Webinar: Poison centre notifications - ensuring compliance for industrial use mixtures

Questions and answers

This document is based on the questions received during the webinar organised on 14 November 2023. Editorial changes have been made to improve clarity and similar questions have been combined.

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#	Question	Answer
1	For non-hazardous substances, is it mandatory to put an emergency response number on the MSDS? If so, could it be the number of another entity located outside the country in which the substance is to be marketed?	I am afraid this question is outside the scope of this webinar, as it touches upon duties on SDS which are determined by the REACH Regulation. You are invited to contact your relevant national helpdesk to seek advice. You can find all their contact details at: https://echa.europa.eu/support/helpdesks/
2	1) Why are PCN not automatically submitted to all Poison Centres in the EU? 2) If my submission was successful but a small	1. You notify where you place on the market 2. You may need to take action but not necessarily, it depends on your specific mixture/product and the information in your dossier. Warning can be ignored if the submitter is confident about the correctness of the information 3. usually should not take long. You can contact the IUCLID team via our Helpdesk in case of prolonged waiting time.

#	Question	Answer
	"warning" triangle is displayed, do I need to take any action? 3) Why does it take so long to load the webpage where one creates the IUCLID dossier?	
3	Why do I have to notify the mixture classification for an already notified mixture with an existing UFI code?	Notification obligations apply to each duty holder individually and in each relevant market. You don't need to notify twice the same mixture which you have already notified (you can add multiple product information in the same notification).
4	Why do I have to notify all single substances of that MiM and their hazard classification?	The info requirements have been discussed and agreed with the poison centres (and Appointed Bodies) , who need the relevant information to be able to provide emergency response
5	7) Since the dossier submitter must type in all the data anyways; Does it even matter if the supplier of a MiM provides a UFI code or not?	The preferred option is to provide full details of the composition of the mixture, including the mixtures you are supplied with (MiM). This is required by the legal text. If you do not know the full composition of the MIM, then you can identify it with the product identifier, concentration and UFI.
6	8 Should single substances within a MiM be classified according to supplier (trust-principle) or does the submitter of the dossier have to do a hazard classification of those substances?	General CLP rules apply also to the poison centre notification duties, therefore you can use the classification and labelling provided by your supplier, unless you have grounds to question it. This can be the case where there is a harmonised classification and labelling which your supplier is not using, or where you have conclusive data for a different classification.
7	A cosmetic mixture is delivered to a bottler in IBCs. Is it already a cosmetic product at this point and therefore excluded or is it an industrial mixture which has to be notified?	A cosmetic product is thus 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 it does, the CPR applies, and all requirements set out in that Regulation shall be fulfilled. 2. At the moment of placing on the market, the cosmetic product is intended for the end user, i.e. it is intended to be ultimately used either by a consumer or professional. and 3. At the moment of placing on the market, the product is in the finished state, i.e. it is in its final composition or formulation. The finished state of a cosmetic product under Article 1(5)(c) of CLP relates to the substance or mixture and not to its packaging. As long as the re-packing of the substance or mixture in bulk does not alter the chemical composition [e.g. a product in a drum or IBC (intermediate bulk container) that will not be chemically altered after having been produced] can therefore be considered in the finished state.

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8	A lot of producers haven't yet an UFI code, but it has to be compliant from 1/01/2024, how can we be informed when a lot of those products will be selled in January 2024? Is there a transitional period because we can't update 4000 Submission dossier in just one day?	Sorry but your role in the supply chain is not clear. If you are using mixtures as MiM, you don't necessarily need the UFI to identify them. You can update your notifications as soon as the new info is available
9	A mixture is send to a third party which does the bottling. Is this step considered placing on the market since it is "made available to a that party"?	Yes. 'Placing on the market' means supplying or making available, whether in return for payment or free of charge, to a third party. The activity of the recipient of the mixture is not relevant for the definition of 'placing on the market'.
10	Can I submit a PCN on behalf of a sister company based in another EU country? Or does the notifier have to be the EU importer? Thank you	Notification duties apply to EU Importers (and DUs) If you (the same as any consultant) want to take over the administrative task of preparing and submitting the poison centre notification, you can use the 'foreign user' functionality available in our IT system. In brief, both companies need to have an ECHA account. You will connect to your sister company's account through yours and be able to create and submit the poison centre notifications. You can find further explanations in the PCN: a practical guide, Appendix 1. Instructions: establishing a foreign user. You are invited to read also the Appendix 2. Using the 'foreign user' functionality may lead to inconsistency of legal entities upon submission and lead to a business rule error, blocking your submission.
11	Could I indicate on MSDS an emergency response number of another entity located outside the country in which the substance is to be marketed?	I am afraid this question is outside the scope of the webinar. You are invited to contact your national helpdesk. You can find their contact details at: https://echa.europa.eu/support/helpdesks
12	Could you clarify the situation and obligations on plastics? After processing there is no mixture but a finished product. The classification/labelling of materials is also different in the market as the "polymer-bound clause" in section 1.3.4 of Annex I is interpreted different from companies.	You need first to define if your plastic can be considered as an article. Articles as such do not need a notification. But, for instance, in case of combinations of an article and a mixture, notification obligations apply. Furthermore, a mixture can also be in solid form and falling under Art.45. To help you in deciding if your product is an article or not, and is notification obligations apply, you are invited to consult the Guidance on Annex VIII (section 3.1.1.4) and the Guidance on requirements for substances in articles. You can download the document directly at: https://echa.europa.eu/documents/10162/2324906/articles_en.pdf
13	Could you please tell me in which country the payment for using the number phone of the poison center (official advisory body) in SDS section 1.4 is needed, and where I can find that information? Thank you in advance.	This is out of the scope of this webinar as it related to SDS. Please, consult our SDS Guidance and relevant information on the ECHA website. Eventually this should be verified with the relevant MSs
14	Do you always have to submit a PCN registration when you buy a product from a manufacturer in Belgium and simply continue trading it on the Belgian	If you are a distributor (and not performing any activity qualifying as DU) placing in the same market/Member State area, then normally no you do not need to notify. But few MSs (including Belgium) apply a slightly different interpretation of what "downstream user activity" means,

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	market (same name/packaging)? Because the product has already been registered by the manufacturer (info already available at the poison control center).	compared to the adopted REACH guidance on DUs. You should therefore verify with the local authorities.
15	Do you have any guidance on how to notify mixtures of UVCB's where the content of the single UVCBs can vary a lot? Like UVCB 1: 50-100%,UVCB 2: 50-100% as they are very similar UVCBs regarding hazard and phys-chem profile? Both UVCB's heavily classified. Impossible to comply with the ranges allowed	UVCB substance components of a mixture follow the standard rules as any other component when it comes to concentration. The maximum ranges allowed are set in tables in Annex VIII. You can consider the possibility to use the ICG option. Please, consult the Guidance on Annex VIII for details. For further and more specific support, please use our contact form with more details about your case. https://comments.echa.europa.eu/comments_cms/Contact_CLP.aspx
16	EUPCS: What would be the code for mixtures used as intermediates in the pharmaceutical industry please?	Have you checked with your industry association? There is an EuPCS code for intermediates, so you need to read the description for that and decide if that is correct for your product.
17	for industrial use the UFI code is mandatory in section 1 of the SDS?	No, it is not mandatory. If you chose to include it on the label, you don't need to include in on the SDS.
18	Good morning. In the case of : - hazardous substances and - substances and/or mixtures NOT classified as dangerous. Is it possible to include the telephone number of the poison centres in the SDS? If so, what formalities should be carried out (notification, payment of fees,...)?	This question is out of scope. It is about SDS compilation. Furthermore, it needs to be verified country by country whether the PC number can be used on SDSs
19	Hi, if we have a mixture that is transported to another factory (in EU) and then, wipes are impregnated with the previous mixture creating the final product that will commercialize to general public, is mandatory to notify the initial mixture?	Yes. PCN duties apply to mixtures as placed on the market, either by import or by formulation. In the first step already, the mixture is placed on the market when being transported between different legal entities. Also the final product seems to be a combination of article and mixture, therefore notification obligations apply to the producer (the duty holder should judge themselves on the basis of the available ECHA Guidance)
20	How can an outside-EU supplier submit the PCN in Echa-Portal?	The CLP Regulation, from which the PCN duties come from, applies only to EU based companies. Therefore, non-EU suppliers cannot submit PCN directly. Your customers, which are the importers based in the EU, are the ones responsible to comply with this duty. If for the sake of confidentiality, you do not want to share the full composition of your mixture, and are also not willing to provide a REACH-compliant SDS, then you can use a workaround. In brief, you need to agree with another EU-based company which you trust, to submit a voluntary PCN with the full composition. Then your customer can refer to it as a 100% MiM, one you provide him with the UFI. It is further explained in the Guidance on Annex VIII, Section 4.2.5 "UFI and non-EU suppliers". You can download the

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		document directly at: https://echa.europa.eu/documents/10162/17235/guidance_on_annex_viii_to_clp_en.pdf/412c5874-f8ec-cf52-fe1e-2fbe08fe2d11?t=1651484042203
21	How ECHA secure my data in the portal in order to guarantee confidentiality of information?	Security is one of the most important aspects of the system. The ECHA IT system for PCN notifications is designed in a way that the information is made available only to the entities that are supposed to receive it. When an industry user has access to ECHA Submission portal, their connection is encrypted by using the standard TLS (Transport Layer Security) protocol. Thus, all the data is encrypted with the commonly used strong encryption algorithms when transmitted through the established communication channel over Internet between Industry user's system (client) and ECHA Submission portal (server). Poison Centres notification data submitted by industry is not encrypted when stored in the ECHA IT-system (data as rest). ECHA IT-environment, and the data stored in the systems, is protected by applying other security measures and controls than encryption. The protection in place is based on common security best practices.
22	How long after the market is ceased the PC notification should be modified	There is no 'expiration date' of a notification as products can remain on the shelves or with the end user for some time after. If you cease market, you can make an update to include this information when the scenario comes to light.
23	How to extend the member state for product with UFi code already validated if the previous legal entity is no more accessible by the company?	Without a full description of your specific scenario, I can only say that in general a company taking over the activity of another one needs to submit their own notifications. UFI can be reused as long as the composition remains exactly the same.
24	If I want to add the same emergency contact for several languages (e.g. Danish and German), do I have to change that person's location to that country (e.g. Germany), even though the company is based in another country (e.g. Denmark).	By "emergency contact" are you referring to the contact's details for rapid access to 'additional detailed product information'? If this is the case, the service can be provided by a third party placed elsewhere. Please refer to Sections 4.4.1 and 4.4.2 of the Guidance on Annex VIII, where this rapid access contact is further explained. You can find the guidance, with its translations into all EU-official languages, at: https://echa.europa.eu/guidance-documents/guidance-on-clp
25	If mixture for industrial use ends in consumer product is supplier of industrially manufactured mixture obliged to notify in PCN for all countries where is consumer product placed on the market? Even if on some markets are placed only product containing industrial mixture and not the mixture itself?	The duty holder (Importer or Downstream user) has to notify in all the Member States where the mixture is placed on the market, by themselves or distributors. They agree with distributors in case they are willing to notify themselves. The type of notification depends on the final end-use of the mixture (itself or formulated in other mixtures). Please check the Guidance on Annex VIII which provide details
26	In case a mixture is in the EU market, will a national submission be required. In such a case, what is the	The Guidance on Annex VIII available on the ECHA website provide detailed information. transitional period applies to mixtures notified according to national requirements before the relevant

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	transition time that is available for CLP compliance and PCN -related submissions?	compliance date. The first compliance date (for cons/prof mixtures) has passed already. Note that in many countries national systems are not available anymore
27	Is it mandatory to indicate the telephone numbers of the poison centres in the SDS?	The SDS is not an information requirement for poison centre notifications so this question is out of scope for us and would need to be directed to your national Helpdesk https://echa.europa.eu/contact
28	Is it ok for the 24/7 rapid assistance to be located outside of the EU (e.g. in the UK)?	This aspect is not defined in the legal text. However, the submitter takes responsibility for the good functioning of the third party who will provide this service. Other conditions have to be complied with, explained in Sections 4.4.1 "Contacts for rapid access to 'additional detailed product information'" and 4.4.2 "Availability and content of the additional information and rapid access" of the Guidance on Annex VII. You can download it directly at: https://echa.europa.eu/documents/10162/17235/guidance_on_annex_viii_to_clp_en.pdf/412c5874-f8ec-cf52-fe1e-2fbe08fe2d11?t=1651484042203
29	Is it possible to add a country to an already submitted PCN via the ECHA website?	Yes. You can make an update - please check the PCN practical guide on how to do this.
30	Is limited submission also a possibility for products that are ITAR classified and that for we are legally not allowed to give the details of the formulations outside of the US? How should we manage this with customers based on EU? It is not possible to share entire composition with them.	Limited submission is possible only for industrial mixtures (i.e. not used in any consumer/professional product). But CLP includes an exemption for sub/mix where necessary in the interest of defence (Art.1(4)). This needs to be discussed with the relevant Member State.
31	May a non-EU supplier use it's own subsidiary EU company to make just a voluntarily submission for the UFI (to be given to its EU customers) without an obligation to become an importer/duty holder?	A non-EU supplier will never be a duty holder nor an importer under EU Regulations. Their actions are voluntary and meant to support the EU customers.
32	Must the emergency contact number be included on the label?	Question out of scope. Please consult the Guidance on labelling and packaging (ECHA website)
33	Our mixtures are used for metal extraction. Unfortunately, I could not find this main-use in IUCLID. Can this be added? We are always using the "uncategorised" use.	Indeed we do not have every type of main intended use in the list, if you have yet to check with your industry association, you might find that the PC-TEC category helpful - even if it is still not listed there the PC-TEC-OTH might be a preferred option. If you would like to request a change it needs to go through the correct channel via our Helpdesk and you need to clearly explain the name of what category you need according to it's intended use, where it best fits in the hierarchy, and a description for it's use.
34	Placing on the market mixtures notified via ECHA Submission portal in Belgium, France, Germany, Italy, Luxemburg and Spain: mixture to be placed on the	You will get enough information in the submission report, available in your ECHA submission portal account. For the countries you mention, you will get a specific message that the notification has been received by then. Please refer also to the document "Overview of Member States decisions in

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	market ONLY AFTER confirmation from the MS appointed body. Can you share information about how long this takes and format of confirmation?	relation to implementation of Annex VIII to the CLP Regulation (Poison Centre Notification)" where this aspect is listed for each country. You can find it, for example, in our webpage on National support: https://poisoncentres.echa.europa.eu/appointed-bodies
35	Please, could you clarify it telephone number of Poison Centers have to be indicated in section 1.4 of SDS or can be put an own emergency telefono number?	I am afraid this question is outside the scope of the webinar. You are invited to contact your relevant national helpdesk for advice. You can find their contact details at: https://echa.europa.eu/support/helpdesks/
36	question about ITAR mix,you replied "CLP includes an exemption for sub/mix where necessary in the interest of defence (Art.1(4)). This needs to be discussed with the relevant Member State." We have to contact each single MS to discuss the exemption? it's possible that some accept it and others no?	Yes, because this is not harmonised across EU and each MS manages this topic individually
37	Regarding substances in IUCLID. E.g. One customer can list methyl alcohol in SDS whereas another Methanol. Can we use the substance originally created in IUCLID under Methyl alcohol, when we have the substance in another SDS listed as Methanol? Is the CAS more important or the name of the substance?	The important thing is to make sure the substance is properly and univocally identified. Substances may be identified by an array of identifiers (numerical or not). You can add multiple identifiers in the notification, normally numerical identifiers are important.
38	Regarding the emergency telephone number in section 1.4 of the SDS, there is no German poison centre named as official advisory body in case of emergency. May a company use a 3rd party located outside of Germany for provide medical advice or is it mandatory to use one of the German poison centres?	I am afraid this question is outside the scope of the webinar. You are invited to contact your relevant REACH national helpdesk for advice. For Germany, you can find their contact details at: https://echa.europa.eu/-/germany-helpdesk
39	Should a UVCB substance be notified to PCN/should it be considered a mixture in this context? And the same question for Surface treated substances	I am afraid the matter of defining if your product is a mixture or a substance is outside the scope of this webinar. Please contact your relevant national helpdesk for advice. You can find their contact details at: https://echa.europa.eu/support/helpdesks
40	Should a UVCB substance be notified?	No. Only mixtures which are classified for physical-chemical or health hazards need to be notified.
41	somebody in my company submitted PCN dossier and have validated UFI code. Now inorder to see which country the UFI code is validated for and how to extend it in other countries in EU?	You can see in the submission report where the notifications have been submitted

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42	somebody in my company submitted PCN dossier and have validated UFI code. This person has left the company and the username and password is not valid for ECHA account. Now inorder to see which country the UFI code is validated for and how to extend it in other countries in EU?	Please, submit a question to our Helpdesk. They will tell what it is possible to do
43	The distributor cannot check the PCN. Is the distributor responsible when the supplier has processed a UFI-code on SDS and label, but the supplier did not notify the material at ECHA? (a empty UFI code)	A notification should be submitted as soon as possible after the UFI is included on a label. In any case it is important to communicate between companies.
44	The notification of an “Industrial Use Only” has a tradename of the country or a generic name? like for example the content of active substance.	The notification must include the trade name of the product that is being placed on the market. There is also the possibility to include other names in the notification as well and notifiers are encouraged to do if relevant for their mixture
45	The use of the UFI is also there to protect confidential information. If I am submitting a PCN of a mixture that already has a UFI with all the confidential information already submitted, do I still have to declare all the substances in my notification?	Your scenario is unclear. Please send your question with further details to our contact form, so we can provide you with a helpful reply. Please use this link: https://comments.echa.europa.eu/comments_cms/Contact_CLP.aspx
46	We have several products with the same trade name e.g. Orange Flavouring and get status “Succeeded with warnings” QLT574 with message: “A submission already exists for the product with the same trade name submitted by your company for the same country [...].“ Is there any possibility to avoid this?	QLT rules are meant to help the submitter in complying correctly with the obligations. These apply to situations which can vary and cannot be failed automatically by the validator. In this case we want to make sure that the correct notification type is used (i.e. update Vs new notification) to be sure the data submitted are clear and clean. We remind you can always include information related to different product in the same notification, as long as the composition is the same. Eventually QLT rules can be ignored, if the submitter is sure about wat they are doing. In addition, there is the possibility to include ‘additional names’ in the notification as they appear on the label. Ultimately the more unambiguous information you send in the notification the better it is for poison centres.
47	We manufacture products for customers, which will be in their name. Do I have to do their PCN or do they have to do it themselves? Do I need to give them information about our PCN notification for our product in our name so that they can link it to their PCN for the product in their name?	According to the legal definition, you are the duty holder and should submit a poison centre notification. However, how to work in practice with your customer, based on your specific scenario, there are a number of options. For example, if you want to use your UFI or your customer wants their UFI to be on the label. For a more comprehensive discussion, please refer to the Guidance on Annex VIII, Section 3.1.1.2 "Formulation activities" which also covers the toll formulation. You can find this document with translations into all EU-official languages at: https://echa.europa.eu/guidance-documents/guidance-on-clp

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48	We manufacture tubes for certain customers, which will be in their name. Do I have to do their PCN or do they have to do it themselves? Do I need to give them information about our PCN for the product in our name so that they can link it to their PCN notification for the product in their name?	Sorry but it is not clear. Only mixtures are under the scope. In any case the Guidance is clear about the duty of the toll formulators (formulating mixture for another company). The toll formulator has to notify.
49	We produce polymer pellets which are sold to manufacturers, for example in the automotive industry. They then make parts for cars, which are sold to consumers. Would we as the polymer pellet producer be able to submit our PCN under the limited submission type?	As we said, the notification type has to consider end-uses. But if the end use is out of the scope of Article45, this can be disregarded. Please, check the section 3.1.1.4 of the Annex VIII guidance where you can see the 4 types of "objects" and whether notification applies.
50	We sell our products in barrels, IBC and with a truck (tank; large quantities). How can I add the truck as packaging to the notification?	There is 'Tank' as a packaging type in the format.
51	We sell our products to French. One of our supliers has not created a notification for their MiM in France. Can we still register our product their?	Provided you have details for the MiM, yes. Please see how to do this in the PCN practical guide.
52	We, German company import a product and sell them in France. The product is shipped directly to French customer from non-EU supplier(not physically marketed in Germany). In this case, we need to notify to Germany?	The notification is required where you place the mixture on the market. We understand you do not place on the German market.
53	What EUPCS is relevant to cosmetic ingredients?	You are advised to check with your industry association first. It is not clear what the main intended use of these ingredients might be but you might find the categories from PC-TEC of most relevance.
54	What is the difference in application between EC Reg. 1907/2006 and EC Reg. 1272/2008 for what concerns the exemption for food additives and flavourings? Do these substances have to be notified if sold at industrial level (B2B)?	The exemption has the same basis, though has different implications in different pieces of legislation. Regarding CLP, you are invited to consult our Q&A 1534 and 1535 about the topic. You can find them at: https://qnapublic.echa.europa.eu/?ids=1534-1535
55	What is the UK national systm?	There is a link to the UK Gov website in the slides. It will explain more there.
56	What kind of mixtures need to be notified? If we have an intermediate substance that is registered as dry substance but is in reality dissolved in water, is this seen as a "mixture" that needs to be notified?	The object of the notification obligations are mixture which are placed on the market. Solutions are mixtures (even if under REACH you register the substance without the solvent which can be removed) and, if placed on the market, need to be notified. "Placed on the market" means make them available to a 3rd party

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57	What will be the consequences if a company has not met the requirements under CLP Annex VIII by 1 January 2024? Both financially and in terms of government controls, for example? What about Belgium?	We replied that the point should be make sure the PCs have the necessary information to do their job. It is up to the national Enforcement Authorities to give penalties
58	When using one standard formula for two or more mixtures, can one UFI be used?	Standard Formulas are meant to cover variable mixtures. As long the mixtures are covered by that Standard Formula you don't need different notifications and the same UFI can be used
59	Where is the submitted PCN information stored? Does it sit on a central ECHA server that national poison centres can access when needed? Or is it on the individual servers of each national appointed body that a PCN has been submitted for?	Recipients of the notifications are Appointed Bodies, which normally make the information available to PCs under their responsibilities. ECHA serves as facilitator and provides necessary tools. Some ABs access the information by accessing the database built by ECHA, others receive the information directly in their own database. Security requirements apply.
60	Which is the country that we have to consider for “Industrial use only products”? The country where it is manufactured or all the countries where the product will be used.	The identification of end-use depends on how the mixture is used down the supply chain, It is not market-specific. Please, remember that consumer products could be moved across countries. The main objective is to make sure PCs have the necessary information at their disposal