

FS No. 37-088-0322

Waste Classification for BOTOX® (OnabotulinumtoxinA)

1. Background

Botulism, a potentially deadly disease, is associated with the bacterium *Clostridium botulinum*, but it is not the bacteria itself that causes botulism. Toxic proteins produced by the *Clostridium botulinum* bacteria are the cause of botulism. BOTOX® is made from the purified form of one of these toxic proteins, onabotulinum toxin A otherwise known as onabotulinumtoxinA. The use of BOTOX for a variety of conditions has risen dramatically in the past few years. It is used in minimizing the appearance of wrinkles (mostly on the face), reducing muscle spasms in a variety of organs, reducing hyperhidrosis (super sweating), and reducing the occurrence of migraines in chronic migraine sufferers.

2. Discussion

Disposal of the waste generated from this treatment process (partial vials and empty vials) has raised some questions regarding its classification for disposal. The debate centers over whether to classify this waste as solid waste or regulated medical waste (RMW). The U.S. Army Medical Command (MEDCOM) and Defense Health Agency (DHA) define RMW as “Waste generated in the diagnosis, treatment, research, or immunization of human beings or animals, which can cause disease or which, if not handled properly, poses a risk to individuals or a community. These wastes are also called ‘infectious waste,’ ‘biohazardous waste,’ ‘clinical waste,’ ‘biomedical waste,’ or simply ‘medical waste.’ Terms will vary based upon locality.”^{1,2} Since there are no live or dead bacterium *Clostridium botulinum* in BOTOX, the U.S. Army Public Health Center (APHC) considers BOTOX (onabotulinumtoxinA) to be a chemical hazard, not an infectious one.

Although APHC does not consider onabotulinumtoxinA a RMW, it is still one of the most deadly toxins known to humans and should not be placed into a landfill or into the sanitary sewer untreated. The World Health Organization (WHO)³ indicates that the toxin produced by bacterium *Clostridium botulinum* is destroyed by boiling (i.e., at internal temperature greater than 85°C for 5 minutes or longer). Since the RMW generated by Medical Treatment Facilities is routinely either steam sterilized or incinerated as the preferred method of treatment, disposing of the onabotulinumtoxinA waste in the RMW stream is the best method to ensure proper inactivation and disposal of this item.

3. Disposal

- a. Vials with residual amounts of BOTOX remaining in them should be placed in sharps containers.
- b. Empty vials should be managed as solid waste and placed in glass recycling containers or the general trash.
- c. Used syringes should be placed in sharps containers.
- d. Unopened, expired, or excess stocks of BOTOX should be returned to a reverse distributor for potential credit.

References

1. DHA. 2021. PM 6050.01, *Medical Logistics (MEDLOG) Regulated Medical Waste (RMW) Management*.
2. MEDCOM. 2017. Regulation 40-35, *Management of Regulated Medical Waste*.
3. “Botulism,” WHO, <https://www.who.int/news-room/fact-sheets/detail/botulism>.

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