiled?

Cosmetic product safety information that contributes to the safety assessment includes, among other things:

- Physical/chemical characteristics and the stability of the cosmetic product under reasonably foreseeable storage conditions.
- The microbiological specifications of the substance or mixture and the cosmetic product, and results of preservation challenge testing.
- The relevant characteristics of the packaging material, in particular the purity and stability (sometimes referred to as compatibility testing).
- Any claims made by a cosmetic product must be substantiated, therefore you may need to perform studies to back up your claims.

The results from the stability, compatibility and challenge tests will be used to help inform a decision on the shelf-life of the product and will also be considered by the Safety Assessor as part of the CPSR (CTPA, n.d.).

What is the difference between challenge testing and microbiological testing?

A challenge test, sometimes referred to as a preservative efficacy test, assesses the robustness of the preservative system in the product and packaging during use by the consumer, as proof of its efficacy. Microbiological testing forms part of the continual quality assurance system and is used to confirm whether the product meets the required specification prior to its release to the consumer (CTPA, n.d.).

What is a Responsible Person (RP)?

A Responsible Person must ensure all the relevant obligations set out in the EU Cosmetics Regulations are met. The RP may be:

- The manufacturer or a brand owner marketing a cosmetic product under their name or trademark.
- The importer who is importing a cosmetic product from outside Great Britain or the EU (depending on which regulation applies).
- A person or a company established within Great Britain or the European Economic Community mandated to act as the RP by the manufacturer/brand owner/importer. In this situation, a mandate should exist and there should be acceptance in writing from the designated person (CTPA, n.d.).

What is a Product Information File (PIF)?

A PIF contains information on the product, and is a legal requirement for the EU (CTPA, n.d.). It should include the following:

- The product description.
- The Cosmetic Product Safety Report.
- Details of methods of manufacture in accordance with GMP.
- Proof of the effect claimed for the cosmetic product, as claims made must be justified by scientific testing.
- Data on animal testing.

Do products containing only natural ingredients/essential oils need a Safety Assessment?

Yes, all products require a Safety Assessment regardless of the origin of the materials.

References

CTPA, s.d. *Cosmetic, Toiletry and Perfumery Association.* [Online]
Available at: https://www.ctpa.org.uk/faqs
[Accessed 30 August 2021].

ECHA, 2021. *Guidance for Annex V Exemptions from the obligation to register.* [Online]
Available at: https://echa.europa.eu/documents/10162/23036412/annex_v_en.pdf/8db56598-f7b7-41ba-91df-c55f9f626545
[Accessed 29 January 2021].

ECHA, s.d. *European Chemcials Agency.* [Online]
Available at: https://echa.europa.eu/support/qas-support/browse?p_p_id=journalqadisplay_WAR_journalqaportlet&p_p_lifecycle=0&_journalqadisplay_WAR_journalqaportlet_topic=CLP&_journalqadisplay_WAR_journalqaportlet_scope=Scope+and+exemptions+under+CLP&_journalqadisplay_W
[Accessed 25 August 2021].

ECHA, s.d. *European Chemicals agency.* [Online]
Available at: https://echa.europa.eu/support/qas-support/browse?p_p_id=journalqadisplay_WAR_journalqaportlet&p_p_lifecycle=0&_journalqadisplay_WAR_journalqaportlet_topic=REACH&_journalqadisplay_WAR_journalqaportlet_scope=Only+Representative+of+non-EU+manufacturer&_jour
[Accessed 26 August 2021].

ECHA, s.d. *European Chemicals Agency.* [Online]
Available at: https://echa.europa.eu/support/qas-support/browse?p_p_id=journalqadisplay_WAR_journalqaportlet&p_p_lifecycle=0&_journalqadisplay_WAR_journalqaportlet_topic=CLP&_journalqadisplay_WAR_journalqaportlet_scope=Understanding+CLP&_journalqadisplay_WAR_journalqap
[Accessed 25 August 2021].

ECHA, s.d. *European Chemicals Agency.* [Online]
Available at: https://echa.europa.eu/support/qas-support/browse?p_p_id=journalqadisplay_WAR_journalqaportlet&p_p_lifecycle=0&_journalqadisplay_WAR_journalqaportlet_topic=REACH&_journalqadisplay_WAR_journalqaportlet_scope=Scope+of+REACH&_journalqadisplay_WAR_journalqapo
[Accessed 25 August 2021].

UNION, T. E. P. A. T. C. O. T. E., 2009. *EU-Lex.* [Online]
Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32009R1223&from=EN
[Accessed 22 January 2021].

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