Environmental Assessment Data Template for FDA Submissions

(b) (4)

15 April 2017

Line	Data Type	Value	Reference
1	Name of applicant.	Altria Client Services Inc. On Behalf of U.S. Smokeless Tobacco Manufacturing Co.	
2	Address of applicant (correspondence).	2325 Bells Road Richmond, Virginia 23234 (804) 335-2853 Rebecca.A.Rivas@altria.com	
3	Description of Proposed Action.		
3.1	Requested approval – document or correspondence number for EA request received from FDA, and any related client document numbers.		
3.2	Need for action – description of the intended use of the substance.		
3.3	Location of use – manufacturing sites, and geographic region where products made with the substance will be used.		
3.4	Disposal Sites – unless other disposal methods are anticipated, it is sufficient to indicate that the products made with the substance will be disposed of in accordance with applicable local, state and federal laws.		
4	Substance identification.		
4.1	Nomenclature.		
4.1.1	Established name.	(b) (4)	
4.1.2	Tradename(s).		
4.1.3	Chemical name.	(b) (4)	
4.1.4	CAS number.		
4.1.5	CAS index name.		

Line	Data Type	Value	Reference
			(b) (4)
4.2	Molecular formula.		(b) (4)
4.3	Structure.		
5	Environmental Issues.		
5.1	Environmental Fate of Released Substance.		
5.1.1	Identification of substance of interest.		
5.1.2	Water solubility.		(b) (4)
5.1.3	Dissociation constant(s).		
5.1.4	Octanol/water partition coefficients (k_{ow}).		
5.1.5	Sorption and/or desorption properties (k_{oc}).		
5.1.6	Vapor pressure and/or Henry's law constant.		
5.1.7	UV/VIS absorption spectrum.		
5.1.8	Melting temperature.		
5.1.9	Density.		

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5.1.10	Hydrolysis.		
5.1.11	Aerobic biodegradation (including removal in sewage treatment plant).		
5.1.12	Soil biodegradation.		
5.1.13	Photolysis.		
5.1.14	Microbial metabolism.		
5.1.15	Environmental fate for each compartment (% water, % sediment, % soil, % air).		
5.1.16	Persistence and/or Bioaccumulation potential.	[redacted] (b) (4)	
5.2	Environmental Concentrations.		
5.2.1	Expected Introduction Concentration (EIC).		
5.2.2	Expected Environmental Concentration (EEC).		
5.3	Aquatic Toxicity.		
5.3.1	Short-term (acute) toxicity to fish. (Results typically based on mortality, reported as LC_{50} or EC_{50} at 24, 48, 72, or 96h.)		
5.3.2	Long-term (chronic) toxicity to fish. (Results typically based on reproduction, growth, behavior, etc. reported as 21-d, 28-d or longer NOEC, LOEC, etc.)		
5.3.3	Short-term (acute) toxicity to invertebrates. (Results based on immobilization/mortality, reported as EC_{50} at 24 or 48h.)		
5.3.4	Long-term (chronic) toxicity to invertebrates. (Results typically based on reproduction, growth, behavior, etc. reported as 21-d, 28-d or longer NOEC, LOEC, etc.)		
5.3.5	Effects on algae and aquatic plants. (Results typically based on growth inhibition, reported as EC_{50} at 72 or 96h, NOEC, LOEC, etc.)		
5.3.6	Microbial inhibition testing (activated sludge) (Results typically based on respiration inhibition, reported as EC_{50} at 72 or 96h, NOEC, LOEC, etc. May also include tests to fungi.)		
5.4	Terrestrial Toxicity.		

Line	Data Type	Value	Reference
5.4.1	Short-term (acute) toxicity to mammals (rat, mouse, rabbit, dog, etc.) (Results typically based on mortality, reported as LC/LD_{50} Specify exposure route – oral, dermal, gavage, etc.)		
5.4.2	Long-term (chronic) toxicity to mammals (rat, mouse, rabbit, dog, etc.) (Results typically based on reproduction or behavior, reported as NOEC, LOEC, etc. Specify exposure route – oral, dermal, gavage, etc.)		
5.4.3	Short-term (acute) toxicity to birds. (Results typically based on mortality, reported as LC/LD_{50} Specify exposure route – oral, dermal, gavage, etc.)		
5.4.4	Long-term (chronic) toxicity to birds. (Results typically based on reproduction or behavior, reported as NOEC, LOEC, etc. Specify exposure route – oral, dermal, gavage, etc.)		
5.4.5	Effects on Plants.		
5.4.6	Effects on Earthworms (or other terrestrial invertebrate).		
5.4.7	Effects on Soil Microbes.		
6	Naturally-derived substance information.		
6.1	Use of flora and fauna.		
6.1.1	Biological information (i.e., common names, synonyms, variety, species, genus, and family).		
6.1.2	Wild or cultivated specimens?		
6.1.3	Geographic region where harvesting of biomass occurs, and whether harvesting occurs on public or private land.		
6.1.4	Description of government oversight of harvesting.		
6.1.5	Is the species listed as a species of special concern?		
6.1.6	What part of the animal or plant is used, and is it renewable?		
6.1.7	Describe the harvesting method.		
6.1.8	Bulk weight or other measure of biomass needed to supply 1 kg of active substance.		
6.1.9	Estimate the total number of plants or animals in the region where the specie is harvested.		
6.1.10	Are there other uses for the plant or animal (food, habitat for other fauna)?		
6.1.11	Plant or animal growth rate and lifespan.		
6.1.12	Does harvesting provide for sustainable yield?		
6.2	Mitigation Measures.		
6.2.1	Mitigation measures taken before (e.g., developing a process that uses a renewable part of a plant), during (e.g., limiting/selecting specimens to be		

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	harvested), and after harvesting (e.g., reforestation).		
6.3	Alternatives.		
6.3.1	What reasonable alternatives that were considered when deciding which biomass source would be used to produce the active moiety or biologic substance.		
7	Test Methods and Reports – Include all reports for data generated by client or on client's behalf specifically for this EA.		
8	Confidential Information – Line items noted above that contain confidential business information may be removed to a confidential appendix.		
9	List of Preparers.	(b) (4)	
10	References.		