### Polyalkylene Glycol Monobutyl Ether (PGME)

Handling

1	Identification of Petitioned Substance		
2	Chemical Names:	18	Trade Names:
3	Poly (ethylene glycol-ran-propylene glycol)	19	JEFFOX WL-660 (Huntsman)
4	monobutyl ether	20	JEFFOX WL-5000 (Huntsman)
5	5	21	UCON <sup>™</sup> 50-HB-660 (Dow)
6	Other Names:	22	UCON <sup>™</sup> 50-HB-3520 (Dow)
7	Polyethylene-propylene glycol, monobutyl	23	UCON <sup>™</sup> 50-HB-5100 (Dow)
8	ether	24	UCON™ HTF 14 (Aldrich)
9	Poly (ethylene glycol-co-propylene glycol)	25	Aldrich 438189
10	monobutyl ether	26	Teritol <sup>™</sup> XD Surfactant
11	Oxirane, methyl-, polymer with oxirane,		
12	monobutyl ether		CAS Numbers:
13	Oxirane, methyl-, polymer with oxirane,		9038-95-3
14	monobutyl ether		
15	PAGMBE		Other Codes:
16	Propylene oxide ethylene oxide polymer		MDL Number MFCD00198079
17	monobutyl ether		PubChem Substance ID 24889994

### Summary of Petitioned Use

28

27

- 29 On October 9, 2012, Pellet Products, Inc. petitioned the USDA National Organic Program to
- 30 include polyalkylene glycol monobutyl ether (PGME) in the National List (NOP, 2012).
- 31 Specifically, PGME was petitioned for §205.605:
- 32 § 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.
- <sup>35</sup> PGME is not added to the mixture intended for animal feed pellet production. Instead it is used
- 36 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
- 38 from water conditioned with PGME comes in direct contact with animal food pellets: PGME is
- 39 initially dissolved in water used in the steam making process.
- 40 In addition to the use of steam for the production of animal feed, clean, dry steam is used in the
- 41 production of processed food such as milk and peeled potatoes (3-A Sanitary Standards, Inc.,
- 42 2004; NPCS, 2007). PGME may be a boiler additive used boilers providing steam for these
- 43 applications.
- 44 PGME was first considered by the National Organic Standards Board (NOSB) for use as a boiler
- 45 water additive at the National Organic Standards Board Meeting in April, 2013 (NOP, 2013b).
- 46 Information provided in a technical report requested by the NOSB Handling subcommittee,
- 47 dated June 7, 2013, indicated that practically, PGME does not contact food, since it is non-volatile,
- 48 precipitates at boiler temperatures, is not delivered with steam, but stays in the boiler as a
- 49 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
- 51 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

- <sup>55</sup> additional, limited scope technical report to support their decision-making.
- 56

57

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

58 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
- 60 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 normaluse?

63 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
- 65 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
- 67 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
- 74 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
- 76 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
- <sup>79</sup> sodium in steam with that in boiler water is used to measure boiler carryover (IAPW, 2008).
- 80 Carryover is caused by (1) priming, water flooding the steam separators, (2) foaming, a buildup
- 81 of small bubbles in and on the water surface in the steam drum, and (3) equipment failure
- 82 (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).
- 85 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
- 91 temperatures and unlikely to carryover dissolved in moisture entrained by steam.
- 92 PGME may be used in the process of producing steam for culinary use, i.e. steam that comes into
- 93 direct contact with product (FDA, 2014). Practices for ensuring safe, clean, and consistent quality
- 94 steam, such as steam coming in contact with milk, milk products or product contact surfaces are
- 95 described in the 3-A "Accepted practices for producing steam of culinary quality, number 609-
- 96 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 feedwater treatment and control shall be under the supervision of trained personnel or a firm
- 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
- 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
- suppose the cultury scale system description begins with the secan file of the culturintent 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 ( $\mu$ ) or larger in
- size  $(5 \mu)$ , a condensate trap, an entrainment separator capable of removing particles greater than
- 106 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
- 109 present as a result of a boiler malfunction.

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

- 112 PGME is added as a processing aid to water that is used to make steam. It functions to prevent
- 113 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
- 115 formation of a distinct foam layer or blanket on the water surface. Instead, it results primarily
- 116 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
- 125 as a result of carry over. Foaming is likely to enhance carry over of dissolved solids. The
- 126 prevention of foaming prevents carryover. PGME prevents foaming eliminating one source of
- 127 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
- 129 from the boiler into the steam as a particulate. PGME is not added directly to the pellet mash.
- 130

131

### References

- 132
- 3-A Sanitary Standards, Inc. (2004) Method of Producing Steam of Culinary Quality, 3-A Sanitary
   Standards, Inc., McLean, Va.
- 135 Andrade, R.C., Gates, J.A., and McCarthy, J.W. (1983) Controlling boiler carryover, Chemical
- 136 Engineering, 90:26, pp. 51-53.
- 137 Cooper, J.R. (2008) Technical guidance document: procedures for the measurement of carryover
- 138 of boiler water into steam, International Association for the Properties of Water and Steam.
- 139 Denman, W.L., (1954) Foaming in Boilers, Industrial and Engineering Chemistry, 46:5, pp. 992-994.
- 140 Harnden, S.G. (1990) Cause, effects, prevention of boiler water carryover analyzed, Pulp and
- 141 Paper, 64:11, pp. 114-119.
- 142 International Association for the Properties of Water and Steam–IAPWS (2008) Technical
- 143 guidance document: procedures for the measurement of carryover of boiler water into steam.

- 144 International Association of Milk, Food and Environmental Sanitarians, US Public Health Service
- and the Dairy Industry Committee–IAMFES (1979) 3-a accepted practices for a method of
- 146 producing steam of culinary quality, number 609 00, Journal of Food Protection, 15:3, pp. 690-
- 147 **693**.
- Kaurov, M.S. (2011) Engineering Chemistry with Laboratory Experiments, PHI Learning Pvt.Ltd., p. 130.
- 150 Matlock, Paul, Brown, William and Clinton, Nye (1999) Polyalkylene Glycols *in* Synthetic
- Lubricants and High-Performance Functional Fluids, eds. Rudnick, Leslie and Shubkin, Ronald,
  Marcel Dekker, New York, NY, pp. 159-194.
- 153 NPCS Board of Consultants and Engineers (2007) Potato and potato products cultivation, seed
- 154 production, manuring, harvesting, organic farming, storage, and processing, Niir Project
- 155 Consultancy Services.
- 156 Spirax-Sarco (2012) Food and beverage: best practice guide to managing steam quality
- 157 US Department of Agriculture, Agricultural Marketing Service, National Organic Program–NOP
- 158 (2012) <u>Petition for the inclusion of Polyalkylene Glycol Monobutyl Ether (CAS No. 9038-95-3) on</u>
- 159 the National List at §205.605 Nonagricultural (nonorganic) substances allowed as ingredients in
- 160 or on processed products labeled as "organic" or "made with organic (specified ingredients or
- 161 <u>food group(s))."</u>
- 162 US Department of Agriculture, Agricultural Marketing Service, National Organic Program–NOP
- (2013b) Meeting of the national organic standards board (NOSB), <u>Meeting Transcript</u>, April 9,
   2013.
- US Department of Agriculture, Agricultural Marketing Service, National Organic Program—NOP
   (2013a) <u>Technical Evaluation Report: Polyalkylene Glycol Monobutyl Ether</u>, June 7, 2013.
- 167 US Department of Agriculture, Agricultural Marketing Service, National Organic Program–NOP
- 168 (2013c) National Organic Standards Board Handling Subcommittee Polyalkylene Glycol
- 169 Monobutyl Ether (PGME) Discussion Document, August 20, 2013, Reviewed January 21, 2014 -
- 170 <u>no revisions</u>.
- 171 US Department of Agriculture, Agricultural Marketing Service, National Organic Program–NOP
- 172 (2014) Meeting of the national organic standards board (NOSB), <u>Meeting Transcript</u>, April 29,
- 173 2014.
- 174 US Department of Agriculture, Agricultural Marketing Service, National Organic Program–NOP
- 175 (2001) Technical evaluation report (compiled by the Organic Materials review Institute (OMRI)):
- 176 <u>Steam generation in organic food processing systems: background paper for the petitions for</u>
- 177 <u>mmonium hydroxide, cycloheximine, diethylaminoethanol, morpholine, and octadecylamine</u>.
- 178 US Food and Drug Administration—FDA (2014) Title 21, Part 173 secondary direct food
- additives permitted in food for human consumption, <u>\$173.310 Boiler water additives</u>.
- 180 Venus-boiler (2015) Technical Papers: <u>Trouble shooting water carry over in boilers</u>.
- 181