Transcript for “Simplifying topical formulation development with co-processed excipients.”

Nigel Langley: In the next minute, 250 babies will be born to add to the world's population. In the next 30 years, the world population is expected to reach 10 billion people. These are the 10 billion reasons we do what we do every day. Please join us as we explore innovative pharmaceutical solutions and sustainability and digitalization initiatives that will help us rise to the challenge.

Hi everyone, my name is Nigel Langley and 10 Billion Reasons is why we're here. This is our theme for these podcasts. And today I have the pleasure of having two guests with me today. There's Gloria and Norman who will be introducing themselves shortly.

And the theme of today's podcast is coprocessed excipients with topical applications. You may know if you've been listening in already to our podcast series that we've had a coprocessed excipient podcast based on oral delivery. But today we will talk about the application of similar materials in topical formulations.

So, with that, over to you Gloria. Would you like to introduce yourself first?

Gloria Ho: Thank you for the warm introduction, Nigel. Hi everybody. My name is Gloria Ho. I am the Global Technical Marketing Manager for our Topicals platform here at BASF Pharma Solutions. I joined BASF in 2018 after receiving my Doctorate in Pharmacy. Prior to that I did work within the personal care space, specializing within cosmetic formulation development, in addition to fragrance toxicology. And I'm so glad to have continued to work within this topical formulation development area.

Nigel Langley: That's great, Gloria. And Norm, would you like to introduce yourself as well?

Norman Richards...: Sure. I'm Norman Richardson. I'm Technical Services Manager, supporting BASF Pharma Solutions. I've been with BASF for 10 years and prior to BASF, well since 1988 I've been involved in topical industry, in research and development, with Unilever, Pfizer, Johnson & Johnson, and I've spent most of my career here at BASF supporting topical product developers.

Nigel Langley: Again, that's great. It's really a pleasure to be with two experts in this area. And, maybe Gloria, if I can start with you and ask a question around the functionalities in coprocessed excipients in the topical area and what kind of functionalities are they. Maybe you can describe this to us a little bit?

Gloria Ho: Sure. in regards to the functionalities, I think it's important for everybody to really understand what a coprocessed excipient is first. When it comes to coprocessed excipients, in the simplest manner of really describing it, we can think of them as either mixtures of combinations of two or more excipients, which are a pharma grade product. Whether that is FDA compliant, whether it is FDA IID compliant or, monographed within a different pharmacopoeia, for example, the European Pharmacopoeia.

In regard to these coprocessed excipients, they aren't simple physical mixtures of these individual components. It's really important to understand that these coprocessed excipients have been processed in a very, unique manner, such that the sum of the individual components is greater than the... is really amplified or is greater than the distinct parts. What I mean by that is the effect that you get is not simply just, the two components together. Ultimately the coprocessed excipient should exert an effect, for example whether it's optimized stability, improvement within the packing of the molecules of the product, to really improve the overall formulation.

Furthermore, when we think about coprocessed excipients, they should be available for multiple dosage forms. and they are available for multiple dosage forms. But the most common one that we will see them in would be cream based formulations.

Nigel Langley: Thank you Gloria. Norm, do you have anything to add to that picture?

Norman Richards...: Well, if we think about the, self-emulsifying coprocessed excipients, there's a- an illustration of this question about, functionality. Would be, that you can take these materials, instead of having multiple excipients that you have to add into the formulation, you can add this one material in, and you can build viscosity, which is very important for creams, and you can emulsify oils, at the same time. So it's like a one-step formation of a cream base.

Instead of maybe having to use several materials and make multiple additions, you can simply add one trade named material into water, heat it up, you know, stir if homogenized, use your usual procedures, and then you end up with a very nice cream base into which you can add many other ingredients.

Nigel Langley: Thank you for Norm for that. So, it sounds to me that you also build a robust formulation consistency in a cream if you're using these types of coprocessed excipients. Is that correct?

Norman Richards...: Yes. And I think the purpose of these materials is to make the life easier for the formulator. So, if they're properly designed and they should be, of course, having the right ratio of emulsifier and maybe a fatty alcohol in that coprocessed, system, then the formulator doesn't have to think a lot about, how

much of those ingredients to use. They could just increase or decrease the amount, but in the end, they can very quickly make a strong cream, good consistency, viscosity. It does make life easier for the formulator, whether you're a novice or whether you're experienced, it's going to accelerate the formulating process, for sure.

Nigel Langley: Thank you, Norman. And Gloria, there's lots of different types of topical formulations. are we just talking mainly about creams? Or can this be applied for different formulation types as well?

Gloria Ho: That's a great question. So when we think about self-emulsifying coprocessed excipients, the most common, material we'll find this in or the most common, dosage form we'll see will typically be creams. Just because when we think about creams, creams are going to be our most complex formulations that are composed of the most, ingredients or excipients. whereas gels and ointments have a smaller, more truncated list of excipients. However, that does not mean that coprocessed excipients cannot be utilized for those, other formulations.

Particularly in those cream based self-emulsifying coprocessed excipients what we'll see is that these types of specialized excipients are composed of, both a wax, as Norman has said, whether it's a fatty alcohol, or another high melting point wax, in addition to emulsifiers. There is quite a range of emulsifiers which have been seen in these products.

We've seen, for example, polysorbates or sorbitan esters, however, there've also been seen, we've also seen, ionic emulsifiers as well in these kinds of self-emulsifying coprocessed excipients. Whether it's Sodium Lauryl Sulfate or Sodium Cetearyl Sulfate. So, there is quite a bit of variation that's available within the market to really suit whatever your, problem may be, or whatever your formulation challenge, needs to be resolved.

Nigel Langley: Thank you Gloria. So, with all these combinations that are available now commercially, Norm, how would you actually select the appropriate coprocessed excipient for the application that you're looking to have?

Norman Richards...: You know, that's actually a good question. Because, I remember back to when I was a formulator, you know, your receive a bottle of material and there's one trade name on there. And the mistake that you could make is just treat this as if it were one material. And just begin, you know, get to work and start formulating. But I would recommend that anybody using these materials would look carefully at the label and understand what the individual components are first of all. And then consider the potential, incompatibilities that could occur with those materials.

So, for example, Gloria has mentioned, ionic and, ionic and non-ionic emulsifiers, right? So, clearly you want to be aware whether you have an ionic or non, sorry, ionic or non-ionic emulsifier. And this will certainly, this could certainly pose a challenge in some formulation cases. So, being aware of that, being aware of the ingredients and how they might interact with the API. and then considering, how, the best processing, methodologies to follow when you're using that combination of materials. So, yeah, so I think it's really important to take some time to think about the components and not just rush into the formulating. But really to think about the chemical, physical, and, other aspects of the composition. And even thinking of the mildness too. And think about the potential for irritation. Just having all of those things in mind before you get to work.

Nigel Langley: Thank you, Norm. And I often think of topical formulations or formulators having the ability to have both the art and the science involved here. And, would you say that's, the case also for coprocessed excipients? That knowledge is very important to have, especially of the properties of the materials in order to get the right type of formulation that you desire.

Norman Richards...: Definitely. I mean, I think both parts were in play. So, understanding the chemistry, making sure that you're not, creating incompatibilities in the formulation, that's very important. But at the same time, some formulators really go, they behave more like a chef, right? They understand the physical properties, they understand how things feel, and they mix...

And we've gotten some amazing feedback from, formulators that use coprocessed excipients that they're using them too, and they're achieving excellent sensory properties, they're achieving excellent stability, and they can use all kinds of different oils. So this is very interesting to consider. Because usually you want to match emulsifiers with oils. So, you'll look at the, relative HLB of the oil, you'll look at the HLB for the emulsifier.

But I've been hearing things that you don't have to worry about that. You can just put it in. If the self-emulsifying material is well-designed, then you can use a variety of different systems, a variety of different oils, and achieve very nice, formulations. And you don't have to be or have a PhD in Physical Chemistry to do it. You're just, the systems are easy to use.

Nigel Langley: That's excellent. I'm enjoying this discussion. And... But we're coming towards the close of the podcast. And, just thought Gloria, it would be helpful to sort of summarize, if you may, the benefits of coprocessed excipients in the topical area for us.

Gloria Ho: Sure. I think really the biggest benefit of these coprocessed excipients is the idea of simplicity. Which is that, as it is, topical formulations, they are so complicated just because you have to consider, the chemistry, you have to consider the compatibility of the materials, and you also have to consider the processing. Especially each time you make any kind of change. When you bring a coprocessed excipient into play, the idea is that you are trying to simplify your life as a formulator. Because the individual components have been balanced for simplicity, or for ease of use.

And as a result, it can ultimately help to improve whether it's lab scale or industrial scale manufacturing. Furthermore, when we think about these topical formulations, what we want to achieve is to really optimize those critical quality attributes, to really optimize that, those performance properties. And by utilizing these coprocessed excipients, we strive to be able to really achieve those goals at a much faster or more expedited rate, with, really by utilizing the science that has been developed by, the individual suppliers that have created these well-balanced products.

Nigel Langley: That's fantastic. Thank you very much, both for summarizing very nicely, Gloria, and also for contributing to this podcast, as well as Norman. I appreciate your insights and your knowledge in this area. And we appreciate that. That actually now closes this current podcast. And in our 10 Billion, Reasons series. And stay tuned for the next, edition to the podcast series. And with that, I thank you again for your attention and your time.

Speaker 4: BASF, we create chemistry.