

**National Organic Standards Board
Handling Subcommittee Proposal
Ancillary Substances Permitted in Cellulose**

January 3, 2017

This proposal addresses the additional ancillary substances for use with cellulose, which is currently listed on the National List at §205.605(b) Cellulose- for use in regenerative casings, as an anti-caking agent (non-chlorine bleached) and filtering aid.

Ancillary substances are intentionally added to a formulated generic handling substance on the National List. These substances do not have a technical or functional effect in the finished product, and are not considered part of the manufacturing process that has already been reviewed by the NOSB. While some of these substances are removed or consumed in their processing, some may remain in the final product in tiny amounts.

While the ancillary substances for use in cellulose in the current chart were approved during the recent sunset review and vote by the NOSB at the St. Louis meeting, there were several additional ancillaries (listed in chart below) that were identified during the second public comment period that were not on that list. These additional ancillary substances were identified after the final proposal had been posted¹ and thus there is a need to bring those forward now.

The Handling Subcommittee believes that this should capture all of the functional classes in use for cellulose, along with those ancillary substances currently in use with cellulose under said functional classes. Any additional ancillaries that fall within one of the functional classes listed below do not need to be reviewed further in order to be used. Any new functional class of ancillaries however, would need to be petitioned in order to be allowed for use with cellulose.

1. Identity of Additional Ancillary Substances Permitted for use in cellulose.

Functional class	Substance name	CAS or INS number- if known	Synonyms
Shirring Aid	Food Grade Mineral Oil		
Shirring Aid	Food Grade "White" Mineral Oil	CAS # 8042-47-5	
Humectant	Glycerin	CAS # 56-81-5	Glycerine
Coating	Polyvinylidene, vinyl chloride	CAS # 9002-85-1	
Coating	Kymene		
Coating, pH control agent	Sodium Hydroxide	CAS # 1310-73-2	
Peeling aid	Carboxymethyl cellulose, with	CAS # 9000-11-7	

¹ Substantive changes are not allowed once the final document has been posted

	Polysorbate 80 as an emulsifier to aid the CMC	CAS # 9005-65-6	
Synthetic binder	Resin		

2. Identify any ancillary substances, or categories of substances prohibited for use in Cellulose:

Mineral oils, untreated or mildly treated, appear on the IARC list - However, “food grade” mineral oils and white mineral oils are not included under this listing. The food grade types of mineral oils go through a refinement process that classifies them as a “highly refined” mineral oil with the potential carcinogens having been removed via these processes. Thus, mineral oils that are untreated or mildly treated, should not be allowed as an ancillary substance for use with cellulose or any other substance used in organic handling. Only highly refined mineral oils (food grade or white) should be allowed. (Information provided in the Report on Carcinogens for Mineral Oil: Untreated or Mildly Treated; Fourteenth Edition. National Toxicology Program, Department of Health and Human Services).

3. Describe need for material, review of material, discussion, and subcommittee vote.

Ancillary substances for cellulose consist of coating agents (used primarily in casings), anti-caking/anti-sticking agents, binders, carriers, and as releasing agents. Because of the 3 different types of listed uses for cellulose on the National List, the presence of these ancillaries may vary slightly depending on how each type of cellulose is intended to be used. Ancillary substances, including those on this additional list, were discussed at the fall 2016 NOSB Meeting in St. Louis. It was at that time the decision was made that an additional proposal would need to come forward so that those additionally identified ancillaries could be added to the ancillary chart for cellulose.

Evaluation Criteria:

- 1. Impact on Humans and Environment:** Is there any evidence the substance(s) may be harmful to human health or the environment?

The Handling Subcommittee ascertains that the small amounts of ancillary substances used in cellulose have not shown to be of concern to human health or the environment. Additionally, the Subcommittee is confident that cellulose manufacturers are following all regulations about waste disposal and are properly adhering to those regulations to ensure worker safety due to any possible unnecessary exposure.

- 2. Essential & Availability:** Is the substance necessary to the handling of the product because of unavailability of wholly natural substitute products, or essential for the handling of an organic product?

During the most recent Sunset Review of cellulose, organic handlers provided the NOSB with comments about essentiality. According to the latest technical evaluation report (TR), while there are sources of cellulose that may not contain ancillary substances, these materials are

needed for consistency and performance in cellulose used for several applications. While some handlers have found alternatives to cellulose, those that still use cellulose provided the NOSB with a broad variety of reasons why it is still essential to their handling process.

3. **Compatibility & Consistency:** Is the substance's use consistent and compatible with organic handling practices?

Yes, the Subcommittee found no reason why the use of these ancillaries in cellulose should not be allowed for the currently allowed uses of cellulose as listed, with annotations, on the National List.

Subcommittee Action & Vote:

Motion to accept this document in support of, or to restrict the use of, the following ancillary substances or categories of substances in cellulose, as shown in the above chart and/or text of this document

Motion by: Harold V. Austin IV

Seconded by: Ashley Swaffer

Yes: 7 No: 0 Abstain: 0 Absent: 2 Recuse: 0

Approved by Lisa de Lima, Handling Subcommittee Chair, to transmit to NOP January 3, 2017