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Helping all people live healthy lives

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Dear Valued Customer,

This letter is in response to your question regarding the latex content of BD Vacutainer® products.

The following products contain dry natural rubber (DNR), which is formed from coagulated natural rubber latex material:

In the stoppers:

- BD Vacutainer® Blood Collection Tubes with yellow stoppers and ACD additive 10mm glass only (Reference Number 364012)
- BD Vacutainer® Blood Collection Tubes with yellow stoppers and SPS additive 10mm glass only (Reference Number 366404)
- BD Vacutainer® Blood Collection Tubes with blue stoppers and Citrate additive 10mm glass only (Reference Numbers 366392 and 366393)

The following products do not contain latex:

- BD Vacutainer® Blood Collection Tubes with Hemogard™ closures
- BD Vacutainer® Blood Collection Tubes with Conventional Closures (stoppers) excluding those listed above.
- BD Microtainer® Blood Collection Tubes
- BD Microtainer® MAP Microtube for Automated Process
- BD Vacutainer® Eclipse™ Blood Collection Needle
- BD Vacutainer® Eclipse™ Blood Collection Needle with Pre-Attached Holder
- BD Vacutainer® Passive Shielding Blood Collection Needles
- BD Vacutainer® Safety-Lok™ Blood Collection Set
- BD Vacutainer® Safety-Lok™ Blood Collection Set with Pre-Attached Holder
- BD Vacutainer® Push Button Blood Collection Set
- BD Vacutainer® Push Button Blood Collection Set with Pre-Attached Holder
- BD Vacutainer® Multiple Sample Luer Adapter
- BD Vacutainer® Blood Transfer Device
- BD Vacutainer® Luer-Lok™ Access Device
- BD Vacutainer® Urine Collection Cup with integrated transfer device

Since latex allergies have become more prevalent among the patient population as well as among healthcare workers (HCW), healthcare facilities have wisely chosen to enact latex-free policies to protect their patients and healthcare workers. BD understands the safety concerns regarding latex allergies and strongly believes that, if handled as described in the package inserts, the

BD Vacutainer® products that contain DNR pose a minimal risk to patients and healthcare workers. At the same time, BD recognizes the growing concern and is in the process of developing a latex-free product portfolio while maintaining the highest clinical performance and quality.

All naturally derived rubber products contain latex proteins. The term "latex" is non-specific in the sense that it has been used to describe products made using either the natural rubber latex process (NRL) or the DNR process. The principal difference between these two substances is the potential for exposure to the proteins found in the natural latex rubber. The DNR process uses coagulated natural latex in the form of dried or milled sheets. Products are formed from dry natural rubber by compression molding, extrusion, or by converting the sheets into a solution for dipping. (This information comes from the FDA's Final Rule on latex labeling issued on 9/30/97, and 21 CFR 801.437). The FDA mandates that any product that has DNR carry the label "Product contains dry natural rubber."

BD products have a low risk profile of an adverse medical reaction to latex for the following reasons:

1) Latex allergy is a contact reaction, which means physical contact with latex allergens or latex particles is necessary for a reaction to occur. The processing of DNR creates a hard, coagulated material that does not release particulate matter as does NRL (i.e. gloves or balloons). As such, it would be extremely difficult to cause aerosolization of latex particles from a DNR material. Also, in most cases, HCW handle the BD Vacutainer® products containing DNR using gloves, as part of the universal specimen handling protocols. It is very unlikely that DNR can cause allergic reactions under these circumstances.

2) The non-patient (NP) sleeve is not intended for patient or HCW contact. Within the normal handling parameters, the likelihood of exposure to the DNR and the latex allergens contained within is very low. Before use, the non-patient end needle sleeve is covered with an NP cap and during use the NP needle is recessed inside the tube holder. Contact with this material is unlikely, and if universal precautions are observed, there should be minimal risk of adverse reaction. Any risk can be further reduced with the adoption of pre-attached holder products.

3) There is an imperceptible risk of exposure to latex through backflow of blood obtained by piercing of the stopper containing DNR. A study that compared the levels of latex allergen contamination of solutions obtained by sampling through DNR-containing stoppers versus when no stoppers were used (latex-free control) showed no difference in latex allergen concentrations between the two sampling methods. Removal of the dry rubber stopper from vials did not yield solutions with less latex allergen than solutions prepared by sampling through the stopper. (Thomsen DJ , Burke TG . Am J Health Syst Pharm. 2000: 57:44-7). These data indicate that the latex present in DNR in blood collection tubes will most likely not increase the risk of exposure to latex allergens.

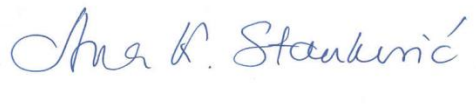
Attached for your reference is a bibliography of supporting information regarding DNR and latex reactions.

1. Thomsen DJ and Burke TG. Lack of latex allergen contamination of solutions withdrawn from vials with natural rubber stoppers. Am J Health Syst Pharm. 2000; 57:44-7.

2. Binkley HM, Schroyer T and Catalfano J. Latex Allergies: A Review of Recognition, Evaluation, Management, Prevention, Education, and Alternative Product Use, Athl Train. 2003; 38:133–140.

If you have any additional questions, please feel free to call the BD Vacutainer Technical Services Department at 1-800-631-0174.

Regards,



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