

1 **DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT**
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3 **Solid and Hazardous Waste Commission/Hazardous Materials and**
4 **Waste Management Division**

5 **6 CCR 1007-3**
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7

8 **HAZARDOUS WASTE**
9

10 **Proposed Depuy Synthes F006 Delisting**

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12 **1) Appendix IX of Part 261 is amended by adding Delisting #009 to read as follows:**
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14
15 **PART 261, APPENDIX IX – WASTES EXCLUDED UNDER §§ 260.20 AND 260.22**
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18
19 **DELISTING #: 009**
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21 **FACILITY:** Depuy Synthes
22

23 **ADDRESS:** 1051 Synthes Avenue, Monument, Colorado 80132
24

25 **WASTE:** Wastewater treatment sludge from the on-site treatment of wastewater
26 generated from electroplating operations (anodizing and chemical
27 etching). EPA hazardous waste code F006 generated after the effective
28 date of this delisting.
29

30 **CONDITIONS:** This delisting is valid only for the waste stream specified above and
31 referenced in the delisting petition submitted on August 4, 2014 and
32 under the following conditions:
33

34 **a. Changes to Current Operations**
35

- 36 1. Depuy Synthes must notify the Hazardous Materials and Waste Management Division
37 (the Division) at least 30-days prior to implementing any major change to the
38 electroplating processes at the Facility. A major change is any change including

39 alteration of the current wastewater treatment process or incorporating different
 40 chemicals or reagents into the process such that the composition of the wastewater
 41 treatment sludge is altered.

42
 43 2. Depuy Synthes must notify the Division within 15-days after implementing any change
 44 to the wastewater treatment or electroplating processes that causes a significant
 45 change in the type or concentration of any hazardous constituent in the waste or causes
 46 the waste to exhibit a hazardous waste characteristic. A significant change is defined as
 47 an increase in the total waste concentration for any constituent identified below:
 48

Constituent	Average Concentration (ppm)	2xs the Standard Deviation	Concentration Requiring Notification to the Division (Two Standard Deviations above the Average Concentration)
Arsenic	Non-detect	Non-detect	Detection
Barium	19.0	42.8	61.8
Cadmium	Non-detect	Non-detect	Detection
Chromium (Total)	6,170	13,585.4	19,755.4
Chromium VI	0.035	0.08	0.12
Copper	525.5	1,157.8	1,683.3
Cyanide (amendable)	Non-detect	Non-detect	Detection
Cyanide (free/reactive)	0.005	0.0002	0.0052
Lead	870.4	2,139.0	3,009.4
Mercury	0.11	0.04	0.15
Nickel	2,197	4,958.6	7,155.6
Selenium	Non-detect	Non-detect	Detection
Silver	1.53	3.44	4.97

49
 50 A significant change also includes the detection of any additional Part 264, Appendix IX
 51 hazardous constituents that are not identified in the above table.

52
 53 3. The Division reserves the right to re-evaluate and, if necessary, remove this approval or
 54 modify these conditions in the event that a significant change, as defined above, is
 55 reported by Depuy Synthes. In such case, the Division may remove this delisting or
 56 impose temporary requirements on the delisted waste until such time as an appropriate
 57 amendment to this delisting can be considered by the Solid and Hazardous Waste
 58 Commission.
 59

60 **b. Sampling Requirements**

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62 Depuy Synthes shall conduct annual verification sampling of the delisted waste in
63 January of each year to monitor for any significant change in the type or concentration
64 of any hazardous constituents in the delisted waste. Annual verification sampling shall
65 be submitted to the Division within sixty (60) days of the sampling event for review
66 against initial criteria and sampling methodology.

67

68 **c. Storage Requirements**

69

- 70 1. The delisted waste generated by Depuy Synthes may not be accumulated on-site for a
71 period in excess of one year.
- 72
- 73 2. The volume of delisted waste accumulated on-site may not exceed 20 cubic yards at any
74 given time.
- 75
- 76 3. The delisted waste must be stored in a container that is capable of being closed. The
77 container must be marked or labeled to identify the contents as “delisted waste” and
78 with an accumulation start date. The container must be kept closed except for when
79 waste is being added to or removed from the container.

80

81 **d. Recordkeeping Requirements**

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- 83 1. Depuy Synthes shall maintain records of the disposal or recycling of all delisted waste
84 that documents that such activities are in accordance with the delisting petition.
- 85
- 86 2. Depuy Synthes shall maintain all records required by paragraph d.i above for a period of
87 at least three years.

88

89 **e. Disposal Requirements**

90

91 The delisted waste shall be disposed in a landfill meeting the requirements of the
92 Colorado Solid Waste Regulations (6 CCR 1007-2) or recycled at an appropriate metals
93 reclamation facility.

94 **2) Section 8.84 {Statement of Basis and Purpose for the Rulemaking Hearing of**
95 **November 18, 2014} is added to Part 8 of the Regulations to read as follows:**

96 **Statement of Basis and Purpose**
97 **Rulemaking Hearing of November 18, 2014**

98
99 **8.84 Basis and Purpose**

100
101 This amendment to 6 CCR 1007-3, Part 261, Appendix IX is made pursuant to the authority
102 granted to the Solid and Hazardous Waste Commission in § 25-15-302(2), C.R.S.

103
104 **Amendment of Part 261, Appendix IX to Conditionally Delist F006 Hazardous Waste**
105 **Generated by Depuy Synthes located at 1051 Synthes Avenue in Monument, Colorado 80132.**

106
107 Appendix IX of Part 261 is being amended to conditionally delist F006 hazardous waste
108 generated at Depuy Synthes in Monument, Colorado. This delisting will allow Depuy Synthes to
109 dispose of this waste at a solid waste landfill meeting the requirements of the Colorado Solid
110 Waste Regulations (6 CCR 1007-2) or a metals recycling facility provided it complies with the
111 conditions of the delisting. The Solid and Hazardous Waste Commission (the “Commission”) is
112 requiring an annual verification sampling of the delisted waste and the results of that
113 verification sampling must be submitted to the Division within sixty (60) days of the sampling
114 event for review against initial delisting criteria and sampling methodology.

115
116 Depuy Synthes operates a manufacturing facility in Monument, Colorado for the production of
117 surgical quality screws, plates and nails for medical use. After manufacturing, a finish is applied
118 to the metal parts in one or more metal finishing operations including electro-polishing
119 (chemical etching), anodizing, or chemical conversion coating (passivation). Rinse water from
120 these metal finishing operations is treated on-site in a wastewater treatment unit to remove
121 heavy metals prior to discharging the treated wastewater to the publicly owned treatment
122 works (POTW). The process of treating the wastewater generates wastewater treatment
123 sludge. Pursuant to the listing description at § 261.31, wastewater treatment sludge generated
124 from electroplating operations is classified as F006 hazardous waste.

125
126 The basis for the F006 hazardous waste listing is described in Appendix VII of Part 261 of the
127 hazardous waste regulations. Each listing is based on hazardous constituents that are typically
128 contained in the waste described by the listing. The hazardous constituents that formed the
129 basis for the F006 listing include cadmium, hexavalent chromium (Chromium VI), nickel and
130 complexed cyanide.

131
132 Samples of the wastewater treatment sludge generated at Depuy Synthes were collected and
133 submitted for analysis prior to submittal of the delisting petition. Four discrete samples of the
134 wastewater treatment sludge were collected in accordance with a sampling and analysis plan

135 that was reviewed and approved by the Hazardous Materials and Waste Management Division
136 at the Colorado Department of Public Health and Environment.

137
138 Analytical results of the wastewater treatment sludge indicate that the sludge does not exhibit
139 any of the hazardous waste characteristics. Sample results confirmed that the sludge does not
140 contain organic toxicity characteristic constituents above detection levels. In addition, the
141 sludge does not exhibit the toxicity characteristic for the eight heavy metals. The waste also
142 does not exhibit the hazardous waste characteristic of corrosivity, ignitability or reactivity.

143
144 Copper and nickel were also analyzed using the toxicity characteristic leaching procedure
145 (TCLP). The results of that analysis indicate that these two constituents were present in the
146 leachate well below the EPA Residential Soil Screening Levels.

147
148 Analytical results of the wastewater treatment sludge indicate that the petitioned sludge
149 contains hazardous constituents that are a basis for listing a waste as a F006 hazardous waste.
150 These constituents include nickel, chromium VI and cyanide. Based on the chemical analysis of
151 the waste samples, the average total concentration for these constituents is as follows: 2,197
152 parts per million (ppm) nickel, 0.005 ppm cyanide and 0.035 ppm chromium VI. With the
153 exception of nickel, these average total constituent constituents are below the EPA Residential
154 and Industrial Soil Screening Levels. The total average concentration of nickel is below the EPA
155 Industrial Soil Screening Level.

156
157 Other constituents detected in the waste samples include barium, copper, lead, mercury and
158 silver. The average total concentration for these constituents is: 19.0 ppm barium, 525.5 ppm
159 copper, 870.4 ppm lead, 0.11 ppm mercury and 1.53 ppm silver. The average total
160 concentration for these constituents is below the EPA Residential Soil Screening Level with the
161 exception of lead. The average total concentration for lead is 70.4 ppm above the EPA
162 Industrial Soil Screening Level of 800 ppm. However, as a condition of this delisting, all waste
163 will be disposed in a solid waste landfill or recycled at an appropriate metals reclamation
164 facility.

165
166 Using the average total concentrations of the constituents in the waste, health risk calculations
167 were determined for residential exposure to the waste. The risk calculations were determined
168 using the EPA's Regional Screening Level Calculator, which utilizes current health based toxicity
169 data obtained from EPA's Integrated Risk Information System (IRIS) and Health Effects
170 Assessment Summary Tables (HEAST). The calculator was used to determine the risk associated
171 with the waste for a residential soil exposure scenario that evaluated the carcinogenic and non-
172 carcinogenic risk through ingestion, dermal and inhalation pathways.

173
174 A total carcinogenic risk of greater than 1×10^{-6} of one added cancer death per million exposed
175 individually represents an unacceptable risk to human health, according to EPA risk assessment

176 guidance. The calculated carcinogenic risk for the wastewater treatment sludge is 1.42×10^{-7} .
177 Therefore, this waste does not pose a carcinogenic risk.

178
179 The risk assessment calculations for the non-carcinogenic risk or cumulative total hazard
180 quotient posed by the concentrations of detected metals in the waste were calculated at a level
181 of 1.75. This level exceeds the hazard quotient index (HI) of 1 for the residential soil exposure
182 scenario due to the presence of nickel. However, when nickel is excluded from the calculation
183 the HI is reduced to 0.21. As a condition of this delisting, the wastewater treatment sludge will
184 be disposed in a solid waste landfill or at a metals recycling facility.

185
186 This delisting is being granted under conditions specifying disposal, record keeping, storage and
187 sampling requirements for the delisted sludge. Conditional delisting of the waste also prohibits
188 any major changes to the metal finishing operations or wastewater treatment process without
189 prior notification, evaluation, and approval by the Division.

190
191 This delisting does not apply to waste that demonstrates a “significant change” as defined in
192 Delisting #009 in Part 261, Appendix IX—Wastes Excluded Under § 260.20 and 260.22(d), or if
193 any of the conditions specified in Part 261, Appendix IX for this delisting are not met. Should
194 either of these occur, the waste is and must be managed as a hazardous waste. While the
195 Commission is approving this conditional delisting for this specific waste at this specific site, the
196 findings and criteria associated with the approval are unique. Other petitions for delisting,
197 even if similar in material or use, will be reviewed by the Division on a case-by-case basis.