

Technical Bulletin

Frequently Asked Questions Concerning Gamma Radiation

What is gamma radiation?

Gamma radiation is a phenomenon of natural radioactivity. When an atom emits either an alpha or beta particle, it often emits a gamma ray at the same time. Gamma rays are a type of electromagnetic radiation similar to X-rays, but of shorter wavelengths. Radioactive emissions are called ionizing radiation, because they are able to cause the formation of ions in matter by knocking off the atoms or molecules in their path. Treatment of materials with gamma radiation, commonly used in medical and pharmaceutical applications, involves exposing those materials to a radioactive Cobalt 60 source under tightly controlled conditions. The gamma rays from this source causes the ionization of water and the formation of highly reactive and short-lived hydroxy radicals which inactivate most microorganisms present by damaging or destroying their nucleic acids.

Why do I need gamma radiated products?

With the use of any animal-derived material, there is an inherent risk of contamination by microorganisms, including bacteria, viruses, mycoplasma and fungi. Although all materials used by SAFC Biosciences are rigorously pre-screened for such extraneous agents according to strict federal regulations, low levels may exist that are below the threshold of detection by current test methodology. SER-TAIN™, SAFC Biosciences' gamma irradiation process, provides greater assurance that any existing low level of microorganisms will be inactivated or reduced and the risks associated with animal-derived components are minimized.

What is SER-TAIN™ processing?

SER-TAIN™ is SAFC Biosciences' gamma irradiation processing system that has been filed with the Food and Drug Administration. SER-TAIN™ is completely validated and provides significant reductions in the level of common microbial contaminants.

What is meant by 'validated process'?

A validated process is one in which every step is fully documented to ensure consistency of methods and product integrity, as well as total traceability. Every step in the SER-TAIN™ process, including the packaging of product by qualified SAFC Biosciences employees, delivery to the irradiation facility via a SAFC Biosciences' truck and calculation of delivered dose, has been qualified and is performed the same way every time. By controlling each and every one of the steps in the process, we can assure our customers quality and consistency in every lot of gamma radiated product we supply.

What is the rationale for the selection of organisms used in the inactivation studies?

The organisms selected are naturally occurring potential contaminants from either the animals themselves or from the environment during the collection process. Organisms that are either not associated with the animal, i.e., Minute Virus of Mice, or are difficult to culture, i.e., Bovine Leukemia Virus, are chosen or substituted with consideration of relevance.

What effect does gamma irradiation have on product performance?

Gamma radiated serum has been tested side-by-side against non-radiated controls on several cell lines for growth promotion, plating efficiency, cloning efficiency and protein production. The radiated serum performed at levels greater than 80% of the controls, with no evidence of significant performance differences. Trypsin products made from radiated powder show no significant loss of dissociation activity when compared to non-radiated controls.

United States

SAFC Biosciences
13804 W. 107th Street
Lenexa, Kansas 66215
USA
Phone +1 913-469-5580
Toll free-USA 1 800-255-6032
Fax +1 913-469-5584

Europe

SAFC Biosciences
Smeaton Road, West Portway
Andover, Hampshire SP10 3LF
UNITED KINGDOM
Phone +44 (0)1264-333311
Fax +44 (0)1264-332412

Asia Pacific

SAFC Biosciences
18-20 Export Drive
Brooklyn, Victoria 3025
AUSTRALIA
Phone +61 (0)3-9362-4500
Toll free-AUS 1 800-200-404
Fax +61 (0)3-9315-1656

How much radiation are these products exposed to?

Because of their differing physical characteristics, serum and trypsin products require different levels of radiation to ensure inactivation of adventitious agents while still maintaining product integrity. Tight controls ensure that serum products are irradiated between 25 - 35 kGy and trypsin powder receives a dosage between 43 - 56 kGy. Other dose ranges are available on a custom basis.

What is the conversion of kilograys (kGy) to megarads (Mrad)?

One gray is equal to 100 rads, and therefore the dosage range of 25 - 35 kGy is equivalent to 2.5 - 3.5 Mrad.

What type of documentation accompanies these products?

A Certificate of Irradiation is provided with every lot of gamma radiated material. This document is generated by the irradiation facility itself and provides information about when the material was processed and what dosage of radiation the material actually received. Certificates of Analysis, which include Country of Origin information, are also available for each lot.

When are serum products tested — pre- or post-irradiation?

Before raw serum is accepted for use by SAFC Biosciences, each lot is screened for the presence of contaminants by the standards outlined in the Federal Code of Regulations, Title 9 (9CFR). After acceptance and initial processing, two methods of testing can be employed. The first method involves performing sterility testing on material pre-irradiation and then performing all other testing post-irradiation. Customers may also request material that has been completely tested prior to irradiation. Because all packages remain sealed and SER-TAIN™ processing is completely non-intrusive, no additional testing is required on these lots. Customized testing can also be arranged in order to best serve our customers' specific applications.

When are trypsin products tested?

Trypsin powder is screened by 9CFR for Porcine Parvovirus (PPV) prior to irradiation, and in fact, prior to acceptance by SAFC Biosciences. Only material in which no PPV can be detected is brought in-house and is then gamma irradiated. All other product testing is done on the final trypsin solutions.

How are gamma radiated products identified?

SAFC Biosciences has employed a unique system of identifying gamma radiated serum products. Prior to the irradiation procedure, a circular yellow indicator label containing catalog and lot numbers are applied to each bottle in addition to the standard labeling. Upon exposure to gamma irradiation, this indicator label changes color from yellow to red. This system

provides customer assurance that each bottle is irradiated, as well as supplying important product identification information. Labels on bottles of gamma radiated trypsin solutions all clearly identify the product as "Gamma Irradiated."

Does gamma irradiation provide protection against Bovine Spongiform Encephalopathy (BSE)?

Currently, there is no conclusive evidence that gamma irradiation effectively inactivates the agent responsible for BSE. Because there are no tests available for screening live animals, the best available assurance that bovine serum does not contain BSE is to source it from countries deemed BSE-free. All SAFC Biosciences bovine sourced products originate from countries recognized as being free of BSE, primarily the United States and Australia.

Do I need to change how I handle and use these products?

Radiated products should be handled, stored and used in the same manner as non-radiated products. The shelf-life and expiration dates of these products are also unchanged. Because there is no significant effect on product performance, when switching from untreated serum to SER-TAIN™ radiated serum, there is no need to alter the volume and concentration normally used.

For more information about this subject or other SAFC Biosciences' products and services, please call our Technical Services department.

Warranty, Limitation of Remedies

SAFC Biosciences warrants to the purchaser for a period of one year from date of delivery that this product conforms to its specifications. Other terms and conditions of this warranty are contained in SAFC Biosciences' written warranty, a copy of which is available upon request. ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING THE IMPLIED WARRANTY OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, ARE EXCLUDED. In no case will SAFC Biosciences be liable for any special, incidental, or consequential damages arising out of this product or the use of this product by the customer or any third party based upon breach of warranty, breach of contract, negligence, strict tort, or any other legal theory. SAFC Biosciences expressly disclaims any warranty against claims by any third party by way of infringement or the like. THIS PRODUCT IS INTENDED FOR PURPOSES DESCRIBED ONLY AND IS NOT INTENDED FOR ANY HUMAN OR THERAPEUTIC USE.

Additional Terms and Conditions are contained in the product Catalog, a copy of which is available upon request.

SER-TAIN™ is a trademark of SAFC Biosciences

© 2005 SAFC Biosciences

Issued October 2005 XT007
0103

United States

SAFC Biosciences
13804 W. 107th Street
Lenexa, Kansas 66215
USA
Phone +1 913-469-5580
Toll free-USA 1 800-255-6032
Fax +1 913-469-5584

Europe

SAFC Biosciences
Smeaton Road, West Portway
Andover, Hampshire SP10 3LF
UNITED KINGDOM
Phone +44 (0)1264-333311
Fax +44 (0)1264-332412

Asia Pacific

SAFC Biosciences
18-20 Export Drive
Brooklyn, Victoria 3025
AUSTRALIA
Phone +61 (0)3-9362-4500
Toll free-AUS 1 800-200-404
Fax +61 (0)3-9315-1656