

Mineral base oils for intended food contact. 3H covers so much more!

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In food and pharmaceutical production, base oils have a crucial role. Not the common solvent refined base oils but the products better known or referred to as highly refined mineral oils. These base oils need to comply with the 21CFR172.878, and are pharmaceutical grade white oils. This code of federal regulations stipulates in detail what specification the base oil has to meet. As such, it is relatively easy to communicate but we are faced with some history in the registration market. In the good old days the USDA, United States Department of Agriculture, created a category called 3H. This category was probably there to help the food safety inspectors do their job more easily when inspecting a plant. If products were used and they were registered 3H at the USDA then the product met the 21CFR172.878. A similar system was created for lubricants with incidental food contact, H1. In the definition of the category 3H it was described as release agent, a limited application. This registration is currently used by NSF and 2Probit, the 2 registering bodies active in this field.

When looking at the 21CFR172.878 the application of release agent is indeed mentioned in the many identified uses of the highly refined mineral base oils, but many other applications are also stated in the CFR. As such a product registered as 3H has a much wider application area than the release agent. One must be aware that there are strict limitations on the amount of product that can come into contact or can be added to the food. The 21CFR172.878 is therefore titled FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION. 3H products can be used as the base oil for lubricants but I do not want to use the word lubricant base oil here on purpose. As soon as it is in a lubricant application it needs to meet H1 and comply with the limitations of H1 i.e. 10 parts per million (ppm). for mineral oil based lubricants.

There are 16 applications stated in the 21CFR172.878 among these defoamer, release agents, protective coatings, dust control and even wine production. All have their specific limitations stated. It pays to read and understand the applicable 21CFR.

Europe is different. The 21CFR is specific US set of regulations and will not meet EU laws. In the EU, one has to deal with not only the EFSA regulations but often also the various national laws that come on top of this. EFSA has given a clear position with its scientific opinion of 2013 where the ADI have been established (ADI = acceptable daily intake). Unfortunately, the EU is not as straight forward as the US system. Mineral oils are regulated for pharmaceutical use but not for food production. References such 'as little as technically feasible' make a quantification difficult, as is ADI. For that reason, many companies will use the US based system to support their GMP (good manufacturing practice) and HACCP (Hazard Analysis and Critical Control Point). EU regulations will continue to develop in the coming years. The MOSH and MOAH discussion has contributed to a better understanding of the safety of mineral base oils. The German government body BfR has adjusted its opinion regarding MOAH and they are leading in this field in the EU. It is expected that MOSH will see an improved acceptance due to the many beneficial uses and the, often, overstated adverse effects of these products by those uninformed. 3H Pharmaceutical grade white oils have their important role in many applications and will continue to support our food and pharmaceutical production.

Reference:

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=172.878>

LINKS
www.fragol.de