Inspections, Compliance, Enforcement, and Criminal Investigations

Evaluation of Production Cleaning Processes for Electronic Medical Devices - Part II, Cleaning Solvents

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The proper selection and use of cleaning solvents is one of the most important factors to check when evaluating a cleaning process. One of the first things that should be checked is compatability of the cleaning solutions with the work to be cleaned. Cleaning solvents used on electronics parts and assemblies should be nonconductive, noncorrosive and should not dissolve or degrade the quality of parts or materials. Other important factors are the chemical purity of the cleaning solvents and cleanliness of the storage container used both in the cleaning operation and to store the chemicals. Often the types of available cleaning solvents dictate the type of components that are used. If the cleaning solvents are not compatable with the components used, degraded performance and even field failures can result. For example, electrolytic capacitors are susceptible to damage from halogenated solvents, Freon{{Registered Trademark}} TF and TMC. These solvents in liquid or vapor stage can diffuse to the inside of the capacitor causing corrosion that can result in failure after a few months. To prevent damage, in this example, alcohols may be used for cleaning or sealed capacitors can be used.

Some of the more common cleaning solvents used in the manufacture of medical devices are methyl, ethyl and isopropyl alcohol, deionized water and the chlorinated and fluorinated solvents. For cleaning electronic parts and assemblies, both polar and nonpolar solvents or appropriate blends of these solvents should be used. The nonpolar solvents dissolve oils, greases and some rosin while the polar solvents dissolve polar soil residues such as finger salts and those found in rosin activators. To achieve the ability to solubilize both polar and nonpolar contaminants, chlorinated and fluorinated solvents have been blended with ethyl and isopropyl alcohol, acetone, water or other appropriate liquids.

Chlorinated cleaners have relatively higher boiling points and are more aggressive in cleaning action than the fluorinated cleaners. Because of this they are typically used in cold-cleaning operations. Fluorinated solvents have a lower boiling temperature and gentler solvency action and are used in both vapor degreasers and for cold cleaning. Degreaser solvents are generally azeotropes or blends of solvents that have the same composition in the liquid and vapor phase.

Ethyl and isopropyl alcohol are considered natural solvents for rosin flux solids, and are commonly used as vehicles fc these fluxes. At least one study has shown that alcohol is probably the best solvent presently available for removing ionic contaminants (Reference 2). This study also showed that ethyl and methyl alcohol are superior to isopropyl alcohol for removal of ionic residues.

Water will not dissolve rosin flux but is used as a solvent for water soluble fluxes. Water soluble flux removal is normally accomplished by a thorough rinsing of the part with deionized water so that no ionic contaminants remain. Deionized water and alcohol are also sometimes used as a final rinse to remove any traces of fluorinated or chlorinated cleaning solvent residue.

Methyl chloroform (l,l,l, - trichloroethane) and trichloroethylene are commonly used chlorinated solvents for removing rosin flux solids. Dow Chemicals Chlorothene VG{{Registered Trademark}} is a commonly used brand of methyl

chloroform. Alpha 564{{Registered Trademark}} (90% perchloroethylene) is also a chlorinated rosin flux remover, but according to the manufacturer's literature, (Alpha Metals, Inc.) it has poor component compatability. Perclean{{Registered Trademark}} and Perchlor{{Registered Trademark}} are common brands of perchloroethylene manufactured respectively by Diamond Shamrock and Pittsburgh Plate Glass.

The fluorinated solvents (particularly trichlorotrifluoroethane) are widely used in the medical device industry. The reason for this is their chemical inertness, which also makes them, by themselves, poor rosin flux solvents although they are grease and oil solvents. They may be mixed with alcohols and other compounds which do dissolve flux solids. The requirements set by the Occupational Safety and Health Act (OSHA) and the Clean Air Act regarding toxicity hazards and flammable solvents have also increased the popularity of the fluorinated solvents.s

Freon{{Registered Trademark}} and Arklone{{Registered Trademark}} are probably the most common brands of the fluorinated solvents with the base trichlorotrifluoroethane. Arklone{{Registered Trademark}} is made by Imperial Chemical Industries, Ltd. and Freon{{Registered Trademark}}, of course, by DuPont. Genesolv D{{Registered Trademark}} is the Dow Chemical brand name for trichlorotrifluoroethane. It is likely that one or more of the Freon{{Registered Trademark}} solvents will be found in use in most medical device firms. Freon{{Registered Trademark}} TF, TE and TMC are probably the most commonly found Freon{{Registered Trademark}} solvents used in medical device manufacturing. Freon{{Registered Trademark}} TF and TMC alone are not effective in removing polar contaminants such as salts and flux activators. If only these solvents are used for cleaning, additional water or alcohol cleaning steps should be added to the process. Special care should be taken when cleaning polystyrene, silicone rubber, acrylic plastics, zinc, aluminum and other reactive metals with Freon{{Registered Trademark}}. A careful study should be made concerning the effect Freon{{Registered Trademark}} may have on these materials and other construction materials prior to use. Plastics may be affected by swelling or dissolving and reaction with reactive metals may cause solvent decomposition and acidity.

The important thing to determine is whether or not the manufacturer is using the proper cleaning solvent to remove the contaminants present in the manufacturing process and does the manufacturer understand the limitations of the solvents used? To aid the Investigator in determining if the proper Freon{{Registered Trademark}} is being used, Table 1 is provided. If additional information is requested, notify the writer.

Table 1 - Freon{{Registered Trademark}} Solvents Used in the Electronics Industry

BRAND NAME SOLVENT/SYSTEM REMOVES

Freon{{Registered Trademark}} TF, Pure Trichlorotrifluoroethane- Grease/oils/ Arklone{{Registered Trademark}} P, used in cold cleaning, vapor particulates Genesolv {{Registered Trademark}} D degreasing, ultrasonic baths. Freon{{Registered Trademark}} PCA (Precision Cleaning Agent) - is the ultra pure grade of Freon{{Registered Trademark}} TF (1 ppm residue)

Freon{{Registered Trademark}} TMC Approximately 50% trichloro- Grease/oils/ trifluorethane and 50% particulates/ methylene Chloride-used rosin flux in cold cleaning, vapor degreasing, ultrasonic baths

Freon{{Registered Trademark}} TE, Trichlorotrifluoroethane Rosin flux, Arklone{{Registered Trademark}} A - with approximately 4% denatured soldering oils, developed for vapor ethyl alcohol-used in vapor water, grease, rosin-type solder fluxes degreasers to remove degreasers, Oils cold cleaning, ultrasonic baths

Freon{{Registered Trademark}} T-WD 602 Emulsion of trichlorotriflu- Fingerprints, oroethane with 6% water and plating salts, 2-1/2% surfactant-usually particulate, followed by vapor degreasing grease, oils to remove surfactant residue

Freon{{Registered Trademark}} T-P 35-A Trichlorotrifluoroethane Organic and polar blended with 35% isopropyl soils resin flux alcohol and an inhibitor- and used as a used in cold cleaning drying agent processes and usually followed by a Freon{{Registered Trademark}} TF rinse

References:

1. Alpha Product Catalog S/M-62, 1976, Jersey City, N.J. 07304.

2. Ionic Residue Removal: Which Solvent is Best? Phillips, Howard E., Electronic Packaging and Production Magazine, 1973.
3. Solvents that Meet Today's Cleaning Needs, Pamphlet, 1976, DuPont Company, Wilmington, DE 19898.
4. 4. Modern Vapor Degreasing, Booklet, 1972, Dow Chemical Company, Midland, Michigan 48640.

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