Q&A

PCN Notification and its implication on SDS: What's the next step? (June 30, 2021)

#	Questions	Answers
1.	I am exporting 35% Organic Product in 65% solvent to Europe. Does it require UFI?	Yes, because if your product has organic product and solvent, it will be treated as a mixture. If it is classified for human health hazard or physical hazard, then UFI is mandatory. Also, if it is classified as environmental hazard then you can do voluntary poison centre notification along with the UFI requirements, but it will depend upon the classification of the mixture.
2.	Should CMR substance to be reported too?	Yes, if you have any component which is CMR component which is more than 0.1% in your mixture, that means your mixture have a CMR classification and you have an obligation to do the PCN notification.
3.	How to obtain PCN certificate?	There is no certificate required for PCN from your supplier, but you can just request for UFI along with updated SDS from your supplier and it will be done. But if you are supplying directly and you have appointed European Legal entity, they can do the PCN for you and can give you the certificate via the UFI number mentioned for their mixture and that UFI number, you need to mention in your SDS. So, if you appoint anyone for doing the PCN, any European legal entity then obviously, they will provide you with the certificate for PCN like the case in GPC, we do provide those certificates.
4.	In India you can change the formula whilst retaining the brand name if there is traceability and if classification is the same. Is this fine with a UFI system?	Yes, this is totally acceptable. You can give the concentration range mentioned in your formula because we have different trade names with slightly different compositions or differences but as long as there is a traceability and the classification is the same, then the same system is applicable in the PCN centre to get the UFI.
5.	We would like to know if once you send the dossier to the PCN, will we get a	So basically, when we are talking about the Poison Centre Notification, first thing is to appoint a European Legal Entity then they

	response, or the authority will send the notified UFI directly to the client?	can prepare a PCN dossier into XML format. That dossier will be submitted on a ECHA submission portal, and you get a submission number along with an active UFI number because when you create a dossier, you already create a UFI to incorporate into the dossier and then that dossier will be submitted to ECHA where you will get a submission number and then that UFI will become active to put in the SDS.
6.	Implications of PCN on SDS and how to make the SDS in UNGHS format along with complying with PCN requirements?	Basically, first, you need to understand the PCN requirements within the CLP regulations. CLP regulation is the UNGHS adaptation of the European Union so whenever you are exporting anything into Europe then you have an obligation for PCN notification which you can do by appointing a European representative who can act on your behalf. Once you get the active UFI number, you can put it in section one, part one of the SDS then you could have these similar sections, 16 sections of the SDS as per the Annex II of REACH regulation so you need to comply with Annex II of REACH regulation for the SDS requirements within Europe.
7.	Is UFI needed on SDSs and labels and what is the deadline?	Yes, UFI is needed in both SDS and label but if your product does not have a packaging system or if your product has only industrial use then you have UFI requirements on only SDS otherwise you can put the UFI on SDS as well as label. If your product is going for consumer or professional use, the deadline is already gone, that was 1st January 2021. But if your mixture is for industrial use, you have a deadline of 1st January 2024.
8.	Any specific discussion on the risk assessment requirements & CMR and ED substance and their labelling requirements?	There is no specific discussion because risk assessment requirements are basically for the substances but when we are talking about mixtures classification, yes, you can do a risk assessment for the mixture as well, but it is a complex process. It is important that you check whether your component is CMR or having an ED substance then you need to classify your mixture accordingly and then you have the labelling requirements based on the hazardous nature of the mixture. There is no specific requirement for risk assessment

		as of now for the mixture but yes, risk assessment is equally important for the substances which are going into the European Union.
9.	Classification of hazard categories under Class 9 and will they also be a part of PCN and its effect on shipping?	It doesn't affect shipping, it is more related to the classification and also, you will have the PCN requirements based on this classification, you can just put the UFI number on the SDS or label and it will resolve the issue.
10.	If we do PCN registration for highest % of mixture then lowest % or diluted can be included in the same notification number or we need to go for registration for different PCN. Please guide	Yes, as long as your classification is not changing, you can consider the ranges of the components within the same notification. But if classification is differing depending on the dilution you are doing, then you have to do different notifications for those mixtures. You can do any number of notifications for the same formulation. You can do different notification for same formulation with different trade names. It all depends on the cost-effective solution you want. One notification is the most cost-effective solution and if you can afford it, you can do any number of notification.
11.	We have a mixture in various delivery forms, the formulation is identical. Can we use the same UFI-Nr. For all delivery forms?	Absolutely, you can use same UFI number.
12.	The identification of hazardous substance is based on the individual raw material SDS from supplier or is the CLP harmonized classification relevant only?	Identification of hazardous substance will be based on the toxicological information available for that particular substance. There could be a possibility that your raw materials supplier may not have classified the substance correctly, so you need to check the correctness of the classification of all component or the raw materials going into the mixture. And if it is already harmonized classified, then you have to use the harmonized classified information of the components presented into the mixture, but the formulator responsible to check the classification of the mixture