



October 3, 2019

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP
1400 Independence Avenue, SW
Room 2648-So., Ag Stop 0268
Washington, DC 20250-0268

Docket: AMS-NOP-19-0038

RE: Handling Subcommittee – 2021 Sunset Reviews for §205.605 and §205.606

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment to the National Organic Standards Board (NOSB) on its 2021 Sunset Review.

The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing over 9,500 organic businesses across 50 states. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's mission is to promote and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

OTA thanks NOSB for carefully considering each handling input scheduled for review as part of the 2021 Sunset Review cycle. Materials that have been placed onto the National List for use in handling should remain on the National List if: 1) they are still essential to and compatible with organic production and handling practices; 2) there are no commercially available alternative materials (natural, organic) or practices; and 3) no new information has been submitted demonstrating adverse impacts on humans or the environment (OFPA SEC. 2118 [7 U.S.C. 6517 and 6518] National List). Furthermore decisions must be transparent, non-arbitrary, and based on the best current information and in the interest of the organic sector and public at-large. Furthermore decisions must be transparent, non-arbitrary, and based on the best current information and in the interest of the organic sector and public at-large. It's critical that NOSB hear from certified handlers on whether these inputs are consistent with and essential to organic handling, or whether there are other effective natural or organic alternatives available.

About OTA Sunset Surveys

OTA is submitting results to our Sunset Surveys created for each input under review as part of the 2021 Sunset Review cycle. These electronic surveys include about 10 questions addressing the **necessity (crop and livestock)** or **essentiality (handling)** of each input. See Appendix A for a sample survey. Our surveys do not address information regarding the impacts on human health or the environment.

The surveys are open to any NOP certified organic operation. The names of the companies submitting the information are confidential (not disclosed to OTA). To ensure wide distribution of the surveys beyond OTA membership, OTA worked with Accredited Certifying Agencies (ACAs) and the Organic Materials

Review Institute (OMRI) to distribute the survey to all of their clients as well as to targeted clients they know are using the inputs under review. OTA also worked through its Farmers Advisory Council¹ to help assist in distribution to NOP certified farmers.

Results of OTA Sunset Surveys

OTA has received 122 responses on our 2021 Handling Sunset Surveys (34 new responses since the spring meeting). Below is a summary of the feedback received via OTA’s Sunset Surveys to date.

§205.605(a) – Non-synthetic Non-agricultural (non-organic) substances allowed as ingredients in or on processed products labeled “organic” or “made with organic (specified ingredients or food group(s)).

Substance	# of responses	Summary of responses	Average rating of Essentiality (from 1 to 5, with 5 being “critical – would leave organic without it”)
Citric acid	13	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Used routinely as a flavor, acidulant, and pH buffer in a wide variety of organic products (beverages, juices, fruit spreads, yogurt, ice cream and other frozen desserts, cookies, crackers, canned meals, snacks, baking mixes, cereal, granola bars, snacks, dressings, refrigerated baked goods, salad dressings, condiments, vegetable oils, fruit concentrates, frozen potatoes, frozen fruits, canned tomatoes, pasta sauce, soup, gummy candy, fruit snacks, nutritional supplement and more). - Essential for shelf-stability of food products. - Essential for food safety - Essential for gel formation: citric acid is used to adjust the pH of pectin products in order for them to form gels - Essential for stabilizing colors: it is critical that a product has the proper pH to achieve the desired color; i.e. anthocyanins are red at low pH and blue at a high pH. <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> - No other alternatives function in the same manner. - Have searched but not found an organic source that supports meets specification requirements in terms of quantity or quality. - No viable alternatives that meet our need to fully acidify certain ingredients while maintaining the sensory attributes and safety of finished products. - Organic lemon juice concentrate can sometimes be a suitable alternative for providing tartness of flavor, but is unsuitable for adjusting pH and can impart undesirable flavors and colors in some applications - No management practices have been identified that could eliminate the need for the substance. <p>If the material were prohibited:</p>	4.5

¹ OTA’s Farmers Advisory Council was established in 2013 to formalize two-way communication between OTA and member producers as well as regional organic producer organizations across the United States. Through dialog and input, FAC gives organic farmers a voice to directly influence OTA’s policy and provides an avenue for OTA to share information and advocacy work with this stakeholder group.

		<ul style="list-style-type: none"> - Significant negative effects to the quality of the organic products (taste, stability, food safety). - Products do not meet customer expectations - Would not be able to safely produce fruit juices. - Reduced production of organic processed products. - Lack of pH control in products can create a food safety risk. - Products would not be able packaged as shelf-stable 	
Lactic acid	7	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Used routinely as a flavor, flavor enhancer, acidulant, buffer, and coagulating agent in a wide variety of organic products (butter, cheese, other dairy products, supplements, cereal, bars, beverages, cookies, various condiments, salty snacks, confectionaries, and more). - Essential for pH control of certain products. - Essential for maintaining freshness - Provides longer lasting tartness in confectionary products <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> - There are no organic alternatives that are commercially produced. - No management practices have been identified that could eliminate the need for the substance. <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Taste, product stability, and food safety would be negatively affected. - Certain products would be unable to be produced in organic form. 	4.3
Calcium chloride	6	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Used routinely as a buffer, firming agent in a variety of organic products (yogurt, condiments, soups, canned diced tomatoes, other tomato products, and more) - Used as coagulant / curd development in dairy and plant-based alternatives <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> - For certain products, depending on the characteristics of the ingredients being used in the product, the material is needed to meet quality standards. - Cannot find reliable supplier of ingredients that do not use the material. - Attempts to find organic alternatives are unsuccessful. - No management practices have been identified that could eliminate the need for the substance. <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Decreased quality of organic products. - Diced tomatoes would not hold their shape during the canning process and would look more like crushed tomatoes. - Unable to make certain products with a consistent viscosity. 	4.8
Dairy cultures	6	<p>Note: In addition to survey responses summarized here, please also see the separate comment submitted by the Organic Trade Association on this material.</p> <p>The material is essential because:</p>	4.8

		<ul style="list-style-type: none"> - Use routinely for acidification, flavor development, and culturing for a variety of dairy products (yogurt, sour cream, cheese, sauces, salad dressings, salty snacks, and more) - Essential for transforming fluid milk into cheese and yogurt <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> - No information on alternative substance of practices was provided <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Cannot make yogurt or cheese without dairy cultures - No management practices have been identified that could eliminate the need for the substance. <p>Ancillary substances: dextrose, polysorbate, sodium formiate, sucrose, maltodextrin</p>	
Enzymes	10	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Used frequently in a variety of organic products (yogurt, latose-free milk, fruit juices, fruit concentrates, frozen desserts, bread products, baked goods, snacks, cheese, condiments, syrups, maltodextrins, sugar, and more) for hydrolysis, breaking down lactose (allowing for less added sugar), fruit depectinazation, coagulant and dough conditioner. - Helps with fruit pulp - Lactase is used to make lactose-free milk <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> - There is no alternative for certain cheese and dairy products - Mechanical centrifuge helps but does not eliminate all of the fruit pulp <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Cannot make yogurt or cheese without enzymes <p>Ancillary substances: glycerol, potassium chloride</p>	4.8
L-Malic acid	1	<p>The material is essential because:</p> <ul style="list-style-type: none"> - We do not currently manufacture a confectionary product using L-Malic acid because it is cost prohibitive when compared to Citric Acid. If there were more marketplace demand and the economies of scale were to enable the price to be more competitive, we would love to have this available for formulating. 	3
Magnesium sulfate	0		
Microorganisms	4	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Used as an acidifier and for flavor development in a variety of organic products (yogurts, teas, cocoa products, variety of cultured products) - Essential to ferment cocoa beans <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> - No information on alternative substance of practices was provided <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - End of business 	4.3

		<ul style="list-style-type: none"> - Cannot make yogurt - Cannot make cocoa products <p>Ancillary substances: dextrose, polysorbate, sodium formiate, sucrose, maltodextrin</p>	
Perlite	3	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Used as a filtering aid for various organic products (fruit juices, fruit concentrates, fruit spreads, various oils) <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> - Have not conducted a search for organic alternatives - No alternative management practices are sufficient - Different fruits do better with specific filtering agents <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Cannot make certain fruit concentrates - Oils would not be as clear - Oils would have shorter shelf life - Discontinue production of product 	5
Potassium iodide	1	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Used as a nutrient in infant formula <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> - No information on alternative substance of practices was provided <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Cannot make infant formula in organic form 	4
Yeast	4	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Used as a leavening agent in a variety of organic baked goods, crackers, bagels - Used for flavor and as a nutritional component in a wide variety of organic <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> - There are organic yeast options available, but not always in the appropriate quantity. Even when organic yeast is commercially available, the quality can vary. - Organic yeasts have not met functional requirements regarding flavor. - Organic yeast is successfully being used as a leavening agent in some organic products. - Organic yeast is not available in the correct quantities and often does not exhibit the correct properties for consistent application. <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Many baked good would no longer be available in an organic form - Reformulating with organic yeasts to meet specific flavor profiles would be a substantial and costly effort. - Reduced production is reformulations are not successful. - Reduced production would lead to reduced purchases of organic ingredients resulting in a loss of business for our organic suppliers and growers. 	5

§205.605(b) – Synthetic Non-agricultural (non-organic) substances allowed as ingredients in or on processed products labeled “organic” or “made with organic (specified ingredients or food group(s)).

Substance	# of responses	Summary of responses	Average rating of Essentiality (from 1 to 5, with 5 being “critical – would leave organic without it”)
Alginic acid	0		
Activated charcoal	4	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Used for filtering batch water used to produce fruit juices - Essential to remove compounds from well water in water purifying system to meet drinking water standards - Used as filtering aid for various oils <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> - Have not conducted a search for organic alternatives - No alternative practices or substances have been identified <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Would not be able to meet safe drinking water standards - Would shut down operations 	5
Ascorbic acid	7	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Used as an acidulant, flavor enhancer, stabilizer, antioxidant, vitamin C source in a variety of organic products (frozen desserts, fruit juices, spreads, syrups, gummy candy, fruit snacks, nutritional supplements) - Essential to hold color during processing of fruit - Essential as source of vitamin C and provides tartness <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> - Have searched for organic alternatives for Vitamin C sources but potential options (rise hips; acerola) are not commercially available or are otherwise functionally unsuitable (higher usage levels are needed; can add undesirable color and fibrous material) - No alternative management practices are sufficient <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Would not be able to produce fresh pressed juices - Would not be able to fortify with Vitamin C which is typical for some products - Unable to meet consumer demands 	4.5
Calcium citrate	2	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Used in fruit fillings to thicken and stabilize the gel structure in various products (yogurt, toaster pastries) - Use to fortify nutritional supplements with calcium - Essential for developing a sugar-acid-pectin gel found in jams, jellies, and other fruit spreads <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> - No other known sources available that provide equivalent functionality <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Decline in quality texture and flow characteristics 	3.8

Ferrous sulfate	1	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Used as a nutrient in infant formula <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> - No information on alternative substance of practices was provided <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Cannot make infant formula in organic form 	3
Hydrogen peroxide	8	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Used as a sanitizer on manufacturing equipment and other food contact surfaces - Used as a sanitizer of food packaging prior to filling the product (fruit juices, yogurt, milk, other beverages) - Sterilant for Aseptic Manufacturing and Packaging - Fluid Milk Filler Sanitation - Essential for sanitation procedures <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> - There are few alternatives and options that are allowed or are appropriate for organic products - No sufficient alternatives have been identified <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - No aseptic packaging of foods - Organic production and handling would be severely limited due to food safety concerns and FSMA requirements - Business would end - People could get sick and die 	5
Nutrient vitamins and minerals	11	<p>Note: In addition to survey responses summarized here, please also see the separate comment submitted by the Organic Trade Association on this material.</p> <p>The material is essential because:</p> <ul style="list-style-type: none"> - Use for nutritional fortification for various organic products (yogurt, milk, fruit juices, cereal, flour, gummy candy, fruit snacks, nutritional supplements, various snacks, cereals, and baked goods, as wells as foods for infants and children) - Essential for meeting nutritional needs - Essential for meeting federal and state regulations for nutrition - Essential for formulating nutritional supplements - Standard milk nutrient fortification ingredient: Vitamins A&D, D <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> - Have used a natural vitamin when commercially available - Organic plant extracts are available that can be used for low level fortification, but are less concentrated in the active ingredients so would need to be used at a much higher usage rate impacting flavor and texture - There are not organic options for many nutrients - No alternative management practices are sufficient <p>If the material were prohibited:</p>	4.9

		<ul style="list-style-type: none"> - Some products would not be produced in organic form due to poor quality - Unable to comply with state and federal laws - Unable to fortify certain products which are for populations with specific nutritional needs. - Would convert to conventional if not possible to reformulate <p>Ancillary substances: acacia gum, corn starch, medium chain triglycerides (from palm oil), tocopherol</p>	
Peracetic acid	11	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Used routinely as a sanitizer on manufacturing equipment across multiple processing lines and production facilities - Used as a wash for organic vegetables prone to high bacteria counts - CIP sanitizer for raw milk tankers - Leaves no residues and has low VOC emissions compared to alternatives - Essential for food safety <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> - There are few alternatives and options that are allowed or are appropriate for organic products - No sufficient alternatives have been identified that would make this material unnecessary - No equal alternative for controlling microorganisms as part of our overall food safety program <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Could not produce organic products - Lowered level of quality and possible safety risks - Organic production and handling would be severely limited due to food safety concerns and FSMA requirements - Business would end - Unable to sell fresh fruits and vegetables 	4.5
Potassium citrate	1	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Used as a buffer salt in confectionary products. When combined with citric acid, the pair provides tartness without as significant drop in pH. This is important in preventing the degradation of sucrose in confectionary products and for achieving consistent pH for the gelling on pectin. It offers an advantage over sodium citrate in that it does not add additional sodium to the product. 	3
Potassium phosphate	0		
Sodium acid pyrophosphate	3	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Used as a leavening agent in various organic products (baked goods, tortillas, snacks, refrigerated baked goods) <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> - Other allowed leavening agents are not stable enough in a high-moisture dough to allow for refrigerated doughs to rise in the oven when baked at home. <p>If the material were prohibited:</p>	4.5

		- Unable to make certain organic baked goods	
Sodium citrate	6	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Used as an antioxidant, stabilizing salt, and buffer in various organic products (infant formula, yogurt, creamer, cheese, toaster pastries, gummy candy, fruit snacks, nutritional supplements, various dairy products) - Essential in a sugar-acid-pectin gel to help control calcium availability so that the pectin doesn't prematurely gel. - When combined with citric acid, the pair provides tartness without as significant drop in pH. This is important in preventing the degradation of sucrose in confectionary products and for achieving consistent pH for the gelling on pectin. - Maintains freshness and pH emulsion <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> - Other allowed alternatives do not have proper pH stabilization properties needed in a pectin-based gummy fruit snack - Citric acid is used in conjunction with Sodium Citrate to balance the pH. <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Decline in quality - Unable to make certain dairy products with a stable and consistent pH 	4.7
Tocopherols	6	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Used as an antioxidant in various organic products (cereals, snacks, cookies, granola bars, milk products) - Essential for preventing rancidity in whole grain products - Used to lesson degradation of flavors due to oxidative rancidity. This extends the shelf life of flavors and of the resulting products made with them. In doing so, the cost of disposing of out of date flavors is reduced and the organoleptic quality of organic products are enhanced. <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> - Have extensively researched organic rosemary extract as an alternative but has not performed equally to tocopherols. - Have trialed rosemary oil but it is as effective as tocopherols as a long-lasting antioxidant. It also imparts a distinct flavor that is not desirable in certain products. <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Certain products would have significantly shorter shelf-life - May switch to conventional production 	4.7

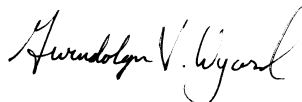
§205.606 – Non-organically produced agricultural products allowed as an ingredient in or on processed products labeled as “organic” only when the product is not commercially available in organic form.

Substance	# of responses	Summary of responses	Average rating of Essentiality (from 1 to 5, with 5 being “critical – would leave organic without it”)
Celery powder	4	<p>Note: In addition to survey responses summarized here, please also see the separate comment submitted by the Organic Trade Association on this material.</p> <p>The material is essential because:</p> <ul style="list-style-type: none"> - Used as a nitrate alternative in processed meat products that carry the “uncured” label, as required by USDA-FSIS (hot dogs, meat sticks, landjager, jerky, summer sausage logs, deli ham, deli summer sausage, pepperoni, bacon, and spiral hams). - Essential for providing additional attributes to curing, including maintaining a pink color, flavoring, and lowering acidity of the finished processed meat product. - Essential for blocking the growth of <i>Listeria monocytogenes</i> and <i>Clostridium botulinum</i> in the processed meat product. <p>Organic alternative are not sufficient because:</p> <ul style="list-style-type: none"> - No supplier is known to produce organic celery powder at this point. - It is difficult to locate organic celery powder in the sufficient quantity. When organic celery powder is available, the quality of the celery powder is often not a sufficient replacement for non-organic versions. - Not able to identify an organic plant source that could effectively provide the properties of non-organic celery powder <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Organic meat producers, would also no longer be able to produce cured products such as ham, bacon, and hot dogs. - Many certified organic processed meat products would be removed from the market. - Increased food safety risk from <i>Listeria monocytogenes</i> and <i>Clostridium botulinum</i> - Decreased quality of food products (color of pepperoni would be a gray-brown, rather than the crimson red typical of pepperoni and other cured meats) 	4.3
Fish oil	2	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Used for Omega 3 supplementation in organic products <p>Organic alternative are not sufficient because:</p> <ul style="list-style-type: none"> - No certified organic fish to get it from. <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Discontinuation of organic products 	4
Gelatin	1	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Used in the manufacturing of organic gummies <p>Organic alternative are not sufficient because:</p>	5

		<ul style="list-style-type: none"> - The nature of the gelatin manufacturing process requires a magnitude of scale (sufficient pig and cow hides) in order to be viable. The organic meat market size has not yet reached this critical mass. We continue to work with our gelatin suppliers in developing a supply chain to support future development of organic gelatin. <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Decline in quality of product - Economically devastating 	
Orange pulp, dried	3	Producers of organic oranges responded to this survey. Year round, these producers generate organic wet orange pulp and peel as a byproduct which is then sold to the food processing industry to be dried or otherwise used.	n/a
Seaweed, Pacific kombu	0		
Seaweed, Wakame	0		

On behalf of our members across the supply chain and the country, the Organic Trade Association thanks the National Organic Standards Board for the opportunity to comment, and for your commitment to furthering organic agriculture.

Respectfully submitted,



Gwendolyn Wyard
 Vice President of Regulatory and Technical Affairs
 Organic Trade Association

cc: Laura Batcha
 Executive Director/CEO
 Organic Trade Association

Appendix A – Sample Survey for Handling Inputs

1. Please describe the types of organic products produced or handled on your operation:
2. How many states are your products sold in? Are they exported to other countries?
3. How many years has your operation been certified organic?
4. Which organic products do you use this substance on/in? (e.g., yogurt, fruit juices, baked goods, etc.)
5. What function does the substance provide in your organic products and why is it essential? (e.g., stabilizer, thickener, flavor, sanitizer, etc.)
6. With what frequency does your operation use the substance? (e.g., seldom, as needed when a certain condition arises, routinely, etc.)
7. Have you conducted a search for the availability of natural (if the substance in question is synthetic) or organic (if the substance in question is natural) alternatives? (e.g. using yeast instead of chemical leavening agents)
 - If so, please describe what your search entailed:
 - Based on your search, describe the availability of allowed alternatives (organic or natural) in terms of quality, quantity and form:
 - If available, have you conducted research (e.g. R & D trials) on the use of allowed natural or organic alternatives in your organic product(s)? Briefly describe the results. Did they meet your specification requirements?
8. Are there any other management practices that would eliminate the need for the substance? (e.g., delayed harvesting instead of using a chemical growth hormone for ripening). If so, please describe the efficacy of the alternative management practices:
9. Describe the impact to your operation should you no longer be allowed to use the substance:
 - Organic product effects (effects to the quality of the organic product(s) you are marketing):
 - Environmental effects (effects to environment if the substance was no longer allowed; effects to environment from potential alternatives):
 - Economic effects (effects to economic health of your operation):
10. On a scale from 1 to 5 stars, rate the overall essentiality of this substance for your organic operation:

Unnecessary (don't need it at all)		Neutral (nice to have but could live without it)		Critical (would leave organic without it)
★	★	★	★	★
11. NOSB collects information about the "ancillary substances" (e.g. carriers, preservatives, stabilizers) that may be used to formulate commercial forms of the substance. Please list any ancillary substances that are identified on the ingredient statement on the specification sheet that accompanies the substance you purchase.