



American Wire Producers Association

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March 23, 2016

Document Control Office (7407M)
Office of Pollution Prevention and Toxics (OPPT)
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Re: Docket No. EPA-HQ-OPPT-2015-0789
Notice – Chlorinated Paraffins: Request for Available Information on PMN Risk Assessments

The American Wire Producers Association (AWPA) appreciates the opportunity to submit comments in response to the US Environmental Protection Agency's (EPA) request for more information related to the Risk Assessment of chlorinated paraffins (80 Fed. Reg. 79886, December 23, 2015).

Background

The AWPA is a trade association which represents companies that collectively produce more than 80% of all carbon, alloy and stainless steel wire and wire products in the United States. The 84 member companies of the AWPA employ more than 22,000 workers in over 215 plants and facilities located in 35 states and 140 Congressional Districts. The industry generates over \$9.1 billion in annual sales.

American wire and wire products manufacturers are entrepreneurial and work hard to maintain their competitive market position despite heavy import competition of their products. They pride themselves on high productivity and constant reinvestment in the latest technology and equipment, keeping the American wire industry one of the most globally competitive segments of the steel industry.

The wire and wire products industry uses metalworking fluids that contain medium-chain and long-chain chlorinated paraffins (MCCPs and LCCPs or CPs) in many applications, especially stainless wire drawing. MCCPs and LCCPs are essential high pressure additives (HPAs) for cold drawing lubricants, which are used for cutting, grinding and machining of parts with the precision and efficiency necessary to make these products. The products are used in a host of industries, including construction, automotive, oil and gas, medical, aerospace and defense.

Critical Uses

The use of chlorinated paraffins (CPs) is critical to stainless and nickel alloy cold finished production and fabrication. Specifically, the fluids that contain chlorinated paraffins are used as lubricants in a process called 'drawing', where the wire or bar is pulled through a die, decreasing the diameter and altering the shape of the wire or bar.

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HPAs are also used in metal cutting fluids for machining and cutting of steel alloys. Lubricants with HPAs are also used in cold fabrication methods such as cold heading, spinning, etc. Denying access to CPs, with no adequate substitutes, will have a serious adverse impact on the ability of stainless wire and wire products manufacturers to fabricate and process products in this industry.

Products manufactured using these lubricants include precision wire-based materials for the medical device industry, stainless steel wire, stainless steel bar, stainless cold heading wire, rivet wire, nickel alloy wire, nickel alloy bar, fine wire, stainless steel weaving wire, and forming wire. Among the many industries to which these stainless and nickel alloy products are sold include automotive, aerospace, food, oil and gas, spring manufacturers, medical device industry (including vascular therapy, orthodontic, orthopedics, endoscopy, implant dentistry, neuro-stimulation and cardiac rhythm management), defense, electronics and the food preparation/processing industry.

Medical Industry

It is necessary to discuss the impact of banning CPs on the medical field. AWPA member companies make products that are used as raw materials and components in the medical device industry. These devices are used to improve and save lives of patients around the world. A few of the applications that use this AWPA member company products include:

- Catheters and guide wires - which are important in non-invasive surgery to reduce the time a patient is in a hospital
- Surgical staples - which ensure proper healing after surgery and reduce the time a patient is in the hospital
- Surgical needles - which ensure proper healing and reduces surgery time
- Orthopedic implants (hips, knees, etc.) - which reduce pain and improve patients' quality of life
- Cardiac pacing leads used in conjunction with implantable cardioverter-defibrillator - which control heart rhythms to ensure the heart beats properly
- Neuro-stimulation leads - which treat depression
- Weight loss devices - which help reduce type II diabetes

Obviously the Food and Drug Administration (FDA) must approve commercialization of these products to ensure that the public is protected from adulterated and misbranded medical devices. In order to commercialize a medical device, stainless wire customers are required to perform extensive validations and submit the information to the FDA via the 510(k) pre-market approval process. After the FDA approves the commercialization of the medical device, the supply chain operates on the principle of fixed processing; meaning that no significant changes are allowed after approval. Changing a manufacturing process, like substituting a lubricant containing chlorinated paraffin, would be considered a significant change since the lubricant could invalidate the biocompatibility of the resulting medical device and cause harm to the patient.

When a significant change is required, such as changing lubricants, the process would be as follows:

- The manufacturer would produce a safety stock of materials for the customer - usually 12 months of material, which takes about 3 months.
- The manufacturer would conduct extensive validation of the new lubricant - approximate cost of \$250,000, which takes about 3 months.
- The manufacturer would ship the materials produced with the new lubricant to the customer.
- The customer would perform extensive validation, which costs about \$500,000 to \$1 million and this takes about 12 months.
- The customer submits its results to the FDA for review and approval which takes about 12 months.
- If the FDA approves the change, the manufacturer is allowed to use the new lubricant. If the FDA does not approve the change, then production would stop and the customer could not be allowed to buy the product.

In total, the process could take over 2 years and cost more than \$750,000 per device.

One AWPA member company has already evaluated 10 alternative lubricants that do not contain chlorinated paraffins. None of the alternatives are direct substitutes that will allow the company to produce the same quality of products at the same processing rates and manufacturing costs. Some substitutes are simply not viable. The few that are potential substitutes require the adjustment of processing parameters, increase manufacturing costs by 20%, increase production fallout by 10% and reduce production rates by 20%.

It is also important to point out how changing a manufacturing process in the medical device industry can result in dire circumstances. In 2000, Sulzer Orthopedics had to pay over \$1 billion in settlement costs because patients who had received their hip replacements had to have them replaced because they were in extreme pain.¹ The problem was that the company had changed their manufacturing process, which led to machining oil residues left on the product. This residue blocked the bone growth necessary for bonding between the device and the pelvic bone.² Changing a lubricant can have many unintended consequences and a similar catastrophe could result in this case.

¹ "Major Recalls of Organ Replacement Devices," Brown University, Spring 2007.

http://biomed.brown.edu/Courses/BI108/BI108_2007_Groups/group05/pages/sulzer.html.

² "When Medical Devices Fail in the Body," New York Times, August 7, 2001.

<http://www.nytimes.com/2001/08/07/science/when-medical-devices-fail-in-the-body.html?pagewanted=all>.

Unavailability of Substitutes Cause an International Trade Disadvantage

Lubricant suppliers to the stainless steel wire industry have indicated there are currently no available substitutes that have the efficacy of CPs. Manufacturers must use liquid lubricants, with HPAs, in the production process for stainless wire and wire products. Powder lubricants do not perform adequately for processing fine wire diameters.

If CPs become unavailable in the US for use in wire drawing lubricants, manufacturers will be unable to continue some or most of their operations. This will result in the loss of jobs in the United States and open the door to imports from countries which are free to manufacture stainless wire and wire products using lubricants with CPs. All of these products are made by foreign competitors in countries such as China, India, Taiwan, and Korea.

One AWPA small business member indicated that these lubricants are used to make products that account for over 50% of their company's volume of sales. If MCCPs and LCCPs are banned, they would be forced to stop manufacturing their products and import the wire from overseas competitors, putting many of his current employees out of work. Other member companies report between 10% and 30% of their product lines will be negatively impacted if they cannot obtain critical metalworking fluids with MCCPs and LCCPs.

Disposal Methods

AWPA member companies strictly abide by all current EPA regulations and guidelines covering the discharge and disposal of metal working fluids. Direct discharge into the environment is not part of the disposal process used by stainless wire and wire products manufacturers.

Therefore, lubricants containing MCCPs and LCCPs are NOT discharged into the waterways. Specifically, lubricants contained within the manufacturing waste stream are captured through bulk part cleaning methods. In stainless wire manufacturing facilities, the liquid waste stream is treated and filtered to remove the lubricants, prior to discharge to a municipality. The resulting solid waste is then disposed in accordance with EPA rules and guidelines.

Companies use a licensed hazardous waste management company to legally dispose of the material that cannot be recycled or cleaned. Any and all lubricants that can no longer be processed or recycled are placed in a secure, hazardous material storage area for disposal. Waste materials are manifested and properly disposed by the hazardous waste management companies and verification of disposal documentation is submitted, as required by state EPAs. Hazardous waste management companies are already heavily regulated to ensure that there are no releases of any hazardous materials into our nation's waterways.

Conclusion

The American Wire Producers Association appreciates the opportunity to submit comments related to the risk assessment of Chlorinated Paraffins and to provide information about the proper disposal of drawing lubricants and the importance of CPs to the stainless wire and wire products industry.

Thank for your consideration of our comments. If you need more information or have additional questions, please contact Janet Kopenhaver, AWPA's Director of Government Relations at 703-528-7822.

Sincerely,

A handwritten signature in black ink, appearing to read "Kimberly Korb". The signature is fluid and cursive, with a large initial "K" and "K" for the last name.

Kimberly Korb
Executive Director
American Wire Producers Association (AWPA)