Identification of Petitioned Substance

<table>
<thead>
<tr>
<th>Chemical Names:</th>
<th>Trade Names:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poly (ethylene glycol-ran-propylene glycol) monobutyl ether</td>
<td>JEFFOX WL-660 (Huntsman)</td>
</tr>
<tr>
<td>monobutyl ether</td>
<td>JEFFOX WL-5000 (Huntsman)</td>
</tr>
<tr>
<td>Other Names:</td>
<td>UCON™ 50-HB-660 (Dow)</td>
</tr>
<tr>
<td>Polyethylene-propylene glycol, monobutyl ether</td>
<td>UCON™ 50-HB-3520 (Dow)</td>
</tr>
<tr>
<td>Oxirane, methyl-, polymer with oxirane, monobutyl ether</td>
<td>UCON™ 50-HB-5100 (Dow)</td>
</tr>
<tr>
<td>PAGMBE</td>
<td>UCON™ HTF 14 (Aldrich)</td>
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<tr>
<td>Propylene oxide ethylene oxide polymer monobutyl ether</td>
<td>Aldrich 438189</td>
</tr>
<tr>
<td>CAS Numbers: 9038-95-3</td>
<td>Teritol™ XD Surfactant</td>
</tr>
<tr>
<td>Other Codes: MDL Number MFCD00198079</td>
<td>PubChem Substance ID 24889994</td>
</tr>
</tbody>
</table>

Summary of Petitioned Use

On October 9, 2012, Pellet Products, Inc. petitioned the USDA National Organic Program to include polyalkylene glycol monobutyl ether (PGME) in the National List (NOP, 2012). Specifically, PGME was petitioned for §205.605:

§ 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s))”, “(b) synthetics allowed.

PGME is not added to the mixture intended for animal feed pellet production. Instead it is used at low concentrations to condition water in boilers providing clean steam to the pellet mill for conditioning pellet mash prior to extrusion through the pellet die (NOP, 2013a). Steam produced from water conditioned with PGME comes in direct contact with animal food pellets: PGME is initially dissolved in water used in the steam making process.

In addition to the use of steam for the production of animal feed, clean, dry steam is used in the production of processed food such as milk and peeled potatoes (3-A Sanitary Standards, Inc., 2004; NPCS, 2007). PGME may be a boiler additive used boilers providing steam for these applications.

PGME was first considered by the National Organic Standards Board (NOSB) for use as a boiler water additive at the National Organic Standards Board Meeting in April, 2013 (NOP, 2013b). Information provided in a technical report requested by the NOSB Handling subcommittee, dated June 7, 2013, indicated that practically, PGME does not contact food, since it is non-volatile, precipitates at boiler temperatures, is not delivered with steam, but stays in the boiler as a precipitate until the boiler cools below the cloud point and may be removed during boiler blow-down (NOP, 2013a). Subsequently, the NOSB Handling Subcommittee developed a proposal on August 20, 2013 that PGME was not required to be on the National List, because PGME in liquid
water did not come into direct contact with organic food and subsequently requested public
comment (NOP, 2013c). At its April 29, 2014 meeting, PGME was further discussed (NOP, 2014a).
Following review and public comment, the NOSB Handling Subcommittee has requested an
additional, limited scope technical report to support their decision-making.

**Evaluation Questions for Substances to be used in Organic Handling**

The document has been limited to the answering the following questions: 1) what evidence is
there that there is entrainment of PGME in water droplets during normal use and 2) if used as
petitioned, would PGME come into contact with the organic product (pelleted feed)?

1) What evidence is there that there is entrainment of PGME in water droplets during normal
use?

Entrainment refers to the amount of moisture (boiler water) carried within steam. Moisture
reduces the temperature and effectiveness of steam. In food production entrainment should be
kept below 2% (Spirax-Sarco, 2012). Carry over is any solid, liquid or vaporous contaminant that
leaves a boiler steam drum along with steam. Entrained boiler water contains dissolved or
suspended solids, which affects the steam purity. Carryover results from incomplete separation
of water from the steam-water mixture (Venus-boiler, 2015). Total carryover into steam consists
of two parts: (1) a mechanical part, the carryover of boiler water droplets and (2) a vaporous part,
the partitioning of dissolved solids (salts, oxides, impurities and other chemicals) between water
and steam (IAPWS, 2008). Vaporous carryover is a factor only in boilers operating above 16 MPa
(2300 psi). Below this pressure, any carry over is likely to be mechanical carryover with the
exception of a few substances like silica, the copper oxides/hydroxides, aluminum compounds
and boric acid, which exhibit significant vaporous carryover even at relatively low pressures. For
boilers below 18 MPa (2600 psi), vaporous carryover is typically less than 0.1 %. Vaporous and
mechanical carryover combined can be as low as 5-10 parts per million consisting mostly of boiler
solids, such as sodium sulfate, sodium chloride, sodium hydroxide and sodium phosphate
dissolved in the moisture entrained in steam (Harnden, 1990). In practice, the ratio of dissolved
sodium in steam with that in boiler water is used to measure boiler carryover (IAPW, 2008).

Carryover is caused by (1) priming, water flooding the steam separators, (2) foaming, a buildup
of small bubbles in and on the water surface in the steam drum, and (3) equipment failure
(Andrade et al., 1983). These causes can be usually be addressed and resolved through proper
boiler design, operation and maintenance with particular emphasis on boiler water quality
(Harnden, 1990).

Polyalkylene glycol monobutyl ether (PGME, e.g. UCON-50 5100) shows the property of inverse
solubility. In other words, its solubility in water decreases as the solution temperature rises. At a
temperature known as the cloud point (~50°C), PGME comes out of solution and forms a turbid
dispersion. At temperatures above the cloud, PGME is highly viscous, involatile and clearly
separated from water (Matlock et al., 1990). Thus, unlike solids that are dissolved in boiler water
at steam producing temperatures, e.g. sodium chloride, PGME is insoluble at steam production
temperatures and unlikely to carryover dissolved in moisture entrained by steam.

PGME may be used in the process of producing steam for culinary use, i.e. steam that comes into
direct contact with product (FDA, 2014). Practices for ensuring safe, clean, and consistent quality
steam, such as steam coming in contact with milk, milk products or product contact surfaces are
described in the 3-A “Accepted practices for producing steam of culinary quality, number 609-
03” (3-A Sanitary Standards, Inc., 2004). This standard mandates a supply of clean, dry steam as
necessary for proper equipment operation; and provides that boilers and steam generation
equipment should be operated in such a manner as to prevent foaming, priming, carryover and
excessive entrainment of boiler water into the steam. The standard also provides that boiler feed water treatment and control shall be under the supervision of trained personnel or a firm specializing in industrial water conditioning and periodic analysis be made of condensate samples. The culinary steam system description begins with the steam inlet of the entrainment separator and terminates at the steam inlet of the process equipment, e.g. the pellet press. This system includes a filtering device capable of removing 95% of particles 2 microns (µ) or larger in size (5 µ), a condensate trap, an entrainment separator capable of removing particles greater than 10 microns in size and a means of sampling the steam or condensate downstream of both filter and separator (3-A Sanitary Standards, Inc., 2004). Entrainment traps and filtration devices incorporated in the 3-A system standard remove particulates, including PGME precipitate if it is present as a result of a boiler malfunction.

2) If used as petitioned, would PGME come into contact with the organic product (pelleted feed)?

PGME is added as a processing aid to water that is used to make steam. It functions to prevent foaming in the boiler. Boiler water foaming is the formation or generation of steam that contains liquid water, i.e. water (moisture) is entrained in steam. Foaming does not result from the formation of a distinct foam layer or blanket on the water surface. Instead, it results primarily from the presence of large number of small bubbles within the volume of boiler water. These small bubbles resist coalescence to form large bubbles and move slowly in boiler water in contrast to steam bubbles which are large and have a pronounced tendency to coalesce. High speed photography has shown that addition of antifoam to foaming boiler water at the appropriate concentration transitions small bubbles to larger bubble that rapidly coalesce and dissipate in the boiler (Denman, 1954). Carry over is the phenomenon of carrying of water (liquid water) by steam (gaseous water) along with dissolved impurities during steam production in the boiler (Kaurov, M.S., 2011). Solids dissolved in boiler water such as sodium chloride are not present in the pure steam. However, steam that has entrained moisture may contain these solids as a result of carry over. Foaming is likely to enhance carryover of dissolved solids. The prevention of foaming prevents carryover. PGME prevents foaming eliminating one source of carryover. In addition, it is not soluble in water at steam producing temperatures. Although, it does in fact come into contact with the water from which steam is produced, it does not evolve from the boiler into the steam as a particulate. PGME is not added directly to the pellet mash.

References


NPCS Board of Consultants and Engineers (2007) Potato and potato products cultivation, seed production, manuring, harvesting, organic farming, storage, and processing, Niir Project Consultancy Services.

Spirax-Sarco (2012) Food and beverage: best practice guide to managing steam quality

US Department of Agriculture, Agricultural Marketing Service, National Organic Program—NOP (2012) Petition for the inclusion of Polyalkylene Glycol Monobutyl Ether (CAS No. 9038-95-3) on the National List at §205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”


