STARCH IRRADIATION

STERIS®

Isomedix Services

TECHNICAL TIP #21

What is Starch?

Starch is a common bulk filler material used to improve the tactile characteristics of texture and feel for many health and beauty aid products such as in cosmetics, deodorants, hair conditioners, and lotions. It is also used in the food industry in powdered food mixes and in pharmaceuticals as an excipient fill substance. Due to the organic nature of starch, it can support microbial growth, and many contain a natural population of microorganisms (or bioburden) of non-pathogenic and possibly even pathogenic organisms; although the most common microorganisms are yeasts and molds. In most cases, a manufacturer will purchase bulk quantities of starch and store it for use over a long period based on manufacturing demands. Storage time and environmental conditions can also affect the bioburden due to the nutritive characteristics of starch and favorable storage conditions to foster microbial reproduction.

Some examples of common types of starch are: corn starch, tapioca starch and starch copolymers (mixed with other bulk powders). These starch related products are known by many trade names depending on the manufacturer.

Starch and Radiation Treatment:

To ensure quality and safety of the end products, bulk starch is frequently treated with radiation to reduce or eliminate microbial contamination resulting in an extended shelf life or the salvage of previously contaminated material. The radiation dose determination required to reduce or eliminate the microbiological contamination follows similar concepts and methodologies used in the medical device industry for sterilization of medical products. The dose required is directly related to the "bioburden". Bioburden can be defined as the total number or microorganisms present and the types of organisms. Different organisms have different levels of resistance to radiation. The model for dose setting assumes that the bioburden is considered to be homogenous throughout the material and the microbial population will reduce logarithmically when exposed to increasing doses of radiation based on the sensitivity of the organism to radiation. The sensitivity of an organism is defined as a D_{10} Value, or the amount of radiation required to reduce the microbial population by 90%. In the medical industry this population reduction meets industry standards for the definition of "sterile" resulting in the probability of one non-sterile unit out of one million. In raw material irradiation, such as starch, the irradiation goal is to achieve a net "zero" microbial population. To achieve these levels requires selecting a radiation exposure based upon the assumptions of bioburden resistance and the actual contamination level of the product measured prior to irradiation by a qualified microbiology laboratory. The pre-irradiation measurement of the microbial population is commonly referred to as a "bioburden test" and is performed on a representative sample of the product. The recommended radiation level to apply to achieve the desired probability of microbial reduction is then determined by applying the results to industry standards.

Limiting Radiation Levels:

Irradiation effects on starch have been studied extensively, mainly in food starches, to control pests. As a result, it is known that higher levels of radiation can affect the polymer, creating undesirable changes. Common effects include: depolymerization (creating smaller polymer chains), change in solubility, pH change in solution, discoloration, and changes in surface properties (feeling sticky for example). As these characteristics are undesirable, radiation exposures used to reduce the microbial contamination levels should be as low as possible. These effects can be examined in more detail by simply irradiating a small volume of the material or product at higher radiation levels to determine if the physical characteristics or product efficacy are maintained.

Evaluating Starch Products for Irradiation:

Before recommending any radiation dose levels for irradiation, the actual product of interest must be evaluated. Starch products come in many forms, some are modified or cross-linked, therefore post-irradiation behavior cannot be determined just by knowing it is a starch. The end uses of the starch can also vary widely, allowing for acceptance of higher doses for some purposes, and rejecting these doses for others. The following criteria should be considered when establishing minimum and maximum radiation doses:

Minimum dose requirements*; *Bioburden levels and species of concern

Initial evaluations should include a determination of the number of microbial organisms and their species. This will allow estimation of the D_{10} value, along with a population count. By using the D_{10} value, a radiation dose exposure can be calculated to provide the reduction of organisms, as required. If only the bioburden population (normally reported in the number of colony forming units, or CFU) is known, an estimated radiation dose can still be determined.

In some cases, a low population of organisms may have no effect on the final product, although if the population reaches a certain level, it could cause negative effects. Pre-screening the bioburden of incoming raw materials, and establishing an action level for radiation processing, may help to reduce the number of processing steps and help to decide when the additional irradiation expense could be justified.

Another method which may be used is to select an “overkill” radiation dose and perform a USP sterility test post-irradiation as release criteria. However, the supplier has to be cautious not to use a “sterility” claim, as the US FDA considers “sterile” to be proven by quantitatively knowing the reduction of the bioburden population, which has not been performed by this method.

Overall, it is critical to understand that a sterile claim is not being made with the processing of bulk starch, and the user should consider the process as reducing the bioburden.

Suggestions for evaluating for maximum dose

It is recommended that products are always tested for material effects at a maximum dose calculated from x times the minimum dose (e.g. 1.5x minimum dose = maximum dose). Controlling the maximum dose can be achieved by selecting the lowest minimum dose acceptable and adjusting the maximum dose by manipulation of the product in the irradiator.

Summary

Different types of starch are known to have different tolerances. But some generalizations can be made:

1. Radiation exposure doses will likely be between 2-6 kGy
2. Cross-linked starches seem to tolerate radiation exposure the best and may be able to run in the 5-15 kGy range
3. Radiation exposure doses over 10 kGy can darken the product
4. Most common microbial contaminations are simple molds, which require only an extremely low level of radiation to provide lethality
5. Gram negative microbes are easier to eliminate than gram positive microbes
6. Minimum radiation levels are determined from microbial information (plate counts, gram stains, species identification)
7. Maximum radiation levels are based upon the product characteristics, effects of irradiation on the final product and efficacy of the product after irradiation

For more information, please contact:

STERIS Isomedix Services, Inc.
5960 Heisley Road
Mentor, Ohio 44060
877.783.7479
www.isomedix.com

STERIS®

Isomedix Services