

Facts on B. Braun Medical Inc.'s use of Ethylene Oxide

- Like other companies in our industry, B. Braun Medical Inc. ("B. Braun") uses ethylene oxide because it is currently the only available alternative to effectively sterilize certain medical products. As stated by the FDA, "For many medical devices, sterilization with ethylene oxide may be the only method that properly sterilizes and does not damage the device during the sterilization process." FDA Fact Sheet
- As with all medical sterilization facilities in this country, our use of ethylene oxide is closely regulated by the federal and state government. Among other applicable standards, our ethylene oxide sterilization operations are authorized by and subject to an air permit issued by the PA Department of Environmental Protection.
- Through our efforts, ethylene oxide emissions from our facility at 901 Marcon Blvd, Allentown have declined during the last several years. In fact, our reported emission levels have been less than 10% of those allowable under our air permit.
- We continuously evaluate our operations for opportunities for further improvement, and monitor developments in cutting-edge technologies related to all aspects of our operations. Consistent with these commitments, we have instituted measures that are not required by any applicable regulatory standard to further decrease emissions of ethylene oxide at our facility, and thereby further reduce our environmental impact in the community.
- We also continue to investigate the availability of alternative sterilization methods that are consistent with our commitment to ensuring the safety of patients, clinicians, our employees and the environment.

Protecting the Health and Safety of our Employees and Neighbors

- B. Braun has a longstanding history of responsible operation of our facilities in a manner designed to fully protect our employees and the communities in which we operate. We would not operate our facility if we believed our operations created an unsafe environment for our employees or our neighbors.
- Regarding the risk analyses discussed in the 2014 National Air Toxics Assessment (NATA) Report, it is important to understand that the reported information is not based on any actual measurements of ethylene oxide levels in the ambient air, either in our community or elsewhere in the country. Nor is it based on an evaluation of any reports of actual negative health effects. Instead, the NATA Report discusses the results of computer

modeling of projected impacts, based on multiple assumptions, including exposure to ethylene oxide for 70 years at modeled levels. The EPA has stated that, "based on available data, we do not expect ethylene oxide levels in the air around facilities to be high enough to cause immediate health effects." <u>EPA FAO</u>

- Dr. Wes Cetnarowski, B. Braun's Chief Medical Officer, has evaluated data from the Pennsylvania Cancer Registry Dataset on cancer types that have been potentially related to exposure to ethylene oxide, and found that rates for these cancer types in the region around our Allentown facility are comparable to, or lower than, the rates in other areas of Pennsylvania.
- B. Braun has pursued, and will always strive to pursue, optimal performance in terms of limiting our environmental impact while providing high quality medical products for millions of Americans.

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