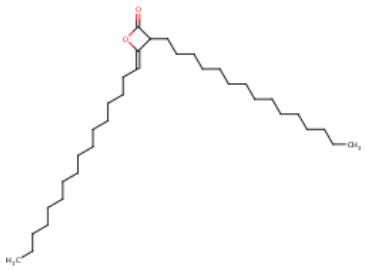
Environmental Assessment Data Template for FDA Submissions

Alkylketene dimer
16 December 2015

Line	Data Type	Value	Reference
1	Name of applicant.	Philip Morris Products S.A.	
2	Address of applicant (correspondence).	Quai Jeanrenaud 3 2000 Neuchatel Switzerland	
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.	Alkylketene dimer	
4.1.2	Tradename(s).		
4.1.3	Chemical name.	2-Oxetanone, 3-C14-16-alkyl 4-C15-17-alkylidene derivs	ChemID Plus: http://chem2.sis.nlm.nih.gov/chemidplus/rn/98246-87-8
4.1.4	CAS number.	98246-87-8	ChemID Plus: http://chem2.sis.nlm.nih.gov/chemidplus/rn/98246-87-8
4.1.5	CAS index name.	2-Oxetanone, 3-C14-16-alkyl 4-C15-17-alkylidene derivs	ChemID Plus: http://chem2.sis.nlm.nih.gov/chemidplus/rn/98246-87-8
4.2	Molecular formula.	C34 H64 O2	US EPA

Line	Data Type	Value	Reference
			ACTOR: http://actor.epa.gov/actor/GenericChemical?casrn=98246-87-8
4.3	Structure.		US EPA ACTOR: http://actor.epa.gov/actor/GenericChemical?casrn=98246-87-8
5	Environmental Issues.		
5.1	Environmental Fate of Released Substance.		
5.1.1	Identification of substance of interest.		
5.1.2	Water solubility.		
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.	1.24E-14mmHg at 25°C	ChemNet: http://www.chemnet.com/cas/en/98246-87-8/2-Oxetanone,-3-C14-16-alkyl-4-C15-17-alkylidene-derivs.html
5.1.7	UV/VIS absorption spectrum.		
5.1.8	Melting temperature.		
5.1.9	Density.	0.903g/cm3	ChemNet: http://www.chemnet.com/cas/en/98246-87-8/2-Oxetanone,-3-C14-16-alkyl-4-C15-17-alkylidene-derivs.html
5.1.10	Hydrolysis.		
5.1.11	Aerobic biodegradation (including removal in sewage treatment plant).		

Line	Data Type	Value	Reference
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.	Not bioaccumulative Not Persistent	US EPA ACTOR: http://actor.epa.gov/actor/GenericChemical?casrn=98246-87-8
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.		
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,		

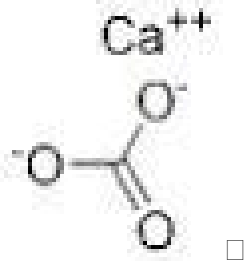
Line	Data Type	Value	Reference
	etc.)		
5.4.3	Short-term (acute) toxicity to birds. (Results typically based on mortality, reported as $LC/LD_{50.}$ Specify exposure route – oral, dermal, gavage, etc.)		
5.4.4	Long-term (chronic) toxicity to birds. (Results typically based on reproduction or behavior, 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 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		

Line	Data Type	Value	Reference
	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.	Laura Judd, MS Senior Project Manager (484) 913-0387 laura.judd@erm.com Thomas Numbers, PE, CPEA, BCEE Senior Consultant (757) 645-7495 thomas.numbers@erm.com Maya Zein, PhD Consultant (847) 258-8982 maya.zein@erm.com ERM, Inc. 1011 East Main Street, Suite 227 Richmond, Virginia 23219	
10	References.		

Environmental Assessment Data Template for FDA Submissions

Calcium Carbonate
18 February 2016

Line	Data Type	Value	Reference
1	Name of applicant.	Philip Morris Products S.A.	
2	Address of applicant (correspondence).	Quai Jeanrenaud 3 2000 Neuchatel Switzerland	
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.	Calcium carbonate	Patnaik, Pradyot (2003). Handbook of Inorganic Chemical Compounds. McGraw-Hill. ISBN 0070494398.
4.1.2	Tradename(s).	Limestone, calcite, aragonite, chalk, marble, pearl	Patnaik, Pradyot (2003). Handbook of Inorganic Chemical Compounds. McGraw-Hill. ISBN 0070494398.
4.1.3	Chemical name.	Calcium carbonate	Patnaik,

Line	Data Type	Value	Reference
			Pradyot (2003). Handbook of Inorganic Chemical Compounds. McGraw-Hill. ISBN 0070494398.
4.1.4	CAS number.	471-34-1	Patnaik, Pradyot (2003). Handbook of Inorganic Chemical Compounds. McGraw-Hill. ISBN 0070494398.
4.1.5	CAS index name.	Carbonic acid, calcium salt	QSAR Toolbox V 2.2.1.1120, OECD
4.2	Molecular formula.	$CaCO_3$	Patnaik, Pradyot (2003). Handbook of Inorganic Chemical Compounds. McGraw-Hill. ISBN 0070494398.
4.3	Structure.		Patnaik, Pradyot (2003). Handbook of Inorganic Chemical Compounds. McGraw-Hill. ISBN 0070494398.
5	Environmental Issues.		
5.1	Environmental Fate of Released Substance.		
5.1.1	Identification of substance of interest.		
5.1.2	Water solubility.	1.5 mg/mL at 25°C 0.017 g/L at 20.0 ± 0.5 °C	Patnaik, Pradyot (2003). Handbook of Inorganic

Line	Data Type	Value	Reference
			Chemical Compounds. McGraw-Hill. ISBN 0070494398. ECHA Dissemination Portal http://echa.europa.eu/registration-dossier/-/registered-dossier/16050/4/9
5.1.3	Dissociation constant(s).	$pK_a = 9.0$	Patnaik, Pradyot (2003). Handbook of Inorganic Chemical Compounds. McGraw-Hill. ISBN 0070494398.
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.	825°C – 1339°C, depending on mineral form	Patnaik, Pradyot (2003). Handbook of Inorganic Chemical Compounds. McGraw-Hill. ISBN 0070494398.
5.1.9	Density.	2.71 g/mol – 2.83 g/mol, depending on mineral form	Patnaik, Pradyot (2003). Handbook of Inorganic Chemical Compounds. McGraw-Hill. ISBN 0070494398.

Line	Data Type	Value	Reference
5.1.10	Hydrolysis.	$CaCO_3 \leftrightarrow Ca^{2+} + CO_3^{2-} \leftrightarrow H_2CO_3 \leftrightarrow HCO_3^- \leftrightarrow CO_2$ pH>10 CO_3^{2-} predominates, 6<pH<10 HCO_3^- predominates pH<6 H_2CO_3 predominates	IUCLID data set http://esis.jrc.ec.europa.eu/doc/existing-chemicals/IUCLID/data_sheets/471341.pdf
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.		
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.)	*Oncorhynchus mykiss* 96 hour LC_{50} and NOEC > 100 % v/v saturation solution (nanomaterial)	ECHA Dissemination Portal http://echa.europa.eu/registration-dossier/-/registered-dossier/16050/4/9
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.)	*Daphnia magna* 48 hour EC_{50} and NOEC > 100 % v/v saturation solution (nanomaterial)	ECHA Dissemination Portal http://echa.europa.eu/registration-dossier/-/registered-dossier/16050/4/9
5.3.4	Long-term (chronic) toxicity to invertebrates. (Results typically based on reproduction, growth,		

Line	Data Type	Value	Reference
	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.)	*Desmodesmus subspicatus* 72 hour EC_{50} >14 mg/L (growth rate and yield); NOEC = 14 mg/L (growth rate and yield)	ECHA Dissemination Portal http://echa.europa.eu/registration-dossier/-/registered-dossier/16050/4/9
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.)	Activated sewage sludge microorganisms 3 hour EC_{50} > 1000 mg/L; NOEC = 1000 mg/L.	ECHA Dissemination Portal http://echa.europa.eu/registration-dossier/-/registered-dossier/16050/4/9
5.4	Terrestrial Toxicity.		
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.)	(a) LD_{50} rat (oral) = 6,450 mg/kg bw (b) Acute inhalation toxicity in rats, 90 min.; LC_{50} 0.0812 mg/L (c) Acute dermal toxicity in rabbits, EC_{50} 500 mg/kg bw (d) LD_{50} rat (oral) >2,000 mg/kg bw (e) 4 hour LC_{50} rat (inhalation) >3 mg/L air (f) LD_{50} rat (dermal) > 2,000 mg/kg (nanomaterial)	IUCLID data set (a-c): http://esis.jrc.ec.europa.eu/doc/existing-chemicals/IUCLID/data_sheets/471341.pdf ECHA Dissemination Portal (d-f): http://echa.europa.eu/registration-dossier/-/registered-dossier/16050/4/9
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.)	No toxicity observed at levels that require classification	ECHA Dissemination Portal http://echa.europa.eu/registration-dossier/-

Line	Data Type	Value	Reference
			/registered-dossier/16050/4/9
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.	*Glycine max (G. soja)* (soybean), *Lycopersicon esculentum* (tomato), and *Avena sativa* (oat) 21 day EC_{50} >1000 mg/kg dw soil (seedling emergence and growth); NOEC = 1000 mg/kg dw soil. (nanomaterial)	ECHA Dissemination Portal http://echa.europa.eu/registration-dossier/-/registered-dossier/16050/4/9
5.4.6	Effects on Earthworms (or other terrestrial invertebrate).	*Eisenia fetida* 14 day LC_{50} >1,000 mg/L; NOEC = 1,000 mg/L (nanomaterial)	ECHA Dissemination Portal http://echa.europa.eu/registration-dossier/-/registered-dossier/16050/4/9
5.4.7	Effects on Soil Microbes.	Soil 28 day EC_{50} >1,000 mg/kg soil dw; NOEC 1,000 mg/kg soil dw (nitrate formation rate) (nanomaterial)	ECHA Dissemination Portal http://echa.europa.eu/registration-dossier/-/registered-dossier/16050/4/9
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		

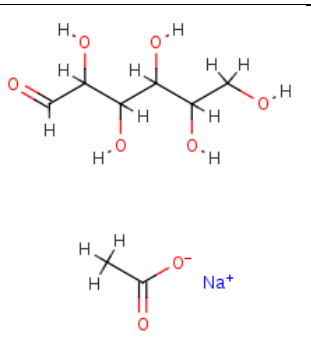
Line	Data Type	Value	Reference
	private land.		
6.1.4	Description of government oversight of harvesting.		
6.1.5	Is the species listed as a species of special concern?		
6.1.6	What part of the animal or plant is used, and is it renewable?		
6.1.7	Describe the harvesting method.		
6.1.8	Bulk weight or 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 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.	Thomas Numbers, PE, CPEA, BCEE Senior Consultant (757) 645-7495 thomas.numbers@erm.com Kristen Schulz Senior Project Manager (513) 830-9041 kristen.schulz@erm.com ERM, Inc. 1011 East Main Street, Suite 227 Richmond, Virginia 23219	

Line	Data Type	Value	Reference
10	References.		

Environmental Assessment Data Template for FDA Submissions

Carboxymethylcellulose
18 February 2016

Line	Data Type	Value	Reference
1	Name of applicant.	Philip Morris Products S.A.	
2	Address of applicant (correspondence).	Quai Jeanrenaud 3 2000 Neuchatel Switzerland	
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.	Carboxymethylcellulose	
4.1.2	Tradename(s).		
4.1.3	Chemical name.	Carboxymethylcellulose sodium salt; Carboxymethylcellulose; Carboxymethylcellulose, Sodium; Cellulose carboxymethyl ether, sodium salt; Cellulose, carboxymethyl ether, sodium salt; Cellulose, carboxymethyl ether, sodium salt; Cellulose, Carboxymethyl; CMC; Polycell product; Sodium carboxymethyl cellulose; Sodium, Carboxymethylcellulose;	EPA ACToR: http://actor.epa.gov/actor/GenericChemical?casrn=9004-32-4

Line	Data Type	Value	Reference
		Sodium, Croscarmellose; Carboxymethyl cellulose (cellulose gum); Edifas B	
4.1.4	CAS number.	9004-32-4	EPA SRS: http://iaspub.epa.gov/sor_internet/registry/substreg/searchandretrieve/advancedsearch/externalSearch.do?p_type=SRSITN&p_value=161786
4.1.5	CAS index name.	Cellulose, carboxymethyl ether, sodium salt	EPA SRS: http://iaspub.epa.gov/sor_internet/registry/substreg/searchandretrieve/advancedsearch/externalSearch.do?p_type=SRSITN&p_value=161786
4.2	Molecular formula.	$C_8H_{15}NaO_8$	EPA ACToR: http://actor.epa.gov/actor/GenericChemical?casrn=9004-32-4
4.3	Structure.		EPA ACToR: http://actor.epa.gov/actor/GenericChemical?casrn=9004-32-4
5	Environmental Issues		
5.1	Environmental Fate of Released Substance.		
5.1.1	Identification of substance of interest.		
5.1.2	Water solubility.	20 mg/mL, soluble	Chemical Book: http://www.che

Line	Data Type	Value	Reference
			micalbook.com /ProductChemi calPropertiesC B5209844_EN. htm
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.	274 °C (dec.)	Chemical Book: http://www.che micalbook.com /ProductChemi calPropertiesC B5209844_EN. htm
5.1.9	Density.	1.6 g/cm^3	Chemical Book: http://www.che micalbook.com /ProductChemi calPropertiesC B5209844_EN. htm
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.	Not bioaccumulative	New Zealand EPA: http://www.epa. govt.nz/search-databases/Pages/ ccid-details.aspx?Sub stanceID=3038
5.2	Environmental Concentrations.		
5.2.1	Expected Introduction Concentration (EIC).		
5.2.2	Expected Environmental Concentration (EEC).		

Line	Data Type	Value	Reference
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.)	a) Not inherently toxic to aquatic organisms; b) Crucian Carp (*Carassius carassius*) 96-h LC50 > 20,000 mg/L; c) Rainbow Trout (*Oncorhynchus mykiss*) 96-h LC50 > 20,000 mg/L	Canadian Domestic Substances List (a): http://webnet.oecd.org/ccrweb/ChemicalDetails.aspx?ChemicalID=A8118EEF-89BD-41B3-9173-82CDB16BDA74 EPA ECOTOX (b-c): http://cfpub.epa.gov/ecotox/quick_query.htm
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.)	Water flea (*Ceriodaphnia dubia)* 48-h EC_{50} = 87.26, 46.04 - 165.37 mg/L	New Zealand EPA: http://www.epa.govt.nz/search-databases/Pages/ccid-details.aspx?SubstanceID=3038
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.)		
5.4	Terrestrial Toxicity.		
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	Guinea pig LD_{50} (oral) = 16,000 mg/kg;	ChemID Plus: http://chem.sis.nlm.nih.gov/ch

Line	Data Type	Value	Reference
	route – oral, dermal, gavage, etc.)	Mouse LD_{50} (oral) > 27,000 mg/kg; Rabbit LD_{50} (oral) > 27,000 mg/kg; Rabbit LD_{50} (dermal) > 2,000 mg/kg; Rat LC_{50} (4-h inhalation) > 5,800 mg/m^3; Rat LD_{50} (oral) = 27,000 mg/kg	emidplus/ProxyServlet?objectHandle=Search&actionHandle=getAll3DMViewFiles&nextPage=jsp%2Fcommon%2FChemFull.jsp%3FcalledFrom%3Dlite&chemid=0009004324&formatType= 3D
5.4.2	Long-term (acute) 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 (acute) 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.	Bean (*Phaseolus vulgaris*), 56-d, 1 x direct application, no significant effect of dose up to 6.14 g/1.8 kg soil; Corn (*Zea mays*), 56-d, 1 x direct application, no significant effect of dose up to 6.14 g/1.8 kg soil.	EPA ECOTOX: http://cfpub.epa.gov/ecotox/quick_query.htm
5.4.6	Effects on Earthworms.		
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.		

Line	Data Type	Value	Reference
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 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.	Thomas Numbers, PE, CPEA, BCEE Senior Consultant (757) 645-7495 thomas.numbers@erm.com Kristen Schulz Senior Project Manager (513) 830-9041 kristen.schulz@erm.com ERM, Inc. 1011 East Main Street, Suite 227 Richmond, Virginia 23219	
10	References.		

Environmental Assessment Data Template for FDA Submissions

Cellulose Acetate
18 February 2016

Line	Data Type	Value	Reference
1	Name of applicant.	Philip Morris Products S.A.	
2	Address of applicant (correspondence).	Quai Jeanrenaud 3 2000 Neuchatel Switzerland	
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.	Cellulose Acetate	
4.1.2	Tradename(s).		
4.1.3	Chemical name.	Cellulose Acetate	ChemID Plus: http://chem.sis.nlm.nih.gov/chemidplus/ProxyServlet?objectHandle=DBMaint&actionHandle=default&nextPage=jsp/chemidlite/ResultScreen.jsp&TXTSUPERLISTID=0009004357
4.1.4	CAS number.	9004-35-7	Common Chemistry: http://www.com

Line	Data Type	Value	Reference
			monchemistry.org/ChemicalDetail.aspx?ref=9004-35-7
4.1.5	CAS index name.	Cellulose, acetate	Common Chemistry: http://www.commonchemistry.org/ChemicalDetail.aspx?ref=9004-35-7
4.2	Molecular formula.	$C_2H_4O_2$•xUnspecified	Common Chemistry: http://www.commonchemistry.org/ChemicalDetail.aspx?ref=9004-35-7
4.3	Structure.	No structure available	ChemID Plus: http://chem.sis.nlm.nih.gov/chemidplus/ProxyServlet?objectHandle=DBMaint&actionHandle=default&nextPage=jsp/chemidlite/ResultScreen.jsp&TXTSUPERLISTID=0009004357
5	Environmental Issues.		
5.1	Environmental Fate of Released Substance.		
5.1.1	Identification of substance of interest.		
5.1.2	Water solubility.	Insoluble in water	HSDB: http://toxnet.nlm.nih.gov/cgi-bin/sis/search/r?dbs+hsdb:@term+@na+CELLULOSE ACETATE
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}).		

Line	Data Type	Value	Reference
5.1.6	Vapor pressure and/or Henry's law constant.	Negligible	Science Lab. Com MSDS: http://www.sciencelab.com/msds.php?msdsId=956
5.1.7	UV/VIS absorption spectrum.		
5.1.8	Melting temperature.	Approximately 260 ˚C	HSDB: http://toxnet.nlm.nih.gov/cgi-bin/sis/search/r?dbs+hsdb:@term+@na+CELLULOSE ACETATE
5.1.9	Density.	1.27 – 1.34	HSDB: http://toxnet.nlm.nih.gov/cgi-bin/sis/search/r?dbs+hsdb:@term+@na+CELLULOSE ACETATE
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.		
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.)	Not ecotoxic	OECD Ecological Categorization Results from the Canadian Domestic Substance List: http://webnet.oecd.org/ccrweb/C

Line	Data Type	Value	Reference
			hemicalDetails.aspx?ChemicalID=1910C43A-4335-4A3F-860D-FF57A42CDC1A
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.)	Not ecotoxic	OECD Ecological Categorization Results from the Canadian Domestic Substance List: http://webnet.oecd.org/ccrweb/ChemicalDetails.aspx?ChemicalID=1910C43A-4335-4A3F-860D-FF57A42CDC1A
5.3.3	Short-term (acute) toxicity to invertebrates. (Results based on immobilization/mortality, reported as EC_{50} at 24 or 48h.)	Not ecotoxic	OECD Ecological Categorization Results from the Canadian Domestic Substance List: http://webnet.oecd.org/ccrweb/ChemicalDetails.aspx?ChemicalID=1910C43A-4335-4A3F-860D-FF57A42CDC1A
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.)	Not ecotoxic	OECD Ecological Categorization Results from the Canadian Domestic

Line	Data Type	Value	Reference
			Substance List: http://webnet.oecd.org/ccrweb/ChemicalDetails.aspx?ChemicalID=1910C43A-4335-4A3F-860D-FF57A42CDC1A
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.		
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.)	Practically nontoxic when administered by inhalation or by oral, intraperitoneal, subcutaneous, or dermal routes. Subchronic and chronic oral studies indicated that the cellulose derivatives were nontoxic.	Cosmetic Ingredient Review: http://www.cosmeticsinfo.org/ingredient_more_details.php?ingredient_id=1992
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).		

Line	Data Type	Value	Reference
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 harvested), and after harvesting (e.g., reforestation).		
6.3	Alternatives.		
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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.	Thomas Numbers, PE, CPEA, BCEE Senior Consultant (757) 645-7495 thomas.numbers@erm.com Kristen Schulz Senior Project Manager (513) 830-9041 kristen.schulz@erm.com ERM, Inc.	

Line	Data Type	Value	Reference
		1011 East Main Street, Suite 227 Richmond, Virginia 23219	
10	References.		

Environmental Assessment Data Template for FDA Submissions

Cellulose Pulp
18 February 2016

Line	Data Type	Value	Reference
1	Name of applicant.	Philip Morris Products S.A.	
2	Address of applicant (correspondence).	Quai Jeanrenaud 3 2000 Neuchatel Switzerland	
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.	Cellulose Pulp	
4.1.2	Tradename(s).		
4.1.3	Chemical name.	Bleached ground wood pulp; Cellulose chemical pulp; Cellulose cotton linter pulp; Cellulose, chemical pulp; Cellulose, pulp; Chemical pulp, non-sulfur; Pulp, cellulose; Pulpwood; Rags	USEPA ACToR: http://actor.epa.gov/actor/GenericChemical?casrn=65996-61-4
4.1.4	CAS number.	65996-61-4	
4.1.5	CAS index name.	Cellulose pulp	Common Chemistry: http://www.commonchemistry.org/ChemicalDetail.aspx?ref=65

Line	Data Type	Value	Reference
			996-61-4
4.2	Molecular formula.		
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.		
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.		
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.	Low ecotoxicological concern	Canadian Domestic Substance List: http://webnet.oecd.org/ccrweb/ChemicalDetails.aspx?ChemicalID=323E114E-3CA3-4AEA-B8A2-3E02C8D1B22E
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,		

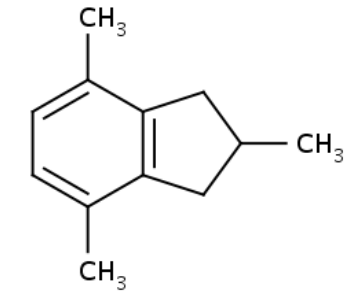
Line	Data Type	Value	Reference
	etc.)		
5.3.3	Short-term (acute) toxicity to invertebrates. (Results based on immobilization/mortality, reported as EC_{50} at 24 or 48h.)		
5.3.4	Long-term (chronic) toxicity to invertebrates. (Results typically based on reproduction, growth, behavior, etc. reported as 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.		
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.)		
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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.		

Line	Data Type	Value	Reference
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 harvested), and after harvesting (e.g., reforestation).		
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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.		
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10	References.		

Environmental Assessment Data Template for FDA Submissions

Cellulose
18 February 2016

Line	Data Type	Value	Reference
1	Name of applicant.	Philip Morris Products S.A.	
2	Address of applicant (correspondence).	Quai Jeanrenaud 3 2000 Neuchatel Switzerland	
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.	Cellulose	US EPA SRS http://ofmpub.epa.gov/sor_internet/registry/substreg/searchandretrieve/advancedsearch/externalSearch.do?p_type=SRSITN&p_value=161794
4.1.2	Tradename(s).	Cellulose Cellulose regenerated Cellulose, microcrystalline Microcrystalline cellulose Rayon Rayon flock Wood pulp, bleached	ChemIDPlus http://chem.sis.nlm.nih.gov/chemidplus/ProxyServlet?objectHandle=DBMaint&actionHandle=default&nextPage=jsp/chemidlite/ResultScreen.jsp&TXTSUPERLISTID

Line	Data Type	Value	Reference
			=0009004346
4.1.3	Chemical name.	Cellulose, microcrystalline	ChemIDPlus http://chem.sis.nlm.nih.gov/chemidplus/ProxyServlet?objectHandle=DBMaint&actionHandle=default&nextPage=jsp/chemidlite/ResultScreen.jsp&TXTSUPERLISTID=0009004346
4.1.4	CAS number.	9004-34-6	US EPA SRS http://ofmpub.epa.gov/sor_internet/registry/substreg/searchandretrieve/advancedsearch/externalSearch.do?p_type=SRSITN&p_value=161794
4.1.5	CAS index name.	Cellulose	US EPA SRS http://ofmpub.epa.gov/sor_internet/registry/substreg/searchandretrieve/advancedsearch/externalSearch.do?p_type=SRSITN&p_value=161794
4.2	Molecular formula.		
4.3	Structure.		EPA ACTor: http://actor.epa.gov/actor/GenericChemical?casrn=9004-34-6
5	Environmental Issues.		
5.1	Environmental Fate of Released Substance.		
5.1.1	Identification of substance of interest.		
5.1.2	Water solubility.	Ca.0 at 25 deg C	IUCLID dataset for Cellulose:

Line	Data Type	Value	Reference
			http://esis.jrc.ec.europa.eu/doc/IUCLID/data_sheets/9004346.pdf
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.	0.77 g/cm3 at 25 deg C	IUCLID dataset for Cellulose: http://esis.jrc.ec.europa.eu/doc/IUCLID/data_sheets/9004346.pdf
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.		
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.)	No known toxicity	IUCLID dataset for Cellulose: http://esis.jrc.ec.europa.eu/doc/IUCLID/data_sheets/9004346.pdf
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.)	No known toxicity	IUCLID dataset for Cellulose: http://esis.jrc.ec.europa.eu/doc/IUCLID/data_sheets/9004346.pdf

Line	Data Type	Value	Reference
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.		
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.)	(a) Rat, Acute oral, LD50>5000mg/kg (b) Rat, Acute inhalation, LC50>5800 mg/m3 (c) Rat, Acute IP, LD50>31600 mg/kg (d) Rabbit, acute dermal, LD50>2000mg/kg	ChemIDPlus: http://chem.sis.nlm.nih.gov/chemidplus/ProxyServlet?objectHandle=Search&actionHandle=getAll3DMViewFiles&nextPage=jsp%2Fcommon%2FChemFull.jsp%3FcalledFrom%3Dlite&chemid=0009004346&formatType=_3D
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.	No known toxicity	IUCLID dataset for Cellulose: http://esis.jrc.ec.europa.eu/doc/IUCLID/data_sheets/9004346.pdf
5.4.6	Effects on Earthworms (or other terrestrial invertebrate).	No known toxicity	IUCLID dataset for Cellulose: http://esis.jrc.ec.europa.eu/doc/IUCLID/data_sheets/9004346.pdf
5.4.7	Effects on Soil Microbes.	No known toxicity	IUCLID dataset

Line	Data Type	Value	Reference
			for Cellulose: http://esis.jrc.ec.europa.eu/doc/IUCLID/data_sheets/9004346.pdf
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?		
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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 harvested), and after harvesting (e.g., reforestation).		
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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.		
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9	List of Preparers.	Thomas Numbers, PE, CPEA, BCEE Senior Consultant (757) 645-7495 thomas.numbers@erm.com	

Line	Data Type	Value	Reference
		Kristen Schulz Senior Project Manager (513) 830-9041 kristen.schulz@erm.com ERM, Inc. 1011 East Main Street, Suite 227 Richmond, Virginia 23219	
10	References.		

Environmental Assessment Data Template for FDA Submissions

Cocoa Extract
19 February 2016

Line	Data Type	Value	Reference
1	Name of applicant.	Philip Morris Products S.A.	
2	Address of applicant (correspondence).	Quai Jeanrenaud 3 2000 Neuchatel Switzerland	
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.	Cocoa Extract	
4.1.2	Tradename(s).		
4.1.3	Chemical name.	Cacao Bean Extract; Chocolate; Cocoa extract; Cocoa or Cocoa Butter; Cocoa or Cocoa Butter [bean]; Theobroma cacao Extract	ChemIDPlus: http://chem.sis.nlm.nih.gov/chemidplus/ProxyServlet?objectHandle=Search&actionHandle=getAll3DMViewFiles&nextPage=jsp%2Fcommon%2FChemFull.jsp%3FcalledFrom%3D&chemid=0084649990&formatType=_3D

Line	Data Type	Value	Reference
4.1.4	CAS number.	84649-99-0	
4.1.5	CAS index name.	Cocoa, ext.	ChemIDPlus: http://chem.sis.nlm.nih.gov/chemidplus/ProxyServlet?objectHandle=Search&actionHandle=getAll3DMViewFiles&nextPage=jsp%2Fcommon%2FChemFull.jsp%3FcalledFrom%3D&chemid=0084649990&formatType=_3D
4.2	Molecular formula.		
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.	At all dilutions only a limited proportion of the substance demonstrates solubility in water. The substance is multi-component, with the components having different solubilities and ca 70-80% of the components insoluble in water. It has therefore not been possible to determine a meaningful solubility for the substance.	ECHA Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/14304/4/9
5.1.3	Dissociation constant(s).		
5.1.4	Octanol/water partition coefficients (k_{ow}).	Log Pow <1.7 at 25 °C	ECHA Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/14304/4/9
5.1.5	Sorption and/or desorption properties (k_{oc}).		

Line	Data Type	Value	Reference
5.1.6	Vapor pressure and/or Henry's law constant.	Due to water being the most volatile component of the test substance and the dried test substance being hygroscopic, it is not possible to determine a meaningful measurement of vapour pressure.	ECHA Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/14304/4/9
5.1.7	UV/VIS absorption spectrum.		
5.1.8	Melting temperature.	The substance cocoa powder per se does not melt. However, two phase changes indicative of melting, most probably of two polymorphic forms of the lipid fraction within the substance, were observed by DSC analysis (according to OECD 102, but not to GLP) in the temperature ranges centring around 25-26°C and 31-32°C, respectively.	ECHA Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/14304/4/9
5.1.9	Density.	1.3369 (1.3363 - 1.3375) at 20.2 °C. This results is for cocoa powder at the higher end of fat content in commercial cocoa powders (typically 20-24%.).	ECHA Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/14304/4/9
5.1.10	Hydrolysis.		
5.1.11	Aerobic biodegradation (including removal in sewage treatment plant).	Readily biodegradable as measured by CO_2 evoluation	ECHA Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/14304/4/9
5.1.12	Soil biodegradation.		
5.1.13	Photolysis.		
5.1.14	Microbial metabolism.		

Line	Data Type	Value	Reference
5.1.15	Environmental fate for each compartment (% water, % sediment, % soil, % air).		
5.1.16	Persistence and/or Bioaccumulation potential.		
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.)	*Oncorhynchus mykiss* 96 hour LL_{50} and NOELR >100 mg/L	ECHA Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/14304/4/9
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.)	*Daphnia magna* 48 hour EL_{50} >100 mg/L and NOELR = 100 mg/L (mobility)	ECHA Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/14304/4/9
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.)	*Pseudokirchnerella subcapitata* 72 hour EyL_{50} (yield) = 27 mg/L WAF; EbL_{50} (biomass) = 30 mg/L WAF; ErL_{50} (growth rate) = 88 mg/L WAF; NOELR (yield) = 1.0 mg/L WAF; NOELR (biomass) = 1.0 mg/L WAF; NOELF (growth rate) = 3.2 mg/L WAF	ECHA Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/14304/4/9
5.3.6	Microbial inhibition testing (activated sludge) (Results typically based on respiration inhibition,		

Line	Data Type	Value	Reference
	reported as EC_{50} at 72 or 96h, NOEC, LOEC, etc. May also include tests to fungi.)		
5.4	Terrestrial Toxicity.		
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.)	LD_{50} mouse (oral) > 3,000 mg/kg bw	ECHA Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/14304/4/9
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.)	Rat, 31-d LOAEL = 2,140 mg/kg bw/day (reproduction) No toxicity observed at levels that require classification	EPA ACToR: http://actor.epa.gov/actor/GenericChemical?casrn=84649-99-0 ECHA Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/14304/4/9
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. ***Data presented are general for the substance Cocoa***		
6.1	Use of flora and fauna.		
6.1.1	Biological information (i.e., common names, synonyms, variety, species, genus, and family).	*Theobroma cacao* Common Name: Cocoa tree Three varieties: Criollo, Forastero (Amelonado),	Legacy Tobacco Library http://legacy.library.ucsf.edu/tid/rzr46b00/pdf?search=%22cocoa%

Line	Data Type	Value	Reference
		Trinitario	22 Food and Agriculture Organization of the United Nations (FOA): http://www.fao.org/docrep/006/AD220E/AD220E01.htm#ch1
6.1.2	Wild or cultivated specimens?	Cultivated	
6.1.3	Geographic region where harvesting of biomass occurs, and whether harvesting occurs on public or private land.	Côte d'Ivoire (over 1 million tons) Ghana (over 0.4 million tons) Indonesia (over 0.3 million tons)	FAO http://www.fao.org/docs/eims/upload/216251/Infosheet_Cocoa.pdf
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?	Seed Pods; yes	FAO http://www.fao.org/docrep/006/AD220E/AD220E01.htm
6.1.7	Describe the harvesting method.	Harvesting involves removing ripe pods from the trees and opening them to extract the wet beans. The pods are harvested manually by making a clean cut through the stalk with a well sharpened blade. The pods are opened to remove the beans within a week to 10 days after harvesting.	ICCO http://www.icco.org/about-cocoa/harvesting-and-post-harvest.html
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.	2.7 million tons beans	FAO http://www.fao.org/docs/eims/upload/216251/Infosheet_Cocoa.pdf
6.1.10	Are there other uses for the plant or animal (food,	Seed pods can also be fed to	FAO

Line	Data Type	Value	Reference
	habitat for other fauna)?	ruminants	http://www.fao.org/wairdocs/ILRI/x5490E/x5490e0w.htm
6.1.11	Plant or animal growth rate and lifespan.	When grown from a seed, the tree goes through a juvenile stage in which the first shoot grows straight up for about 6 feet (2 m) with leaves along its length. At this point, one to two years of age, the tree sends out a whorl of side shoots that form an umbrella-like structure called a jourquette. This is the first stage of the adult plant. The young adult trees will start to flower as early as 18 months but more typically at 2 to 3 years of age. The trees will grow for over 100 years and remain productive if well cared for and fertilized.	HERSHEY'S http://www.hersheys.com/nutrition-professionals/cocoa-bean/cocoa-life-cycle.aspx
6.1.12	Does harvesting provide for sustainable yield?	Profitable life span of *Theobroma cacao* up to 50 years, with highest cocoa yields between 15 and 25 years. Through sustainable cocoa growing, small farmers cultivate cacao trees as part of a renewable agricultural environment — one that can support the farmer year after year, balancing economic needs with preservation of the natural environment.	African Journal of Agricultural Research http://www.academicjournals.org/ajar/pdf/Pdf2006/Dec/Olaiya%20et%20al.pdf World AgroForestry Center http://worldagroforestry.org/treesandmarkets/inaforesta/documents/agrof_cons_biodiv/Ch.3-Growing-Cocoa-Beans.pdf

Line	Data Type	Value	Reference
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 harvested), and after harvesting (e.g., reforestation).	During harvesting it is important not to damage the flower cushion which will produce the flowers and fruits of subsequent harvests, and care must be taken not to damage the tree, which would make it easy for parasitic fungi to penetrate the tissues of the tree.	International Cocoa Organization: http://www.icco.org/faq/58-cocoa-harvesting/130-how-exactly-is-cocoa-harvested.html
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.	Thomas Numbers, PE, CPEA, BCEE Senior Consultant (757) 645-7495 thomas.numbers@erm.com Laura Judd, M.S. Senior Project Manager (610) 524-3784 laura.judd@erm.com Kristen Schulz Senior Project Manager (513) 830-9041 kristen.schulz@erm.com ERM, Inc. 1011 East Main Street, Suite 227 Richmond, Virginia 23219	
10	References.		

Environmental Assessment Data Template for FDA Submissions

(b) (4)

18 February 2016

Line	Data Type	Value	Reference
1	Name of applicant.	Philip Morris Products S.A.	
2	Address of applicant (correspondence).	Quai Jeanrenaud 3 2000 Neuchatel Switzerland	
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.		
4.1.4	CAS number.		
4.1.5	CAS index name.		
4.2	Molecular formula.		

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

Line	Data Type	Value	Reference
			(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.)	(b) (4)	
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		

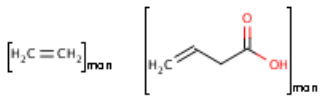
Line	Data Type	Value	Reference
	typically based on growth inhibition, reported as EC_{50} at 72 or 96h, NOEC, LOEC, etc.)		
5.3.6	Microbial inhibition testing (activated sludge) (Results typically based on respiration inhibition, reported as EC_{50} at 72 or 96h, NOEC, LOEC, etc. May also include tests to fungi.)		
5.4	Terrestrial Toxicity.		
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.		

Line	Data Type	Value	Reference
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 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.	Thomas Numbers, PE, CPEA, BCEE Senior Consultant (757) 645-7495 thomas.numbers@erm.com Kristen Schulz Senior Project Manager (513) 830-9041 kristen.schulz@erm.com ERM, Inc. 1011 East Main Street, Suite 227 Richmond, Virginia 23219	
10	References.		

Environmental Assessment Data Template for FDA Submissions

Ethylene/Vinyl Acetate, Copolymer (b) (4)
18 February 2016

Line	Data Type	Value	Reference
1	Name of applicant.	Philip Morris Products S.A.	
2	Address of applicant (correspondence).	Quai Jeanrenaud 3 2000 Neuchatel Switzerland	
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.	Ethylene/Vinyl Acetate, Copolymer (b) (4) (b) (4)	
4.1.2	Tradename(s).		
4.1.3	Chemical name.	Acetic acid, ethenyl ester, polymer with ethane; Ethylene/VA copolymer; Ethylenevinylacetate copolymer; Ethylene vinyl acetate polymer; Vinyl acetate, ethene polymer; Vinyl acetate, ethylene polymer; Vinyl acetate-ethylene copolymer, minimum number average molecular weight (in amu), 69,000	ChemID Plus: http://chem.sis.nlm.nih.gov/chemidplus/ProxyServlet?objectHandle=Search&actionHandle=getAll3DMViewFiles&nextPage=jsp%2Fcommon%2FChemFull.jsp%3FcalledFrom%3Dlite&chemid=0024937788&formatType

Line	Data Type	Value	Reference
			= 3D
4.1.4	CAS number.	24937-78-8	
4.1.5	CAS index name.	Acetic acid ethenyl ester, polymer with ethane	CAS Presents Common Chemistry: http://www.commonchemistry.org/ChemicalDetail.aspx?ref=24937-78-8
4.2	Molecular formula.	$(C_4H_6O_2.C_2H_4)x$-	ChemID Plus: http://chem.sis.nlm.nih.gov/chemidplus/ProxyServlet?objectHandle=Search&actionHandle=getAll3DMViewFiles&nextPage=jsp%2Fcommon%2FChemFull.jsp%3FcalledFrom%3Dlite&chemid=0024937788&formatType=3D
4.3	Structure.		ChemID Plus: http://chem.sis.nlm.nih.gov/chemidplus/ProxyServlet?objectHandle=Search&actionHandle=getAll3DMViewFiles&nextPage=jsp%2Fcommon%2FChemFull.jsp%3FcalledFrom%3Dlite&chemid=0024937788&formatType=3D
5	Environmental Issues.		
5.1	Environmental Fate of Released Substance.		
5.1.1	Identification of substance of interest.		
5.1.2	Water solubility.		

Line	Data Type	Value	Reference
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.	43 g/ 10 min (190˚C/2.16 kg) (Vinyl acetate, 33% wt)	SIGMA-ALDRICH Product Information: http://www.sigmaaldrich.com/catalog/product/aldrich/346918?lang=en&region=US
5.1.9	Density.	0.93 g/cm^3	Chemical Book (Meryer (Shanghai) Chemical Technology Co., Ltd.): http://www.chemicalbook.com/ProductMSDSDetailCB0356004_EN.htm
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.		
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.)	Not ecotoxic	OECD Ecological Categorization Results from the Canadian Domestic

Line	Data Type	Value	Reference
			Substance List: http://webnet.oecd.org/ccrweb/ChemicalDetails.aspx?ChemicalID=E8903CF6-D8F5-4307-B910-6493CF9584DB
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.)	Not ecotoxic	OECD Ecological Categorization Results from the Canadian Domestic Substance List: http://webnet.oecd.org/ccrweb/ChemicalDetails.aspx?ChemicalID=E8903CF6-D8F5-4307-B910-6493CF9584DB
5.3.3	Short-term (acute) toxicity to invertebrates. (Results based on immobilization/mortality, reported as EC_{50} at 24 or 48h.)	Not ecotoxic	OECD Ecological Categorization Results from the Canadian Domestic Substance List: http://webnet.oecd.org/ccrweb/ChemicalDetails.aspx?ChemicalID=E8903CF6-D8F5-4307-B910-6493CF9584DB
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.)	Not ecotoxic	OECD Ecological Categorization Results from

Line	Data Type	Value	Reference
			the Canadian Domestic Substance List: http://webnet.oecd.org/ccrweb/ChemicalDetails.aspx?ChemicalID=E8903CF6-D8F5-4307-B910-6493CF9584DB
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.)	Not ecotoxic	OECD Ecological Categorization Results from the Canadian Domestic Substance List: http://webnet.oecd.org/ccrweb/ChemicalDetails.aspx?ChemicalID=E8903CF6-D8F5-4307-B910-6493CF9584DB
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.		
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.)	May cause irritation of the digestive tract; May cause respiratory tract irritation; May cause skin and/or eye irritation	Chemical Book (Meryer (Shanghai) Chemical Technology Co., Ltd.): http://www.chemicalbook.com/ProductMSDSD

Line	Data Type	Value	Reference
			etailCB0356004_EN.htm
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 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.		

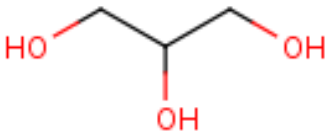
Line	Data Type	Value	Reference
7	Test Methods and Reports – Include all reports for data generated by client or on client's behalf specifically for this EA.		
8	Confidential Information – Line items noted above that contain confidential business information may be removed to a confidential appendix.		
9	List of Preparers.	Thomas Numbers, PE, CPEA, BCEE Senior Consultant (757) 645-7495 thomas.numbers@erm.com Kristen Schulz Senior Project Manager (513) 830-9041 kristen.schulz@erm.com ERM, Inc. 1011 East Main Street, Suite 227 Richmond, Virginia 23219	
10	References.		

Environmental Assessment Data Template for FDA Submissions

Glycerol
18 February 2016

Line	Data Type	Value	Reference
1	Name of applicant.	Philip Morris Products S.A.	
2	Address of applicant (correspondence).	Quai Jeanrenaud 3 2000 Neuchatel Switzerland	
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.	Glycerol	US EPS SRS http://ofmpub.epa.gov/sor_internet/registry/substreg/searchandretrieve/advancedsearch/externalSearch.do?p_type=SRSITN&p_value=2279
4.1.2	Tradename(s).	1,2,3-Propanetriol Glycerin Glycerine Glycerol	ChemIDPlus http://chem.sis.nlm.nih.gov/chemidplus/ProxyServlet?objectHandle=DBMaint&actionHandle=default&nextPage=jsp/chemid

Line	Data Type	Value	Reference
			lite/ResultScreen.jsp&TXTSUPERLISTID=0000056815
4.1.3	Chemical name.	Glycerol	US EPS SRS http://ofmpub.epa.gov/sor_internet/registry/substreg/searchandretrieve/advancedsearch/externalSearch.do?p_type=SRSITN&p_value=2279
4.1.4	CAS number.	56-81-5	US EPS SRS http://ofmpub.epa.gov/sor_internet/registry/substreg/searchandretrieve/advancedsearch/externalSearch.do?p_type=SRSITN&p_value=2279
4.1.5	CAS index name.	1,2,3-Propanetriol	US EPS SRS http://ofmpub.epa.gov/sor_internet/registry/substreg/searchandretrieve/advancedsearch/externalSearch.do?p_type=SRSITN&p_value=2279

Line	Data Type	Value	Reference
4.2	Molecular formula.	C3H8O3	US EPS SRS http://ofmpub.epa.gov/sor_internet/registry/substreg/searchandretrieve/advancedsearch/externalSearch.do?p_type=SRSITN&p_value=2279
4.3	Structure.		ChemIDPlus http://chem.sis.nlm.nih.gov/chemidplus/ProxyServlet?objectHandle=DBMaint&actionHandle=default&nextPage=jsp/chemidlite/ResultScreen.jsp&TXTSUPERLISTID=000056815
5	Environmental Issues.		
5.1	Environmental Fate of Released Substance.		
5.1.1	Identification of substance of interest.		
5.1.2	Water solubility.	5.296 x 10^6 mg/L at 25 °C 1,000,000 mg/L at 25 °C	Hazardous Substances Data Bank: http://toxnet.nlm.nih.gov/cgi-bin/sis/search/f?./temp/~PEgQDN:1 ECHA Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/14481/4/8
5.1.3	Dissociation constant(s).	pKa = 14.4	Hazardous

Line	Data Type	Value	Reference
			Substances Data Bank: http://toxnet.nlm.nih.gov/cgi-bin/sis/search/f?./temp/~PEgQDN:1
5.1.4	Octanol/water partition coefficients (k_{ow}).	log Kow = -1.76 log Pow = -1.75 at 25 °C and pH 7.4	Hazardous Substances Data Bank: http://toxnet.nlm.nih.gov/cgi-bin/sis/search/f?./temp/~PEgQDN:1 ECHA Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/14481/4/8
5.1.5	Sorption and/or desorption properties (k_{oc}).		
5.1.6	Vapor pressure and/or Henry's law constant.	VP: 1.68 x 10^{-4} mm Hg at 25 °C; HLC: 1.73 x 10^{-8} atm cu-m/mol at 25 °C VP: < 0.001 mmHg at room temperature and < 0.2 mmHg at 100 °C; HLC: 0 atm m^3/mol at 25 °C and 1 atm	Hazardous Substances Data Bank: http://toxnet.nlm.nih.gov/cgi-bin/sis/search/f?./temp/~PEgQDN:1 ECHA Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/14481/4/8
5.1.7	UV/VIS absorption spectrum.	Index of refraction: 1.4746 at 20 °C;	Hazardous Substances Data

Line	Data Type	Value	Reference
		UV: 3-12	Bank: http://toxnet.nlm.nih.gov/cgi-bin/sis/search/f?./temp/~PEgQDN:1
5.1.8	Melting temperature.	18.1 °C 18.17 °C	Hazardous Substances Data Bank: http://toxnet.nlm.nih.gov/cgi-bin/sis/search/f?./temp/~PEgQDN:1 ECHA Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/14481/4/8
5.1.9	Density.	1.2613 g/cu cm at 20 °C 1.26108 g/ml at 20 °C	Hazardous Substances Data Bank: http://toxnet.nlm.nih.gov/cgi-bin/sis/search/f?./temp/~PEgQDN:1 ECHA Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/14481/4/8
5.1.10	Hydrolysis.	Hydrolysis is not expected to be an important environmental fate process since this compound lacks	Hazardous Substances Data Bank: http://toxnet.nl

Line	Data Type	Value	Reference
		functional groups that hydrolyze under environmental conditions	m.nih.gov/cgi-bin/sis/search/f?./temp/~PEgQDN:1
5.1.11	Aerobic biodegradation (including removal in sewage treatment plant).	Readily biodegradable in industrial activated sludge and nearly completely degraded within 24 hours.	ECHA Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/14481/4/8
5.1.12	Soil biodegradation.	A 63% of theoretical BOD using activated sludge in the Japanese MITI test suggests that biodegradation is an important environmental fate process in soil and water.	Hazardous Substances Data Bank: http://toxnet.nlm.nih.gov/cgi-bin/sis/search/f?./temp/~PEgQDN:1
5.1.13	Photolysis.	Glycerin does not contain chromophores that absorb at wavelengths >290 nm, and therefore is not expected to be susceptible to direct photolysis by sunlight	Hazardous Substances Data Bank: http://toxnet.nlm.nih.gov/cgi-bin/sis/search/f?./temp/~PEgQDN:1
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.	The potential for bioconcentration in aquatic organisms is low.	Hazardous Substances Data Bank: http://toxnet.nlm.nih.gov/cgi-bin/sis/search/f?./temp/~PEgQDN:1
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,	a) LC_{50}; Goldfish; >5000	Hazardous

Line	Data Type	Value	Reference
	48, 72, or 96h.)	mg/L for 24 hr - modified ASTM D 1345; b) *Leuciscus idus ssp. melanotus* (Carp), 48 h LC_{50}, > 10,000 mg/L; c) *Oncorhynchus mykiss*, 96 h LC_{50} = 54,000 mg/L	Substances Data Bank (a): http://toxnet.nlm.nih.gov/cgi-bin/sis/search/f?./temp/~PEgQDN:1 EPA ECOTOX (b): http://cfpub.epa.gov/ecotox/quick_query.htm ECHA Dissemination Portal (c): http://echa.europa.eu/registration-dossier/-/registered-dossier/14481/4/8
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.)	a) LC_{50},24-h; *Daphnia magna* (Water flea) >10,000 mg/L; b) Toxicity threshold (cell multiplication inhibition test) Protozoa (*Entosiphon sulcatum*) 3,200 mg/l; c) *Daphnia magna* (Water Flea), 24 h, EC_{50}/LC_{50} > 10,000 mg/L (effects on behavior and mortality); d) *Xenopus laevis* (African Clawed Frog) 96 h LC_{50}, 8,250 mg/L	Hazardous Substances Data Bank (a-b): http://toxnet.nlm.nih.gov/cgi-bin/sis/search/f?./temp/~PEgQDN:1 EPA ECOTOX (c-d): http://cfpub.epa.gov/ecotox/quick_query.htm ECHA Dissemination Portal (a): http://echa.europa.eu/registration-dossier/-/registered-

Line	Data Type	Value	Reference
			dossier/14481/4/8
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.)	a) Toxicity threshold (cell multiplication inhibition test) Algae (*Microcystis aeruginosa*) 2,900 mg/l; b) *Scenedesmus quadricauda* (Green Algae), LOEC, 10,000 mg/L	Hazardous Substances Data Bank (a): http://toxnet.nlm.nih.gov/cgi-bin/sis/search/f?./temp/~PEgQDN:1 EPA ECOTOX (b): http://cfpub.epa.gov/ecotox/quick_query.htm ECHA Dissemination Portal (b): http://echa.europa.eu/registration-dossier/-/registered-dossier/14481/4/8
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.)	*Pseudomonas putida* toxicity threshold (comparable to a NOEC) in a 16 hour study was >10,000 mg./L.	ECHA Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/14481/4/8
5.4	Terrestrial Toxicity.		
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.)	a) LD_{50} Rat (oral) 12.6 g/kg b) LD_{50} Rat (oral) 5.57 g/kg c) LC_{50} Rat (inhalation) > 570 mg/cu m/1 hr d) LD_{50} Rabbit (dermal) >	Hazardous Substances Data Bank (a-c): http://toxnet.nlm.nih.gov/cgi-bin/sis/search/f?./temp/~PEgQD

Line	Data Type	Value	Reference
		10 gm/kg e) LD_{50} Rat (oral) 18,300 mg/kg f) LD_{50} Guinea Pig (dermal) 45 mL/kg (56,750 mg/kg) g) 4h LC_{50} Rat (inhalation) >2.75 mg/L (calculated from 1 hour LC_{50} based on nominal concentration	N:1 Chem ID Plus (d) http://chem.sis.nlm.nih.gov/chemidplus/ProxyServlet?objectHandle=Search&actionHandle=getAll3DMViewFiles&nextPage=jsp%2Fcommon%2FChemFull.jsp%3FcalledFrom%3Dlite&chemid=000005681 5&formatType= 3D ECHA Dissemination Portal (e-g): http://echa.europa.eu/registration-dossier/-/registered-dossier/14481/4/8
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.)	No toxicity at levels requiring classification	ECHA Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/14481/4/8
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.	*Lactuca sativa* (Lettuce) 72 h EC50 of 76 mM on	EPA ECOTOX:

Line	Data Type	Value	Reference
		germination	http://cfpub.epa.gov/ecotox/quick_query.htm
5.4.6	Effects on Earthworms (or other terrestrial invertebrate).	*Varroa destructor* (Varroa Mite) 48 h NOEL of 1 AI ug/cm2 on mortality	EPA ECOTOX: http://cfpub.epa.gov/ecotox/quick_query.htm
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 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.		

Line	Data Type	Value	Reference
9	List of Preparers.	Thomas Numbers, PE, CPEA, BCEE Senior Consultant (757) 645-7495 thomas.numbers@erm.com Brian D. McDonald Staff Scientist (585) 315-6095 brian.mcdonald@erm.com Kristen Schulz Senior Project Manager (513) 830-9041 kristen.schulz@erm.com ERM, Inc. 1011 East Main Street, Suite 227 Richmond, Virginia 23219	
10	References.		

Environmental Assessment Data Template for FDA Submissions

(b) (4)

18 February 2016

Line	Data Type	Value	Reference
1	Name of applicant.	Philip Morris Products S.A.	
2	Address of applicant (correspondence).	Quai Jeanrenaud 3 2000 Neuchatel Switzerland	
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.		
4.1.4	CAS number.		

Line	Data Type	Value	Reference
		(b) (4)	
4.1.5	CAS index name.		
4.2	Molecular formula.		
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.		
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.		
5.1.10	Hydrolysis.		
5.1.11	Aerobic biodegradation (including removal in sewage treatment plant).		
5.1.12	Soil biodegradation.		
5.1.13	Photolysis.		

Line	Data Type	Value	Reference
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.		
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.		
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		

Line	Data Type	Value	Reference
	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 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.	Thomas Numbers, PE, CPEA, BCEE Senior Consultant	

Line	Data Type	Value	Reference
		(757) 645-7495 thomas.numbers@erm.com Kristen Schulz Senior Project Manager (513) 830-9041 kristen.schulz@erm.com ERM, Inc. 1011 East Main Street, Suite 227 Richmond, Virginia 23219	
10	References.		

Environmental Assessment Data Template for FDA Submissions

Guar Gum
18 February 2016

Line	Data Type	Value	Reference
1	Name of applicant.	Philip Morris Products S.A.	
2	Address of applicant (correspondence).	Quai Jeanrenaud 3 2000 Neuchatel Switzerland	
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.	Guar Gum	
4.1.2	Tradename(s).	Guar Gum	
4.1.3	Chemical name.	Gendriv 162; Gentril Thik; Guar gum (cyamopsis tetragonolobus); Guar gum; Solvent purified guar gum; Guar powder, micronized	EPA ACToR: http://actor.epa.gov/actor/GenericChemical?casrn=9000-30-0
4.1.4	CAS number.	9000-30-0	
4.1.5	CAS index name.	Guar Gum	EPA SRS: http://iaspub.epa.gov/sor_internet/registry/substreg/searchandretrieve/advancedsearch/externalSearch.do?p_ty

Line	Data Type	Value	Reference
			pe=SRSITN&p_value=160390
4.2	Molecular formula.	Various	
4.3	Structure.	Various	
5	Environmental Issues.		
5.1	Environmental Fate of Released Substance.		
5.1.1	Identification of substance of interest.	Generally Recognised as Safe	http://toxnet.nlm.nih.gov/cgi-bin/sis/search/f?./temp/~7lF2Hf:4
5.1.2	Water solubility.	Completely soluble	HSDB: http://toxnet.nlm.nih.gov/cgi-bin/sis/search/r?dbs+hsdb:@term+@rn+@rel+9000-30-0
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.		
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.		
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.)	*Oncorhynchus mykiss* (rainbow trout) 96-h LC50 = 218 mg/L	USEPA ECOTOX: http://cfpub.epa.gov/ecotox/quick_query.htm
5.3.2	Long-term (chronic) toxicity to fish. (Results		

Line	Data Type	Value	Reference
	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.)	*Daphnia magna* 48-h LC50 = 42 mg/L; *Daphnia magna* 96-h LC50 = <6.2 mg/L.	USEPA ECOTOX: http://cfpub.epa.gov/ecotox/quick_query.htm
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.		
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.)	LD50 Rat (oral) = 6770 mg/kg; LD50 Mouse (oral) = 8100 mg/kg; LD50 Rabbit (oral) = 7000 mg/kg; LD50 Hamster (oral) = 6000 mg/kg.	HSDB http://toxnet.nlm.nih.gov/cgi-bin/sis/search/r?dbs+hsdb:@term+@rn+@rel+9000-30-0
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.)	High levels of GG adversely affect fetal growth of rats	Olejeme et al. (1992). Effects of different types and levels of dietary fibre on foetal development of rats. FASEB J. 6 (5), A1941.
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,		

Line	Data Type	Value	Reference
	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).	Seeds of the Guar plant (*Cyamopsis tetragonolobus*)	HSDB: http://toxnet.nlm.nih.gov/cgi-bin/sis/search/r?dbs+hsdb:@term+@na+GUAR GUM
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 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		

Line	Data Type	Value	Reference
	that contain confidential business information may be removed to a confidential appendix.		
9	List of Preparers.	Thomas Numbers, PE, CPEA, BCEE Senior Consultant (757) 645-7495 thomas.numbers@erm.com Laura Judd, M.S. Senior Project Manager (610) 524-3784 Laura.judd@erm.com ERM, Inc. 1011 East Main Street, Suite 227 Richmond, Virginia 23219	
10	References.		

Environmental Assessment Data Template for FDA Submissions

Hydrocarbon resin
15 December 2015

Line	Data Type	Value	Reference
1	Name of applicant.	Philip Morris Products S.A.	
2	Address of applicant (correspondence).	Quai Jeanrenaud 3 2000 Neuchatel Switzerland	
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.	Hydrocarbon resin	
4.1.2	Tradename(s).		
4.1.3	Chemical name.	Polycyclopentadiene	
4.1.4	CAS number.	68132-00-3	
4.1.5	CAS index name.	Naphtha (petroleum), light steam-cracked debenzenized polymers hydrogenated	
4.2	Molecular formula.	Unspecified	
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.	Insoluble	MSDS Guidechem: http://img1.guidechem.com/msdspdf/68132-00-3.pdf

Line	Data Type	Value	Reference
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.		
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.	Persistent Not bioaccumulative	US EPA ACTOR: http://actor.epa.gov/actor/GenericChemical?casrn=68132-00-3
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.		

Line	Data Type	Value	Reference
	May also include tests to fungi.)		
5.4	Terrestrial Toxicity.		
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.)	(a) Rat, acute oral, LD50 > 5000 mg/kg (b) Rabbit, acute dermal, LD50 > 3160 mg/kg	MSDS Guidechem: http://img1.guidechem.com/msdspdf/68132-00-3.pdf
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?		

Line	Data Type	Value	Reference
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 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.	Laura Judd, MS Senior Project Manager (484) 913-0387 laura.judd@erm.com Thomas Numbers, PE, CPEA, BCEE Senior Consultant (757) 645-7495 thomas.numbers@erm.com Maya Zein, PhD Consultant (847) 258-8982 maya.zein@erm.com ERM, Inc. 1011 East Main Street, Suite 227 Richmond, Virginia 23219	
10	References.		

Environmental Assessment Data Template for FDA Submissions

(b) (4)

18 February 2016

Line	Data Type	Value	Reference
1	Name of applicant.	Philip Morris Products S.A.	
2	Address of applicant (correspondence).	Quai Jeanrenaud 3 2000 Neuchatel Switzerland	
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)	

Line	Data Type	Value	Reference
		(b) (4)	
4.1.4	CAS number.		
4.1.5	CAS index name.		
4.2	Molecular formula.		
4.3	Structure.		
5	Environmental Issues.		
5.1	Environmental Fate of Released Substance.		

Line	Data Type	Value	Reference
5.1.1	Identification of substance of interest.		
5.1.2	Water solubility.		
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.	(b) (4)	
5.1.9	Density.		
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.	(b) (4)	
5.2	Environmental Concentrations.		
5.2.1	Expected Introduction Concentration (EIC).		
5.2.2	Expected Environmental Concentration (EEC).		
5.3	Aquatic Toxicity.		

Line	Data Type	Value	Reference
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.)	(b) (4)	
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.		
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		

Line	Data Type	Value	Reference
	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 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.		
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8	Confidential Information – Line items noted above that contain confidential business information may be removed to a confidential appendix.		
9	List of Preparers.	Thomas Numbers, PE, CPEA, BCEE Senior Consultant (757) 645-7495 thomas.numbers@erm.com Kristen Schulz Senior Project Manager (513) 830-9041 kristen.schulz@erm.com ERM, Inc. 1011 East Main Street, Suite 227 Richmond, Virginia 23219	
10	References.		

Environmental Assessment Data Template for FDA Submissions

(b) (4)

18 February 2016

Line	Data Type	Value	Reference
1	Name of applicant.	Philip Morris Products S.A.	
2	Address of applicant (correspondence).	Quai Jeanrenaud 3 2000 Neuchatel Switzerland	
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.		
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3.3	Location of use – manufacturing sites, and geographic region where products made with the substance will be used.		
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4	Substance identification.		
4.1	Nomenclature.		
4.1.1	Established name.	(b) (4)	
4.1.2	Tradename(s).		
4.1.3	Chemical name.		
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.	(b) (4)	
5.1.8	Melting temperature.		
5.1.9	Density.	(b) (4)	

Line	Data Type	Value	Reference
		(b) (4)	
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.		
5.2	Environmental Concentrations.		
5.2.1	Expected Introduction Concentration (EIC).		
5.2.2	Expected Environmental Concentration (EEC).		
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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.)	(b) (4)	
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.)	(b) (4)	
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.)	(b) (4)	
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		

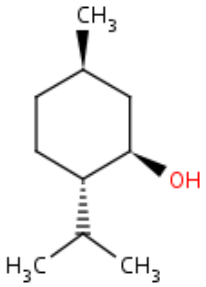
Line	Data Type	Value	Reference
	supply 1 kg of active substance.		
6.1.9	Estimate the total number of plants or animals in the region where the specie is harvested.		
6.1.10	Are there other uses for the plant or animal (food, habitat for other fauna)?		
6.1.11	Plant or animal growth rate and lifespan.		
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 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.	Thomas Numbers, PE, CPEA, BCEE Senior Consultant (757) 645-7495 thomas.numbers@erm.com Brian McDonald Staff Scientist (585) 387-0510 brian.mcdonald@erm.com ERM, Inc. 1011 East Main Street, Suite 227 Richmond, Virginia 23219	
10	References.		

Environmental Assessment Data Template for FDA Submissions

L-Menthol
18 February 2016

Line	Data Type	Value	Reference
1	Name of applicant.	Philip Morris Products S.A.	
2	Address of applicant (correspondence).	Quai Jeanrenaud 3 2000 Neuchatel Switzerland	
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.	L-Menthol	ChemIDPlus http://chem.sis.nlm.nih.gov/chemidplus/ProxyServlet?objectHandle=DBMaint&actionHandle=default&nextPage=jsp/chemidlite/ResultScreen.jsp&TXTSUPERLISTID=0002216515

Line	Data Type	Value	Reference
4.1.2	Tradename(s).	Levomenthol; (l)-Menthol; Levomenthol [INN:BAN]; (-)-Menthol; (-)-Menthyl alcohol; (-)-trans-p-Menthan-cis-ol; (1R)-(-)-Menthol; (1R-(1-alpha,2-beta,5-alpha))-5-Methyl-2-(1-methylethyl) cyclohexanol; AI3-52408; CCRIS 3728; D-(-)-Menthol; Levomenthol; Levomentholum; Levomentholum [INN-Latin]; Menthol, (1R,3R,4S)-(-)-; Menthol, l-; NSC 62788; U.S.P. Menthol; UNII-BZ1R15MTK7; l-(-)-Menthol; l-Menthol; l-Menthol (natural);	EPS SRS http://ofmpub.epa.gov/sor_internet/registry/substreg/searchandretrieve/advancedsearch/externalSearch.do?p_type=SRSITN&p_value=98707 ChemIDPlus http://chem.sis.nlm.nih.gov/chemidplus/ProxyServlet?objectHandle=DBMaint&actionHandle=default&nextPage=jsp/chemidlite/ResultScreen.jsp&TXTSUPERLISTID=0002216515
4.1.3	Chemical name.	Cyclohexanol, 5-methyl-2-(1-methylethyl)-, (1R,2S,5R)-	EPS SRS http://ofmpub.epa.gov/sor_internet/registry/substreg/searchandretrieve/advancedsearch/externalSearch.do?p_type=SRSITN&p_value=98707
4.1.4	CAS number.	2216-51-5	EPS SRS http://ofmpub.epa.gov/sor_internet/registry/substreg/searchandretrieve/advancedsearch/externalSearch.do?p_type=SRSITN&p_value=98707 ChemIDPlus http://chem.sis.nlm.nih.gov/chemi

Line	Data Type	Value	Reference
			dplus/ProxyServlet?objectHandle=DBMaint&actionHandle=default&nextPage=jsp/chemidlite/ResultScreen.jsp&TXTSUPERLISTID=0002216515
4.1.5	CAS index name.	Cyclohexanol, 5-methyl-2-(1-methylethyl)-, (1R,2S,5R)-	EPS SRS http://ofmpub.epa.gov/sor_internet/registry/substreg/searchandretrieve/advancedsearch/externalSearch.do?p_type=SRSITN&p_value=98707
4.2	Molecular formula.	$C_{10}H_{20}O$	EPS SRS http://ofmpub.epa.gov/sor_internet/registry/substreg/searchandretrieve/advancedsearch/externalSearch.do?p_type=SRSITN&p_value=98707
4.3	Structure.		ChemIDPlus http://chem.sis.nlm.nih.gov/chemidplus/ProxyServlet?objectHandle=DBMaint&actionHandle=default&nextPage=jsp/chemidlite/ResultScreen.jsp&TXTSUPERLISTID=0002216515
5	Environmental Issues.		
5.1	Environmental Fate of Released Substance.		
5.1.1	Identification of substance of interest.	Solid, white organic	ECHA Registration

Line	Data Type	Value	Reference
			dossier: http://oecdsids.jrc.ec.europa.eu/i5browser/ShowDocument.do?uuid=IUC4-f8e3aa08-0842-33f6-bda2-0e70f8eacc67%2FIUC5-a4a8d3f0-7015-4964-ae44-88624b27e68b
5.1.2	Water solubility.	431 mg/L at 20 °C	ECHA Registration dossier: http://oecdsids.jrc.ec.europa.eu/i5browser/ShowDocument.do?uuid=IUC4-f8e3aa08-0842-33f6-bda2-0e70f8eacc67%2FIUC5-a4a8d3f0-7015-4964-ae44-88624b27e68b
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.	VP: 0.085 hPa at 25 °C	ECHA Registration dossier: http://oecdsids.jrc.ec.europa.eu/i5browser/ShowDocument.do?uuid=IUC4-f8e3aa08-0842-33f6-bda2-0e70f8eacc67%2FIUC5-a4a8d3f0-7015-4964-ae44-

Line	Data Type	Value	Reference
			88624b27e68b
5.1.7	UV/VIS absorption spectrum.		
5.1.8	Melting temperature.	Ca. 42 °C	ECHA Registration dossier: http://oecdsids.jrc.ec.europa.eu/i5browser/ShowDocument.do?uuid=IUC4-f8e3aa08-0842-33f6-bda2-0e70f8eacc67%2FIUC5-a4a8d3f0-7015-4964-ae44-88624b27e68b
5.1.9	Density.	0.89 g/cm3 at 20 °C	ECHA Registration dossier: http://oecdsids.jrc.ec.europa.eu/i5browser/ShowDocument.do?uuid=IUC4-f8e3aa08-0842-33f6-bda2-0e70f8eacc67%2FIUC5-a4a8d3f0-7015-4964-ae44-88624b27e68b
5.1.10	Hydrolysis.		
5.1.11	Aerobic biodegradation (including removal in sewage treatment plant).	The biodegradation in the toxic controls exceeded 25 %. According to the guideline, the test substance is not toxic to the medium. 93% degr after 21d sampling time.	ECHA Registration dossier: http://oecdsids.jrc.ec.europa.eu/i5browser/ShowDocument.do?uuid=IUC4-f8e3aa08-0842-33f6-bda2-0e70f8eacc67%2FIUC5-

Line	Data Type	Value	Reference
			a4a8d3f0-7015-4964-ae44-88624b27e68b
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).	Air: 43.2 %Water: 40.6 %Soil: 8.0 %Sediment: 8.1 %Biota: 0.005 %	ECHA Registration dossier: http://oecdsids.jrc.ec.europa.eu/i5browser/ShowDocument.do?uuid=IUC4-f8e3aa08-0842-33f6-bda2-0e70f8eacc67%2FIUC5-a4a8d3f0-7015-4964-ae44-88624b27e68b
5.1.16	Persistence and/or Bioaccumulation potential.	Aquatic sediment: BCF: <0.5 - 15 l/kg at 0.2 mg/l BCF: <4.6 - 11 l/kg at 0.02 mg/l	ECHA Registration dossier: http://oecdsids.jrc.ec.europa.eu/i5browser/ShowDocument.do?uuid=IUC4-f8e3aa08-0842-33f6-bda2-0e70f8eacc67%2FIUC5-a4a8d3f0-7015-4964-ae44-88624b27e68b
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.)	*Pimephales promelas* (96h, flow through) LC_{50}= 18.9 mg/L and EC_{50} = 18.4 mg/L.	ECHA Registration dossier: http://oecdsids.jrc.ec.europa.eu/i5

Line	Data Type	Value	Reference
		Brachydanio rerio (new name: *Danio rerio*) (96h, static) LC_0=13.2mg/L LC_{50}=15.6 mg/L LC_{100}=18.4 mg/L. *Oryzias latipes* (48h, static or semi-static) LC_{50}= 26 mg/L	browser/ShowDocument.do?uuid=IUC4-f8e3aa08-0842-33f6-bda2-0e70f8eacc67%2FIUC5-a4a8d3f0-7015-4964-ae44-88624b27e68b
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.)	*Daphnia magna* (48h, static) EC_0=11.35 mg/L EC_{50}= 26.6 mg/L EC_{100}= 92.35 mg/L	ECHA Registration dossier: http://oecdsids.jrc.ec.europa.eu/i5browser/ShowDocument.do?uuid=IUC4-f8e3aa08-0842-33f6-bda2-0e70f8eacc67%2FIUC5-a4a8d3f0-7015-4964-ae44-88624b27e68b
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.)	*Scenedesmus subspicatus* (new name: *Desmodesmus subspicatus*) (72 h) EC_{50}: 20 mg/l EC_{50}: 21.4 mg/l NOEC: 9.65 mg/l LOEC: 18.75 mg/l NOEC: 9.65 mg/l LOEC: 18.75 mg/l	ECHA Registration dossier: http://oecdsids.jrc.ec.europa.eu/i5browser/ShowDocument.do?uuid=IUC4-f8e3aa08-0842-33f6-bda2-0e70f8eacc67%2FIUC5-

Line	Data Type	Value	Reference
			a4a8d3f0-7015-4964-ae44-88624b27e68b
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.)	Activated sludge (aquatic) EC_{10}= 51 mg/L EC_{50}=237 mg/L Aerobic microorganisms: Menthol showed no activity against any of the tested microorganisms.	ECHA Registration dossier: http://oecdsids.jrc.ec.europa.eu/i5browser/ShowDocument.do?uuid=IUC4-f8e3aa08-0842-33f6-bda2-0e70f8eacc67%2FIUC5-a4a8d3f0-7015-4964-ae44-88624b27e68b
5.4	Terrestrial Toxicity.		
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.)	Rat (oral) LD_{50} = 2,426 mg/kg bw Mouse (oral) LD_{50} = 4,380 mg/kg bw Cat lethal dose = 800-1,000 mg/kg bw Rat (subcutaneous) LD = 1,000-2,500 mg/kg bw Mouse (subcutaneous) LD = 5,000-6,000 mg/kg bw Rat (IP) LD_{50} = 710 mg/kg bw Rabbit (IP) LD_{50} = ca. 2000 mg/kg bw Mouse (IP) LD_{50} = 6600 mg/kg bw	ECHA Registration dossier: http://oecdsids.jrc.ec.europa.eu/i5browser/ShowDocument.do?uuid=IUC4-f8e3aa08-0842-33f6-bda2-0e70f8eacc67%2FIUC5-a4a8d3f0-7015-4964-ae44-88624b27e68b
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,	Mouse (3month, Inhalation) NOAEL= 5 ppm (male)	ECHA Registration dossier:

Line	Data Type	Value	Reference
	etc. Specify exposure route – oral, dermal, gavage, etc.)	Mouse (oral gavage, gestation days 6-15) NOEL Maternal Toxicity= 185 mg/kg bw/day, NOEL Teratogenicity= 185 mg/kg bw/day Hamster (oral gavage, gestation days 6-15) NOEL Maternal Toxicity= 405 mg/kg bw/day, NOEL Teratogenicity= 405 mg/kg bw/day Rabbit (oral gavage, gestation days 6-18) NOEL Maternal Toxicity= 425 mg/kg bw/day, NOEL Teratogenicity= 425 mg/kg bw/day Rat (oral gavage, gestation days 6-15) NOEL Maternal Toxicity= 218 mg/kg bw/day, NOEL Teratogenicity= 218 mg/kg bw/day	http://oecdsids.jrc.ec.europa.eu/i5browser/ShowDocument.do?uuid=IUC4-f8e3aa08-0842-33f6-bda2-0e70f8eacc67%2FIUC5-a4a8d3f0-7015-4964-ae44-88624b27e68b
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		

Line	Data Type	Value	Reference
	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 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.	Thomas Numbers, PE, CPEA, BCEE Senior Consultant (757) 645-7495 thomas.numbers@erm.com Kristen Schulz Senior Project Manager (513) 830-9041 kristen.schulz@erm.com ERM, Inc. 1011 East Main Street, Suite 227 Richmond, Virginia 23219	

Line	Data Type	Value	Reference
10	References.		

Environmental Assessment Data Template for FDA Submissions

Paraffin
18 February 2016

Line	Data Type	Value	Reference
1	Name of applicant.	Philip Morris Products S.A.	
2	Address of applicant (correspondence).	Quai Jeanrenaud 3 2000 Neuchatel Switzerland	
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.	Paraffin	
4.1.2	Tradename(s).		
4.1.3	Chemical name.	Microcrystalline cheesewax; Octane, all isomers; Paraffin; Paraffin wax; Paraffin wax (petroleum); Paraffin wax fume; Paraffin waxes; Paraffin waxes and hydrocarbon waxes; Paraffin, n-	USEPA ACToR: http://actor.epa.gov/actor/GenericChemical?casrn=8002-74-2
4.1.4	CAS number.	8002-74-2	
4.1.5	CAS index name.	Paraffin waxes and Hydrocarbon waxes	USEPA SRS: http://iaspub.epa.gov/sor_internet/registry/substreg/searchandre

Line	Data Type	Value	Reference
			trieve/advanced search/external Search.do?p_type=SRSITN&p_value=157313
4.2	Molecular formula.		
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.		
5.1.3	Dissociation constant(s).		
5.1.4	Octanol/water partition coefficients (k_{ow}).	Log Pow > 6 Log Pow 5.3-6.7	IUCLID Data Set: http://esis.jrc.ec.europa.eu/doc/IUCLID/data_sheets/8002742.pdf ECHA Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/15503/4/8
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.	45 °C – 95 °C 43 °C – 95 °C	IUCLID Data Set: http://esis.jrc.ec.europa.eu/doc/IUCLID/data_sheets/8002742.pdf ECHA Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-

Line	Data Type	Value	Reference
			dossier/15503/4/8
5.1.9	Density.	0.73 - 0.84 g/cm^3 at 100°C 0.79 – 0.94 g/cm^3 at 15 °C	IUCLID Data Set: http://esis.jrc.ec.europa.eu/doc/IUCLID/data_sheets/8002742.pdf ECHA Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/15503/4/8
5.1.10	Hydrolysis.		
5.1.11	Aerobic biodegradation (including removal in sewage treatment plant).		
5.1.12	Soil biodegradation.	Oil-pollued soil with 20 mg/l of test substance: 28 d = 21% degradation	IUCLID Data Set: http://esis.jrc.ec.europa.eu/doc/IUCLID/data_sheets/8002742.pdf
5.1.13	Photolysis.		
5.1.14	Microbial metabolism.		
5.1.15	Environmental fate for each compartment (% water, % sediment, % soil, % air).	a) n-tetradecane: Air = 76.7%, Water = 0.0%, Soil = 22.8%, Sediment = 0.5%; n-eicosane: Air = 0.0%, Water = 0.0%, Soil = 97.7%, Sediment = 2.2% b) Per PETRORISK Model: Air = 36.32%, Water = 0.07%, Soil = 25.16%, Sediment = 34.01%	IUCLID Data Set (a): http://esis.jrc.ec.europa.eu/doc/IUCLID/data_sheets/8002742.pdf ECHA Dissemination Portal (b): http://echa.europa.eu/registration-dossier/-/registered-dossier/15503/4

Line	Data Type	Value	Reference
			/8
5.1.16	Persistence and/or Bioaccumulation potential.		
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.)	*Pimephales promelas* 96 hour LL_{50} >100 mg/L *Pimephales promelas* 96 hour NOEL ≥ 100 mg/L (read-across based on grouping of substances (category approach))	ECHA Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/15503/4/8
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.)	*Gammarus pulex* 96 hour WAF of MVI (N) 40 base oil LL_{50} >10,000 mg/L *Gammarus pulex* 96 hour WAF of MVI (N) 40 base oil NOEL ≥ 10,000 mg/L *Daphnia magna* 48 hour EL_{50} and NOEL ≥ 10,000 mg/L (read-across based on grouping of substances (category approach))	ECHA Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/15503/4/8
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.)	*Daphnia magna* 21 day NOEL = 10 mg/L based on effects to reproduction. (read-across based on grouping of substances (category approach))	ECHA Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/15503/4/8
5.3.5	Effects on algae and aquatic plants. (Results typically based on growth inhibition, reported as	*Pseudokirchneriella subcapitata* 72 hour NOEL	ECHA Dissemination

Line	Data Type	Value	Reference
	EC_{50} at 72 or 96h, NOEC, LOEC, etc.)	≥ 100 mg/L based on average specific growth rate and cell yield. (read-across based on grouping of substances (category approach))	Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/15503/4/8
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.		
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.)	LD_{50} rat (oral) > 5000 mg/kg bw LD_{50} rat (dermal) > 3600 mg/kg bw	IUCLID Data Set: http://esis.jrc.ec.europa.eu/doc/IUCLID/data_sheets/8002742.pdf ECHA Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/15503/4/8
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.)	Not toxicity observed at levels requiring classification	ECHA Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/15503/4/8
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.)		

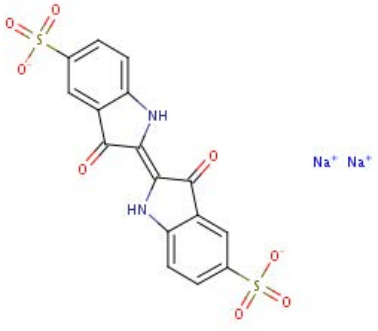
Line	Data Type	Value	Reference
5.4.5	Effects on Plants.		
5.4.6	Effects on Earthworms (or other terrestrial invertebrate).		
5.4.7	Effects on Soil Microbes.		
6	Naturally-derived substance information.		
6.1	Use of flora and fauna.		
6.1.1	Biological information (i.e., common names, synonyms, variety, 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 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.	Thomas Numbers, PE, CPEA, BCEE Senior Consultant (757) 645-7495 thomas.numbers@erm.com	

Line	Data Type	Value	Reference
		Brian McDonald Staff Scientist (585) 315-6095 brian.mcdonald@erm.com Kristen Schulz Senior Proejct Manager (513) 830-9041 kristen.schulz@erm.com ERM, Inc. 1011 East Main Street, Suite 227 Richmond, Virginia 23219	
10	References.		

Environmental Assessment Data Template for FDA Submissions

Pigment Indogo Carmine
11 December 2015

Line	Data Type	Value	Reference
1	Name of applicant.	Philip Morris Products S.A.	
2	Address of applicant (correspondence).	Quai Jeanrenaud 3 2000 Neuchatel Switzerland	
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.	Pigment Indogo Carmine	
4.1.2	Tradename(s).		
4.1.3	Chemical name.	C.I. Acid Blue 74	US EPA ACTOR: http://actor.epa.gov/actor/GenericChemical?casrn=860-22-0
4.1.4	CAS number.	860-22-0	US EPA SRS: http://iaspub.epa.gov/sor_internet/registry/substreg/searchandretrieve/advancedsearch/search.do;jsessionid=o0Sr6-bG5DEZluAvm

Line	Data Type	Value	Reference
			TDryU25lsxT7oS0oYTPA9eub9TQfgBy43It!-1432212414?synId=1065158&displaySynonym
4.1.5	CAS index name.	1H-Indole-5-sulfonic acid, 2-(1,3-dihydro-3-oxo-5-sulfo-2H-indol-2-ylidene)-2,3-dihydro-3-oxo-, sodium salt (1:2)	US EPA SRS: http://iaspub.epa.gov/sor_internet/registry/substreg/searchandretrieve/advancedsearch/search.do;jsessionid=o0Sr6-bG5DEZluAvmTDryU25lsxT7oS0oYTPA9eub9TQfgBy43It!-1432212414?synId=1065158&displaySynonym=
4.2	Molecular formula.	C16 H8 N2 Na2 O8 S2	US EPA ACTOR: http://actor.epa.gov/actor/GenericChemical?casrn=860-22-0
4.3	Structure.		US EPA ACTOR: http://actor.epa.gov/actor/GenericChemical?casrn=860-22-0
5	Environmental Issues.		
5.1	Environmental Fate of Released Substance.		
5.1.1	Identification of substance of interest.		

Line	Data Type	Value	Reference
5.1.2	Water solubility.	1.00E+04 mg/l @ 25 ^{o}C	ChemId Plus: http://chem2.sis.nlm.nih.gov/chemidplus/rn/860-22-0
5.1.3	Dissociation constant(s).		
5.1.4	Octanol/water partition coefficients (k_{ow}).	Log P -3.570	ChemId Plus: http://chem2.sis.nlm.nih.gov/chemidplus/rn/860-22-0
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.	>300 °C	Santa Cruz Biotechnology MSDS : http://www.scbt.com/datasheet-206056-indigo-carmine.html
5.1.9	Density.		
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).	Air Half Life = 1,000 H_2O Half Life = 11.10000038 Sedement Half Life = 1,440 Soil Half Life= 1,440	US EPA ACTOR: http://actor.epa.gov/actor/GenericChemical?casrn=860-22-0
5.1.16	Persistence and/or Bioaccumulation potential.		
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.)	Acute, Ptychocheilus oregonensis,	
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,		

Line	Data Type	Value	Reference
	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.		
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.)	(a) Rat, acute oral, LD50 2000mg/kg	ChemId Plus: http://chem2.sis.nlm.nih.gov/chemidplus/rn/860-22-0
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		

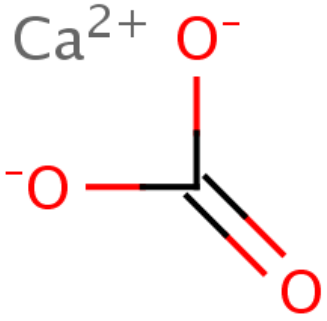
Line	Data Type	Value	Reference
	private land.		
6.1.4	Description of government oversight of harvesting.		
6.1.5	Is the species listed as a species of special concern?		
6.1.6	What part of the animal or plant is used, and is it renewable?		
6.1.7	Describe the harvesting method.		
6.1.8	Bulk weight or 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 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.	Laura Judd, MS Senior Project Manager (484) 913-0387 laura.judd@erm.com Thomas Numbers, PE, CPEA, BCEE Senior Consultant (757) 645-7495 thomas.numbers@erm.com Maya Zein, PhD Consultant (847) 258-8982 maya.zein@erm.com	

Line	Data Type	Value	Reference
		ERM, Inc. 1011 East Main Street, Suite 227 Richmond, Virginia 23219	
10	References.		

Environmental Assessment Data Template for FDA Submissions

Pigment White (b) (4)
18 February 2016

Line	Data Type	Value	Reference
1	Name of applicant.	Philip Morris Products S.A.	
2	Address of applicant (correspondence).	Quai Jeanrenaud 3 2000 Neuchatel Switzerland	
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.	Pigment White (b)	
4.1.2	Tradename(s).		
4.1.3	Chemical name.	Agricultural limestone; Agstone; Bell mine pulverized limestone; Chalk; Domolite; Franklin; Limestone; Lithograpic stone; Natural calcium carbonate; Portland stone; Sohnhofen stone	ChemID Plus: http://chem.sis.nlm.nih.gov/chemidplus/jsp/common/ChemInfo.jsp?calledFrom=lite&type=names
4.1.4	CAS number.	1317-65-3	ChemID Plus: http://chem.sis.nlm.nih.gov/chemidplus/jsp/common/ChemInfo.jsp?calledFrom=lite&type=names

Line	Data Type	Value	Reference
4.1.5	CAS index name.	Limestone	OECD: http://webnet.oecd.org/Hpv/UI/SIDS_Details.aspx?id=05A69EB7-978F-46E1-ABFD-F1DFAC506122
4.2	Molecular formula.	$CaCO_3$	EPA ACToR: http://actor.epa.gov/actor/GenericChemical?casrn=1317-65-3
4.3	Structure.		EPA ACToR: http://actor.epa.gov/actor/GenericChemical?casrn=1317-65-3
5	Environmental Issues.		
5.1	Environmental Fate of Released Substance.		
5.1.1	Identification of substance of interest.		
5.1.2	Water solubility.	0.001%	CAMEO: http://cameochemicals.noaa.gov/chemical/25038
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.	VP: Approx. 0 mm Hg	CAMEO: http://cameochemicals.noaa.gov/chemical/25038
5.1.7	UV/VIS absorption spectrum.		
5.1.8	Melting temperature.	1517-2442°F (Decomposes)	CAMEO: http://cameochemicals.noaa.gov/chemical/2503

Line	Data Type	Value	Reference
			8
5.1.9	Density.	2.7-2.9 g/cm^3	CAMEO: http://cameochemicals.noaa.gov/chemical/25038
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.		
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.		
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		

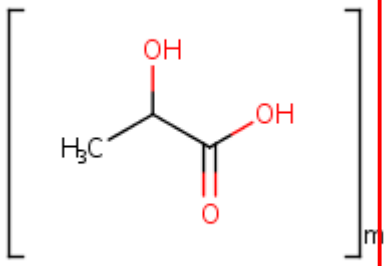
Line	Data Type	Value	Reference
	route – oral, dermal, gavage, etc.)		
5.4.2	Long-term (chronic) toxicity to mammals (rat, mouse, rabbit, dog, etc.) (Results typically based on reproduction or behavior, reported as NOEC, LOEC, etc. Specify exposure route – oral, dermal, gavage, etc.)		
5.4.3	Short-term (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 harvested), and after harvesting (e.g., reforestation).		
6.3	Alternatives.		

Line	Data Type	Value	Reference
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.	Thomas Numbers, PE, CPEA, BCEE Senior Consultant (757) 645-7495 thomas.numbers@erm.com Kristen Schulz Senior Project Manager (513) 830-9041 kristen.schulz@erm.com ERM, Inc. 1011 East Main Street, Suite 227 Richmond, Virginia 23219	
10	References.		

Environmental Assessment Data Template for FDA Submissions

Poly lactic acid
11 December 2015

Line	Data Type	Value	Reference
1	Name of applicant.	Philip Morris Products S.A.	
2	Address of applicant (correspondence).	Quai Jeanrenaud 3 2000 Neuchatel Switzerland	
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.	Poly(lactic acid)	ChemIDplus: http://chem2.sis.nlm.nih.gov/chemidplus/rn/26100-51-6
4.1.2	Tradename(s).		
4.1.3	Chemical name.		
4.1.4	CAS number.	26100-51-6	ChemIDplus: http://chem2.sis.nlm.nih.gov/chemidplus/rn/26100-51-6
4.1.5	CAS index name.	Propanoic acid, 2-hydroxy-, homopolymer	EPA SRS: http://iaspub.epa.gov/sor_internet/registry/substreg/searchandretrieve/advanced

Line	Data Type	Value	Reference
			search/external Search.do?p_type=CASNO&p_value=26100-51-6
4.2	Molecular formula.	(C3-H6-O3)x-	ChemIDplus: http://chem2.sis.nlm.nih.gov/chemidplus/rn/26100-51-6
4.3	Structure.		ChemIDplus: http://chem2.sis.nlm.nih.gov/chemidplus/rn/26100-51-6
5	Environmental Issues.		
5.1	Environmental Fate of Released Substance.		
5.1.1	Identification of substance of interest.		
5.1.2	Water solubility.		
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.	1758 ^{o}C	USDA: http://naldc.nal.usda.gov/download/4048/PDF
5.1.9	Density.		
5.1.10	Hydrolysis.		
5.1.11	Aerobic biodegradation (including removal in sewage treatment plant).	Based on the starting material and its molecular weight, the chemical is likely to be biodegradable and non-hazardous.	
5.1.12	Soil biodegradation.		
5.1.13	Photolysis.		
5.1.14	Microbial metabolism.		
5.1.15	Environmental fate for each compartment		

Line	Data Type	Value	Reference
	(% water, % sediment, % soil, % air).		
5.1.16	Persistence and/or Bioaccumulation potential.		
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.)	Acute, *Brachydanio rerio*, 96 hr, LC50 > 200 mg/L (similar substance)	HERA: http://www.heraproject.com/files/HERA_P-AA_final_v3_23012014.pdf
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.)	Chronic, *Brachydanio rerio*, 28 days, NOEC > 450 mg/L (similar substance)	HERA: http://www.heraproject.com/files/HERA_P-AA_final_v3_23012014.pdf
5.3.3	Short-term (acute) toxicity to invertebrates. (Results based on immobilization/mortality, reported as EC_{50} at 24 or 48h.)	Acute, *Daphnia magna*, 48 hr, EC50 > 200 mg/L (similar substance)	HERA: http://www.heraproject.com/files/HERA_P-AA_final_v3_23012014.pdf
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.)	Chronic, *Daphnia magna*, 21 days, NOEC =100 mg/L (similar substance)	HERA: http://www.heraproject.com/files/HERA_P-AA_final_v3_23012014.pdf
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.)	(a) Acute, *Skeletonema costatum*, 72h, EC50 = 821.34 mg/L (similar substance)	HERA: http://www.heraproject.com/files/HERA_P-AA_final_v3_23012014.pdf
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.		
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	(a) Rat, acute, oral, LD50 >5000 mg/kg-bw (similar substance);	HERA: http://www.heraproject.com/file

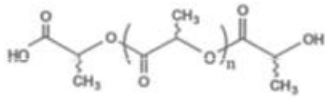
Line	Data Type	Value	Reference
	route – oral, dermal, gavage, etc.)	(b) Rabbit, acute dermal, LD50 > 5000 mg/kg (similar substance);	s/HERA_P-AA_final_v3_23012014.pdf
5.4.2	Long-term (chronic) toxicity to mammals (rat, mouse, rabbit, dog, etc.) (Results typically based on reproduction or behavior, reported 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 harvested),		

Line	Data Type	Value	Reference
	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.	Laura Judd, MS Senior Project Manager (484) 913-0387 laura.judd@erm.com Thomas Numbers, PE, CPEA, BCEE Senior Consultant (757) 645-7495 thomas.numbers@erm.com Maya Zein, PhD Consultant (847) 258-8982 maya.zein@erm.com ERM, Inc. 1011 East Main Street, Suite 227 Richmond, Virginia 23219	
10	References.		

Environmental Assessment Data Template for FDA Submissions

Poly lactic resin
11 December 2015

Line	Data Type	Value	Reference
1	Name of applicant.	Philip Morris Products S.A.	
2	Address of applicant (correspondence).	Quai Jeanrenaud 3 2000 Neuchatel Switzerland	
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.		
4.1.2	Tradename(s).		
4.1.3	Chemical name.	1,4-Dioxane-2,5-dione, 3,6-dimethyl-, (3R,6R)-, polymer with rel-(3R,6S)-3,6-dimethyl-1,4-dioxane-2,5-dione and (3S,6S)-3,6-dimethyl-1,4-dioxane-2,5-dione	EPA SRS: http://iaspub.epa.gov/sor_internet/registry/substreg/searchandretrieve/advancedsearch/externalSearch.do?p_type=SRSITN&p_value=165134
4.1.4	CAS number.	9051-89-2	EPA SRS: http://iaspub.epa.gov/sor_internet/registry/substreg/searchandretrieve/advanced

Line	Data Type	Value	Reference
			search/external Search.do?p_type=SRSITN&p_value=165134
4.1.5	CAS index name.	1,4-Dioxane-2,5-dione, 3,6-dimethyl-, (3R,6R)-, polymer with rel-(3R,6S)-3,6-dimethyl-1,4-dioxane-2,5-dione and (3S,6S)-3,6-dimethyl-1,4-dioxane-2,5-dione	EPA SRS: http://iaspub.epa.gov/sor_internet/registry/substreg/searchandretrieve/advancedsearch/external Search.do?p_type=SRSITN&p_value=165134
4.2	Molecular formula.	(C6H8O4.C6H8O4.C6H8O4)x	EPA SRS: http://iaspub.epa.gov/sor_internet/registry/substreg/searchandretrieve/advancedsearch/external Search.do?p_type=SRSITN&p_value=165134
4.3	Structure.		FDA: http://www.fda.gov/downloads/Food/FoodIngredientsPackaging/EnvironmentalDecisions/UCM214608.pdf
5	Environmental Issues.		
5.1	Environmental Fate of Released Substance.		
5.1.1	Identification of substance of interest.		
5.1.2	Water solubility.	Solubility in water at 20°C (mg/l) insoluble (substance concentration >98%)	MSDS Futerro: http://www.futerro.com/documents/msds_pla_en.pdf
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.		

Line	Data Type	Value	Reference
5.1.8	Melting temperature.	150 -180°C (substance concentration >98%)	MSDS Futerro: http://www.futerro.com/documents/msds_pla_en.pdf
5.1.9	Density.	1.25 g/cc (substance concentration >98%)	MSDS Makerbot: http://downloads.makerbot.com/filament/PLA+MSDS.pdf
5.1.10	Hydrolysis.	Under aerobic conditions, PLA decomposes to lactic acid and other smaller compounds, ultimately to carbon dioxide and water. hydrolysis half-life of lactide at 25ºC is 3.3 hours in neutral and aqueous media.	FDA: http://www.fda.gov/downloads/Food/FoodIngredientsPackaging/EnvironmentalDecisions/UCM214608.pdf
5.1.11	Aerobic biodegradation (including removal in sewage treatment plant).	Readily biodegradable, 45 days, 91 %	FDA: http://www.fda.gov/downloads/Food/FoodIngredientsPackaging/EnvironmentalDecisions/UCM214608.pdf
5.1.12	Soil biodegradation.	the product is inherently biodegradable (substance concentration >98%)	MSDS Futerro: http://www.futerro.com/documents/msds_pla_en.pdf
5.1.13	Photolysis.		
5.1.14	Microbial metabolism.		
5.1.15	Environmental fate for each compartment (% water, % sediment, % soil, % air).	water / air there is a slow loss by evaporation; soil and sediments because of its physico-chemical properties, the product has a low soil mobility (substance concentration >98%)	MSDS Futerro: http://www.futerro.com/documents/msds_pla_en.pdf
5.1.16	Persistence and/or Bioaccumulation potential.	potential bioaccumulation of the product in environment is very low because of its structure, the product should	MSDS Futerro: http://www.futerro.com/documents/msds_pla_e

Line	Data Type	Value	Reference
		not be dangerous for aquatic life (substance concentration >98%)	n.pdf
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.)	Acute, Algae , 72 hr, EC50 > 1100 mg/l	MSDS Makerbot: http://downloads.makerbot.com/filament/PLA+MSDS.pdf
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.		
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.)	(a) Rat , acute oral, LD50 >5000 mg/kg; (b) Rabbit, acute dermal, LD50 >2000 mg/kg;	MSDS Makerbot: http://downloads.makerbot.com/filament/PLA+MSDS.pdf
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		

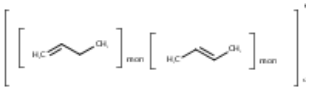
Line	Data Type	Value	Reference
	typically based on mortality, reported as $LC/LD_{50.}$ Specify exposure route – oral, dermal, gavage, etc.)		
5.4.4	Long-term (chronic) toxicity to birds. (Results typically based on reproduction or behavior, reported as NOEC, LOEC, etc. Specify exposure route – oral, dermal, gavage, etc.)		
5.4.5	Effects on Plants.	No adverse ecotoxicity was observed in summer barley (plant growth) and water cress (seed germination).	FDA: http://www.fda.gov/downloads/Food/FoodIngredientsPackaging/EnvironmentalDecisions/UCM214608.pdf
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 harvested), and after harvesting (e.g., reforestation).		
6.3	Alternatives.		
6.3.1	What reasonable alternatives that were considered		

Line	Data Type	Value	Reference
	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.	Laura Judd, MS Senior Project Manager (484) 913-0387 laura.judd@erm.com Thomas Numbers, PE, CPEA, BCEE Senior Consultant (757) 645-7495 thomas.numbers@erm.com Maya Zein, PhD Consultant (847) 258-8982 maya.zein@erm.com ERM, Inc. 1011 East Main Street, Suite 227 Richmond, Virginia 23219	
10	References.		

Environmental Assessment Data Template for FDA Submissions

Polyisobutylene
11 December 2015

Line	Data Type	Value	Reference
1	Name of applicant.	Philip Morris Products S.A.	
2	Address of applicant (correspondence).	Quai Jeanrenaud 3 2000 Neuchatel Switzerland	
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.		
4.1.2	Tradename(s).		
4.1.3	Chemical name.	Polybutene	ChemID Plus: http://chem2.sis.nlm.nih.gov/chemidplus/rn/9003-29-6
4.1.4	CAS number.	9003-29-6	ChemID Plus: http://chem2.sis.nlm.nih.gov/chemidplus/rn/9003-29-6
4.1.5	CAS index name.	1-Butene, homopolymer	US EPA SRS: http://iaspub.epa.gov/sor_internet/registry/substreg/substance/details.do?displayPopup=displayPopup&id=37668
4.2	Molecular formula.	(C4-H8)x-	ChemID Plus:

Line	Data Type	Value	Reference
			http://chem2.sis.nlm.nih.gov/chemidplus/rn/9003-29-6
4.3	Structure.		ChemID Plus: http://chem2.sis.nlm.nih.gov/chemidplus/rn/9003-29-6
5	Environmental Issues.		
5.1	Environmental Fate of Released Substance.		
5.1.1	Identification of substance of interest.		
5.1.2	Water solubility.	< 2.4 mg/L @ 20 °C	ECHA REACH DOSSIER: http://apps.echa.europa.eu/registered/data/dossiers/DISS-9fdbe802-7da4-5888-e044-00144f67d031/AGGR-506c59d1-427f-4d80-b085-27a03f8a31b1_DISS-9fdbe802-7da4-5888-e044-00144f67d031.html#AGGR-506c59d1-427f-4d80-b085-27a03f8a31b1
5.1.3	Dissociation constant(s).		
5.1.4	Octanol/water partition coefficients (k_{ow}).	log Pow 7.6 7.8 ; PH=7, 20 °C	http://apps.echa.europa.eu/registered/data/dossiers/DISS-9fdbe802-7da4-ECHA REACH DOSSIER: 5888-e044-00144f67d031/AGGR-288ce15d-7fa7-4abb-a237-a4a0f1ca266c_DISS-9fdbe802-7da4-5888-e044-00144f67d031.html#AGGR-288ce15d-7fa7-4abb-a237-a4a0f1ca266c

Line	Data Type	Value	Reference
5.1.5	Sorption and/or desorption properties (k_{oc}).	log Koc 6.42	ECHA REACH DOSSIER: http://apps.echa.europa.eu/registered/data/dossiers/DISS-9fdbe802-7da4-5888-e044-00144f67d031/AGGR-b73861e7-7630-44bf-a986-a1454ec851c2_DISS-9fdbe802-7da4-5888-e044-00144f67d031.html#AGGR-b73861e7-7630-44bf-a986-a1454ec851c2
5.1.6	Vapor pressure and/or Henry's law constant.	H= 701.38 Pa m³/mol @ 20 °C (calculated)	ECHA REACH DOSSIER: http://apps.echa.europa.eu/registered/data/dossiers/DISS-9fdbe802-7da4-5888-e044-00144f67d031/AGGR-a89a092f-dacd-4e8e-b7f8-7175469f95fb_DISS-9fdbe802-7da4-5888-e044-00144f67d031.html#AGGR-a89a092f-dacd-4e8e-b7f8-7175469f95fb
5.1.7	UV/VIS absorption spectrum.		
5.1.8	Melting temperature.		
5.1.9	Density.	0.77 g/ml at 20°C	ECHA REACH DOSSIER: http://apps.echa.europa.eu/registered/data/dossiers/DISS-9fdbe802-7da4-5888-e044-00144f67d031/AGGR-bee9eea6-d0d6-4370-9446-724d4e87845f_DISS-9fdbe802-7da4-5888-e044-00144f67d031.html#AG

Line	Data Type	Value	Reference
			GR-bee9eea6-d0d6-4370-9446-724d4e87845f
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.	Bioaccumulative log Pow = 7.8. BCF = 30199.5 (calculated)	ECHA REACH DOSSIER: http://apps.echa.europa.eu/registered/data/dossiers/DISS-9fdbe802-7da4-5888-e044-00144f67d031/AGGR-91b8790d-3cf1-45b1-a40d-565999908ee0_DISS-9fdbe802-7da4-5888-e044-00144f67d031.html#AGGR-91b8790d-3cf1-45b1-a40d-565999908ee0
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.)	Acute, Fish, *Cyprinus carpio*, 96 hr, LC50 > 1.55 mg/L (Read across substance tetrabutene)	ECHA REACH DOSSIER: http://apps.echa.europa.eu/registered/data/dossiers/DISS-9fdbe802-7da4-5888-e044-00144f67d031/AGGR-9de0ca5c-fc72-4bfb-91c4-a3ecd4c7251f_DISS-9fdbe802-7da4-5888-e044-00144f67d031.html#AGGR-9de0ca5c-fc72-4bfb-

Line	Data Type	Value	Reference
			91c4-a3ecd4c7251f
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.)	Acute, Invertebrate, *Daphnia magna*, 48 hr, EC50 > 100 mg/L (Substance purity 99.6%)	ECHA REACH DOSSIER: http://apps.echa.europa.eu/registered/data/dossiers/DISS-9fdbe802-7da4-5888-e044-00144f67d031/AGGR-c250ab07-ec9e-4a72-a5f8-7d07e3a37306_DISS-9fdbe802-7da4-5888-e044-00144f67d031.html#AGGR-c250ab07-ec9e-4a72-a5f8-7d07e3a37306
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.)	Acute, Algae, *Desmodesmus subspicatus*, 72 hr, EC50 > 19.2 mg/L	ECHA REACH DOSSIER: http://apps.echa.europa.eu/registered/data/dossiers/DISS-9fdbe802-7da4-5888-e044-00144f67d031/AGGR-fbf54303-f751-475f-b2f9-ca21b801103f_DISS-9fdbe802-7da4-5888-e044-00144f67d031.html#AGGR-fbf54303-f751-475f-b2f9-ca21b801103f
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.		
5.4.1	Short-term (acute) toxicity to mammals (rat,	(a) Rat, acute oral, LD_{50}	ECHA REACH

Line	Data Type	Value	Reference
	mouse, rabbit, dog, etc.) (Results typically based on mortality, reported as LC/$LD_{50.}$ Specify exposure route – oral, dermal, gavage, etc.)	> 10,000 mg/kg; (b) Rat, acute inhalation, 4 hr, LC50 > 19.17 mg/L (similar substance); (c) Rat, acute dermal, LD50 > 2000 mg/kg, (similar substance); (d) Not irriating to rabbit's eye (similar substance) (e) Not regarded as a skin sensitizer (f) In vitro tests did not show mutagenic effects (similar substance) In vivo tests did not show mutagenic effects (similar substance) (g) Animal testing did not show any effects on fertility (Similar substance) Did not show teratogenic effects in animal experiments (similar substance)	DOSSIER: http://apps.echa.europa.eu/registered/data/dossiers/DISS-9fdbe802-7da4-5888-e044-00144f67d031/AGGR-625d376e-da5e-42d2-9359-971a2ae56dd8_DISS-9fdbe802-7da4-5888-e044-00144f67d031.html#AGGR-625d376e-da5e-42d2-9359-971a2ae56dd8
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.)	Acute, oral, *Colinus virginianus*, 14d, LD50> 2150 ppm	EPA ECOTOX: http://cfpub.epa.gov/ecotox/report.cfm?type=long&refresh=y&newRecordNum=2064170
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).	Acute, *Eisenia fetida*, 14d, NOEC 1000 mg/kg	ECHA REACH DOSSIER:

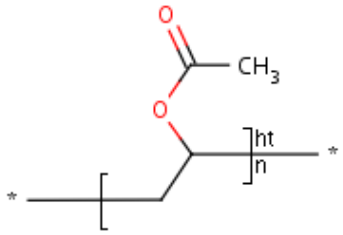
Line	Data Type	Value	Reference
		soil dw.	http://apps.echa.europa.eu/registered/data/dossiers/DISS-9fdbe802-7da4-5888-e044-00144f67d031/AGGR-5eeea466-190d-44fd-be6e-638441b7c256_DISS-9fdbe802-7da4-5888-e044-00144f67d031.html#AGGR-5eeea466-190d-44fd-be6e-638441b7c256
5.4.7	Effects on Soil Microbes.		
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 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.		

Line	Data Type	Value	Reference
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.	Laura Judd, MS Senior Project Manager (484) 913-0387 laura.judd@erm.com Thomas Numbers, PE, CPEA, BCEE Senior Consultant (757) 645-7495 thomas.numbers@erm.com Maya Zein, PhD Consultant (847) 258-8982 maya.zein@erm.com ERM, Inc. 1011 East Main Street, Suite 227 Richmond, Virginia 23219	
10	References.		

Environmental Assessment Data Template for FDA Submissions

Polyvinyl Acetate
18 February 2016

Line	Data Type	Value	Reference
1	Name of applicant.	Philip Morris Products S.A.	
2	Address of applicant (correspondence).	Quai Jeanrenaud 3 2000 Neuchatel Switzerland	
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.	Polyvinyl acetate	
4.1.2	Tradename(s).		
4.1.3	Chemical name.	Acetic acid ethenyl ester, homopolymer; Poly(vinyl acetate); Vinyl acetate homopolymer; Vinyl acetate polymer;	EPA ACToR: http://actor.epa.gov/actor/GenericChemical?casrn=9003-20-7
4.1.4	CAS number.	9003-20-7	EPA ACToR: http://actor.epa.gov/actor/GenericChemical?casrn=9003-20-7
4.1.5	CAS index name.	Acetic acid ethenyl ester, homopolymer	EPA ACToR: http://actor.epa.gov/actor/GenericChemical?casrn=9003-20-7

Line	Data Type	Value	Reference
4.2	Molecular formula.	(C4H6O2)x	EPA SRS: http://iaspub.epa.gov/sor_internet/registry/substreg/searchandretrieve/advancedsearch/externalSearch.do?p_type=CASNO&p_value=9003-20-7
4.3	Structure.		HSDB: http://toxnet.nlm.nih.gov/cgi-bin/sis/download.txt
5	Environmental Issues.		
5.1	Environmental Fate of Released Substance.		
5.1.1	Identification of substance of interest.		
5.1.2	Water solubility.	Insoluble in water	HSDB: http://toxnet.nlm.nih.gov/cgi-bin/sis/download.txt
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.	35 – 50 °C with softening	HSDB: http://toxnet.nlm.nih.gov/cgi-bin/sis/download.txt
5.1.9	Density.	1.19 @ 15 °C	HSDB: http://toxnet.nlm.nih.gov/cgi-bin/sis/download.txt
5.1.10	Hydrolysis.	Hydrolyzed by water to polyvinyl alcohol	HSDB: http://toxnet.nlm.nih.gov/cgi-

Line	Data Type	Value	Reference
			bin/sis/download.txt
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.	Persistent	EAP ACToR: http://actor.epa.gov/actor/GenericChemical?casrn=9003-20-7
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.		
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.)	Rat LD_{50} > 25,000mg/kg Mouse LD_{50} > 25,000mg/kg	EPA ACToR: http://actor.epa.gov/actor/GenericChemical?cas

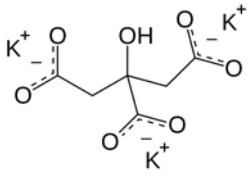
Line	Data Type	Value	Reference
			rn=9003-20-7
5.4.2	Long-term (chronic) toxicity to mammals (rat, mouse, rabbit, dog, etc.) (Results typically based on reproduction or behavior, reported as NOEC, LOEC, etc. Specify exposure route – oral, dermal, gavage, etc.)	12 Month Oral repeat dose of 250 mg/kg, Rats, caused fluctuations in wt, changes in blood composition, changes in liver:body wt ratio; changes in activity of catalase; cholinesterase.	IARC: Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Man. Geneva: World Health Organization, International Agency for Research on Cancer, 1972-PRESENT. (Multivolume work). Available at: http://monographs.iarc.fr/index.php, p. V19 351
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?		

Line	Data Type	Value	Reference
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.		
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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 harvested), and after harvesting (e.g., reforestation).		
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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.	Thomas Numbers, PE, CPEA, BCEE Senior Consultant (757) 645-7495 thomas.numbers@erm.com Kristen Schulz Senior Project Manager (513) 830-9041 kristen.schulz@erm.com ERM, Inc. 1011 East Main Street, Suite 227 Richmond, Virginia 23219	
10	References.		

Environmental Assessment Data Template for FDA Submissions

Potassium Citrate
20 January 2013

Substance populated using data for (b) (4) potassium citrate (CAS # 866-84-2).

Line	Data Type	Value	Reference
1	Name of applicant.	Philip Morris Products S.A.	
2	Address of applicant (correspondence).	Quai Jeanrenaud 3 2000 Neuchatel Switzerland	
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.	Potassium Citrate	
4.1.2	Tradename(s).	Potassium Citrate, Potassium Citrate Monohydrate	MSDS ChemID Plus: http://chem.sis.nlm.nih.gov/chemidplus/rn/6100-05-6
4.1.3	Chemical name.	Citric Acid, Potassium Salt	MSDS
4.1.4	CAS number.	6100-05-6	
4.1.5	CAS index name.	Citric Acid, Potassium Salt	MSDS
4.2	Molecular formula.	$C_6H_5K_3O_7$	MSDS
4.3	Structure.		MSDS
5	Environmental Issues.		

Line	Data Type	Value	Reference
5.1	Environmental Fate of Released Substance.		
5.1.1	Identification of substance of interest.		
5.1.2	Water solubility.	606 g/L at 25 °C; 1,540 g/L at 25 °C	ECHA Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/14309/4/9
5.1.3	Dissociation constant(s).	pKa values of 3.13, 4.76 and 6.4 at 25°C have been reported	ECHA Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/14309/4/9
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.	VP: 0 Pa at 25°C (extrapolated)	ECHA Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/14309/4/9
5.1.7	UV/VIS absorption spectrum.		
5.1.8	Melting temperature.	Decomposition temperature = 230 °C	ECHA Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/14309/4/9
5.1.9	Density.	1.98 at 20 °C	ECHA Dissemination Portal: http://echa.euro

Line	Data Type	Value	Reference
			pa.eu/registration-dossier/-/registered-dossier/14309/4/9
5.1.10	Hydrolysis.		
5.1.11	Aerobic biodegradation (including removal in sewage treatment plant).	Readily biodegradable	ECHA Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/14309/4/9
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.	Calculated BCF = 3.2 L/kg	ECHA Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/14309/4/9
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.)	*Leuciscus idus melanotus* 48 hour LC_{50} = 440 mg/L (tested as citric acid) *Leuciscus idus melanotus* 48 hour LC_{50} = 760 mg/L (tested as citric acid)	ECHA Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/14309/4/9
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,		

Line	Data Type	Value	Reference
	etc.)		
5.3.3	Short-term (acute) toxicity to invertebrates. (Results based on immobilization/mortality, reported as EC_{50} at 24 or 48h.)	*Daphnia magna* 24 hour EC_{50} = 85 mg/L	ECHA Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/14309/4/9
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.)	*Scenedesmus quadricauda* 8d TT = 640 mg/L; 8 day NOEC = 425 mg/L	ECHA Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/14309/4/9
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.)	*Pseudomonas putida* 16 hour TT >10,000 mg/L	ECHA Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/14309/4/9
5.4	Terrestrial Toxicity.		
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.)	LD_{50} mouse (oral) = 5,400 mg/kg bw LD_{50} rat (dermal) > 2,000 mg/kg bw	ECHA Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/14309/4/9
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,	No toxicity observed at levels requiring classification	ECHA Dissemination Portal:

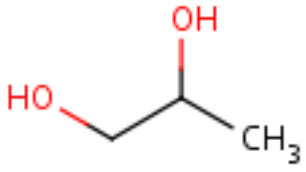
Line	Data Type	Value	Reference
	etc. Specify exposure route – oral, dermal, gavage, etc.)		http://echa.europa.eu/registration-dossier/-/registered-dossier/14309/4/9
5.4.3	Short-term (acute) toxicity to birds. (Results typically based on mortality, reported as LC/LD_{50}. Specify exposure route – oral, 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 harvested), and after harvesting (e.g., reforestation).		
6.3	Alternatives.		

Line	Data Type	Value	Reference
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.	Thomas Numbers, PE, CPEA, BCEE Senior Consultant (757) 645-7495 thomas.numbers@erm.com Brian D. McDonald Staff Scientist (585) 315-6095 brian.mcdonald@erm.com Kristen Schulz Senior Project Manager (513) 830-9041 kristen.schulz@erm.com ERM, Inc. 1011 East Main Street, Suite 227 Richmond, Virginia 23219	
10	References.		

Environmental Assessment Data Template for FDA Submissions

Propylene Glycol
18 February 2016

Line	Data Type	Value	Reference
1	Name of applicant.	Philip Morris Products S.A.	
2	Address of applicant (correspondence).	Quai Jeanrenaud 3 2000 Neuchatel Switzerland	
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.	Propylene glycol	
4.1.2	Tradename(s).		
4.1.3	Chemical name.	Propylene glycol	US EPA SRS http://ofmpub.epa.gov/sor_internet/registry/substreg/searchandretrieve/advancedsearch/externalSearch.do?p_type=SRSITN&p_value=2584

Line	Data Type	Value	Reference
4.1.4	CAS number.	57-55-6	US EPA SRS http://ofmpub.epa.gov/sor_internet/registry/substreg/searchandretrieve/advancedsearch/externalSearch.do?p_type=SRSITN&p_value=2584
4.1.5	CAS index name.	1,2-Propanediol	US EPA SRS http://ofmpub.epa.gov/sor_internet/registry/substreg/searchandretrieve/advancedsearch/externalSearch.do?p_type=SRSITN&p_value=2584
4.2	Molecular formula.	C3H8O2	US EPA SRS http://ofmpub.epa.gov/sor_internet/registry/substreg/searchandretrieve/advancedsearch/externalSearch.do?p_type=SRSITN&p_value=2584
4.3	Structure.		ChemIDPlus http://chem.sis.nlm.nih.gov/chemidplus/ProxyServlet?objectHandle=DBMaint&actionHandle=default&nextPage=jsp/chemidlite/ResultScreen.jsp&TXTSUPERLISTID=000057556
5	Environmental Issues.		
5.1	Environmental Fate of Released Substance.		

Line	Data Type	Value	Reference
5.1.1	Identification of substance of interest.		
5.1.2	Water solubility.	100 vol% at 20 °C and pH >7.1-<7.8	ECHA Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/16001/4/9
5.1.3	Dissociation constant(s).		
5.1.4	Octanol/water partition coefficients (k_{ow}).	Log Pow = -1.07 at 20.5 °C and pH >6.2-<6.4	ECHA Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/16001/4/9
5.1.5	Sorption and/or desorption properties (k_{oc}).		
5.1.6	Vapor pressure and/or Henry's law constant.	H = 0.006 at 12 °C (EUSES calculation); VP = 20 Pa at 25 °C	ECHA Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/16001/4/9
5.1.7	UV/VIS absorption spectrum.		
5.1.8	Melting temperature.	< -20 °C at ca. 101.325 Pa	ECHA Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/16001/4/9
5.1.9	Density.	Relative density = 1.03 at 20 °C	ECHA Dissemination Portal: http://echa.europa.eu/registratio

Line	Data Type	Value	Reference
			n-dossier/-/registered-dossier/16001/4/9
5.1.10	Hydrolysis.		
5.1.11	Aerobic biodegradation (including removal in sewage treatment plant).	95.8% and 90.6% biodegradability in seawater in 64 days (domestic activated sludge) as measured by CO_2 evolution and DOC removal, respectively	ECHA Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/16001/4/9
5.1.12	Soil biodegradation.	High concentrations of propylene glycol released into a soil environment can be expected to biodegrade. The rate of biodegradation is likely to be a function of a variety of physical, chemical and biological factors. Complete degradation to methane can be expected to occur once a consortium of fermentative, acetogenic and methanogenic bacteria becomes established. Transient accumulation of propionic acid as an intermediate may alter soil pH and limit degradation. The natural buffering capacity of the soil, however, is likely to mitigate this.	ECHA Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/16001/4/9
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.		
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.)	*Oncorhynchus mykiss* 96 hour LC_{50} = 40,613 mg/L	ECHA Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/16001/4/9
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.)	*Ceriodaphnia dubia* 48 hour LC_{50} = 18,340 mg/L *Americamysis bahia* 96 hour LC_{50} = 18,800 mg/L	ECHA Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/16001/4/9
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.)	*Ceriodaphnia sp.* 7 day NOEC = 13020 mg/l (for reproduction or growth was), NOEC = 29000 mg/l (mortality).	ECHA Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/16001/4/9
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.)	*Skeletonema costatum* 24 hour EC_{50} = 31,500 (27,600 – 36,200) mg/l; 48 hour EC_{50} = 19,000 (16,600 – 21,600) mg/l; 72 hour EC_{50} = 19,300 (16,900 – 21,800) mg/l; 96 hour EC_{50} = 19,100 (17,200 – 21,000) mg/l *Selenastrum capricornutum* 24 hour EC_{50} < 5,200 mg/l; 48 hour EC_{50} = 34,100 (29,100 – 40,600) mg/l; 72 hour EC_{50} = 24,200 (22,100 – 26,500) mg/l; 96 hour EC_{50}	ECHA Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/16001/4/9

		= 19,000 (16,700 – 21,400) mg/l	
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.)	*Pseudomonas putida* 18 hour NOEC >10,000 mg/L (growth inhibition)	ECHA Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/16001/4/9
5.4	Terrestrial Toxicity.		
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.)	LD_{50} rat (oral) = 22,000 mg/kg 2 hour LC_{50} rabbit (inhalation) > 317,042 mg/m³ air LD_{50} rabbit (dermal) >2,000 mg/kg	ECHA Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/16001/4/9
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.)	No toxicity was observed at levels requiring classification	ECHA Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/16001/4/9
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 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.	Thomas Numbers, PE, CPEA, BCEE Senior Consultant (757) 645-7495 thomas.numbers@erm.com Kristen Schulz Senior Project Manager (513) 830-9041 kristen.schulz@erm.com ERM, Inc. 1011 East Main Street, Suite 227	

		Richmond, Virginia 23219	
10	References.		

Environmental Assessment Data Template for FDA Submissions

Rosin
18 February 2016

Line	Data Type	Value	Reference
1	Name of applicant.	Philip Morris Products S.A.	
2	Address of applicant (correspondence).	Quai Jeanrenaud 3 2000 Neuchatel Switzerland	
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.	Rosin	
4.1.2	Tradename(s).		
4.1.3	Chemical name.	Disproportionated rosin; Gum Rosin; Cholofonium; Colophony; Pine Resin; Pitch tar	EPA ACToR: http://actor.epa.gov/actor/GenericChemical?casrn=8050-09-7
4.1.4	CAS number.	8050-09-7	
4.1.5	CAS index name.	Rosin	IUCLID: http://esis.jrc.ec.europa.eu/doc/IUCLID/data_sheets/8050097.pdf
4.2	Molecular formula.		
4.3	Structure.		
5	Environmental Issues.		
5.1	Environmental Fate of Released Substance.		

Line	Data Type	Value	Reference
5.1.1	Identification of substance of interest.		
5.1.2	Water solubility.	Slightly soluble = 0.9 mg/L at 20°C	EHCA REACH Dissemination Portal: http://apps.echa.europa.eu/registered/data/dossiers/DISS-97d7e4ae-629b-26d8-e044-00144f67d031/AGGR-7359f2ee-885c-4703-bc5c-21f1d96c123a_DISS-97d7e4ae-629b-26d8-e044-00144f67d031.html#AGGR-7359f2ee-885c-4703-bc5c-21f1d96c123a
5.1.3	Dissociation constant(s).		
5.1.4	Octanol/water partition coefficients (k_{ow}).	log Pow = 3-6.2 at pH 6-7; log Pow = 1.9-7.7 at pH 2	EHCA REACH Dissemination Portal: http://apps.echa.europa.eu/registered/data/dossiers/DISS-97d7e4ae-629b-26d8-e044-00144f67d031/AGGR-7359f2ee-885c-4703-bc5c-21f1d96c123a_DISS-97d7e4ae-629b-26d8-e044-00144f67d031.html#AGGR-7359f2ee-885c-4703-bc5c-21f1d96c123ag
5.1.5	Sorption and/or desorption properties (k_{oc}).		
5.1.6	Vapor pressure and/or Henry's law constant.	VP: 0.06 mbar at 20˚C	IUCLID: http://esis.jrc.ec.europa.eu/doc/IUCLID/data_sheets/8050097.pdf
5.1.7	UV/VIS absorption spectrum.		
5.1.8	Melting temperature.	66.5 – 93.4°C	EHCA REACH Dissemination Portal: http://apps.echa.europa.eu/registered/data/dossiers/DISS-97d7e4ae-

Line	Data Type	Value	Reference
			629b-26d8-e044-00144f67d031/AGGR-7359f2ee-885c-4703-bc5c-21f1d96c123a_DISS-97d7e4ae-629b-26d8-e044-00144f67d031.html#AGGR-7359f2ee-885c-4703-bc5c-21f1d96c123a
5.1.9	Density.	Relative density = 1,034 kg/m^3	EHCA REACH Dissemination Portal: http://apps.echa.europa.eu/registered/data/dossiers/DISS-97d7e4ae-629b-26d8-e044-00144f67d031/AGGR-7359f2ee-885c-4703-bc5c-21f1d96c123a_DISS-97d7e4ae-629b-26d8-e044-00144f67d031.html#AGGR-7359f2ee-885c-4703-bc5c-21f1d96c123a
5.1.10	Hydrolysis.		
5.1.11	Aerobic biodegradation (including removal in sewage treatment plant).	Readily biodegradable, day 1 = 15% and day 10 = 63%;	EHCA REACH Dissemination Portal: http://apps.echa.europa.eu/registered/data/dossiers/DISS-97d7e4ae-629b-26d8-e044-00144f67d031/AGGR-7359f2ee-885c-4703-bc5c-21f1d96c123a_DISS-97d7e4ae-629b-26d8-e044-00144f67d031.html#AGGR-7359f2ee-885c-4703-bc5c-21f1d96c123a
5.1.12	Soil biodegradation.		

Line	Data Type	Value	Reference
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.	Substance is not considered an PBT/vPvB	EHCA REACH Dissemination Portal: http://apps.echa.europa.eu/registered/data/dossiers/DISS-97d7e4ae-629b-26d8-e044-00144f67d031/AGGR-7359f2ee-885c-4703-bc5c-21f1d96c123a_DISS-97d7e4ae-629b-26d8-e044-00144f67d031.html#AGGR-7359f2ee-885c-4703-bc5c-21f1d96c123a
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.)	*Brachydanio rerio*: 24 h $LL_{100} \leq 10$ mg/L; (semi-static); *Brachydanio rerio*: 96 h $LL_{100} \leq 10$ mg/L; (semi-static); *Brachydanio rerio*: 96 h $LL_{50} < 10$ mg/L; (semi-static); *Brachydanio rerio*: 96 h NOELR 1 mg/L; (semi-static);	IUCLID: http://esis.jrc.ec.europa.eu/doc/IUCLID/data_sheets/8050097.pdf
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,	*Daphnia magna*: 24 h EC_{50} = 7.3 – 14.1 mg/L;	IUCLID: http://esis.jrc.ec.europ

Line	Data Type	Value	Reference
	reported as EC_{50} at 24 or 48h.)	*Daphnia magna*: 24 h EC_0 = 2.15 mg/L, EC_{50} = 9.6 mg/L, EC_{100} = 17.2 mg/L; *Daphnia magna*: 48 h EC_{50} = 3.8 – 5.4 mg/L; *Daphnia magna*: 48 h EC_0 = 2.15 mg/L, EC_{50} = 4.5 mg/L, EC_{100} = 17.2 mg/L ---------- *Daphnia magna*: 48 h EL50 = 911 mg/L (static); *Daphnia magna:* 48 h NOELR = 750 mg/L (static);	a.eu/doc/IUCLID/data_sheets/8050097.pdf ---------- EHCA REACH Dissemination Portal: http://apps.echa.europa.eu/registered/data/dossiers/DISS-97d7e4ae-629b-26d8-e044-00144f67d031/AGGR-7359f2ee-885c-4703-bc5c-21f1d96c123a_DISS-97d7e4ae-629b-26d8-e044-00144f67d031.html#AGGR-7359f2ee-885c-4703-bc5c-21f1d96c123a
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.)	*Scenedesmus subspicatus*: 72 h EC_{10} = 140 mg/L, EC_{50} = 400 mg/L; *Scenedesmus subspicatus*: 72 h EC_{10} = 230 mg/L, EC_{50} = 410 mg/L	IUCLID: http://esis.jrc.ec.europa.eu/doc/IUCLID/data_sheets/8050097.pdf
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.)	*Photobacterium phosphoreum*: 30 min EC_{10} = 3.8 mg/L, EC_{50} = 31.5 mg/L, EC_{20} = 8.3 mg/L; *Pseudomonas putida*: EC_{10} = 53.9 mg/L, EC_{50} = 76.1 mg/L; ---------- Activated sludge – domestic sewage: 3 h EC_{50} > 10,000 mg/L (static)	IUCLID: http://esis.jrc.ec.europa.eu/doc/IUCLID/data_sheets/8050097.pdf ---------- EHCA REACH Dissemination Portal: http://apps.echa.europa.eu/registered/data/dossiers/DISS-97d7e4ae-629b-26d8-e044-00144f67d031/AGGR-7359f2ee-885c-4703-bc5c-21f1d96c123a_DISS-

Line	Data Type	Value	Reference
			97d7e4ae-629b-26d8-e044-00144f67d031.html#AGGR-7359f2ee-885c-4703-bc5c-21f1d96c123a
5.4	Terrestrial Toxicity.		
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.)	Rat LD_{50} (oral) = 1710 mg/kg; Mouse LD_{50} (oral) = 4600 mg/kg; Guinea Pig LD_{50} (oral) = 4100 mg/kg; Rat 6 h (inhalation) = 1.5 mg/L; Rabbit LD_{50} (dermal) > 2500 mg/kg; ---------- Rat LD_{50} (oral) = 2,800 mg/kg; Guinea Pig LD_{50} (oral) 1,000 – 2,000 mg/kg; Rat LD_{50} (dermal) 24 h > 2,000 mg/kg	IUCLID: http://esis.jrc.ec.europa.eu/doc/IUCLID/data_sheets/8050097.pdf ---------- EHCA REACH Dissemination Portal: http://apps.echa.europa.eu/registered/data/dossiers/DISS-97d7e4ae-629b-26d8-e044-00144f67d031/AGGR-7359f2ee-885c-4703-bc5c-21f1d96c123a_DISS-97d7e4ae-629b-26d8-e044-00144f67d031.html#AGGR-7359f2ee-885c-4703-bc5c-21f1d96c123a
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.)	Rats were exposed to substance via diet for 2 years. There were no significant treatment-related dose-dependent effects on mortality, clinical signs, or hematology or urinalysis parameters. Statistically significant reductions in food consumption at the 1.0% dietary level were attributed to palatability of the test diet. Statistically significant reductions in body weight gain were	EHCA REACH Dissemination Portal: http://apps.echa.europa.eu/registered/data/dossiers/DISS-97d7e4ae-629b-26d8-e044-00144f67d031/AGGR-7359f2ee-885c-4703-bc5c-21f1d96c123a_DISS-97d7e4ae-629b-26d8-e044-00144f67d031.html#AGGR-7359f2ee-885c-4703-bc5c-

Line	Data Type	Value	Reference
		observed in both males and females consuming the 1.0% diets at both the 12-month and 24-month (terminal) sacrifices. Statistically significant decreases/increases in body weight in the 0.05% dose group occurred in only one sex or at only one time period. All gross and microscopic changes in tissues and organs in animals exposed to the test material in the diet for two years were comparable to those observed in the control animals. There was also no increase in tumor incidence in the study and types of tumors observed in the test groups were similar to those observed in the control groups. Although statistically significantly reduced body weights were noted for animals exposed to the 1.0% diets, the body weight changes were considered to have been caused by the diet's palatability.	21f1d96c123a
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.		

Line	Data Type	Value	Reference
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 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.	Thomas Numbers, PE, CPEA, BCEE Senior Consultant (757) 645-7495 thomas.numbers@erm.com	

Line	Data Type	Value	Reference
		Brian McDonald Staff Scientist (585) 387-0510 brian.mcdonald@erm.com ERM, Inc. 1011 East Main Street, Suite 227 Richmond, Virginia 23219	
10	References.		

Environmental Assessment Data Template for FDA Submissions

Titanium Dioxide
18 February 2016

Line	Data Type	Value	Reference
1	Name of applicant.	Philip Morris Products S.A.	
2	Address of applicant (correspondence).	Quai Jeanrenaud 3 2000 Neuchatel Switzerland	
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.	Titanium Dioxide	US EPA SRS http://ofmpub.epa.gov/sor_internet/registry/substreg/searchandretrieve/advancedsearch/externalSearch.do?p_type=SRSITN&p_value=186908
4.1.2	Tradename(s).		

Line	Data Type	Value	Reference
4.1.3	Chemical name.	Titanium dioxide; Titanium oxide; Anatase; anatase titanium dioxide; Bayertitan; Bayertitan A; C.I. Pigment White 6; Calcotone White T; Tioxide; Titanox; Unitane; Uniwhite; Zopaque	US EPA SRS http://ofmpub.epa.gov/sor_internet/registry/substreg/searchandretrieve/advancedsearch/externalSearch.do?p_type=SRSITN&p_value=186908
4.1.4	CAS number.	13463-67-7	US EPA SRS http://ofmpub.epa.gov/sor_internet/registry/substreg/searchandretrieve/advancedsearch/externalSearch.do?p_type=SRSITN&p_value=186908
4.1.5	CAS index name.	Titanium oxide (TiO2)	US EPA SRS http://ofmpub.epa.gov/sor_internet/registry/substreg/searchandretrieve/advancedsearch/externalSearch.do?p_type=SRSITN&p_value=186908
4.2	Molecular formula.	O_2Ti	US EPA SRS http://ofmpub.epa.gov/sor_internet/registry/substreg/searchandretrieve/advancedsearch/externalSearch.do?p_type=SRSITN&p_value=186908

Line	Data Type	Value	Reference
4.3	Structure.		ChemIDPlus http://chem.sis.nlm.nih.gov/chemidplus/ProxyServlet?objectHandle=DBMaint&actionHandle=default&nextPage=jsp/chemidlite/ResultScreen.jsp&TXTSUPERLISTID=0013463677
5	Environmental Issues.		
5.1	Environmental Fate of Released Substance.		
5.1.1	Identification of substance of interest.		
5.1.2	Water solubility.	insoluble (< 0.1 mg/L) 3.4 ug/L at 21.9 °C and pH of 6 <1 ug/L at 20 °C and pH of 6	ECHA Disseminatin Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/15560/4/9
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.	1843 °C	ECHA (see link above)
5.1.9	Density.	4.17 g/cm³ at 20 °C	ECHA (see link above)
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.	Ti concentrations in the various fish tissues stayed constant over the	ECHA (see link above)

Line	Data Type	Value	Reference
		concentration range of TiO_2 in water tested (0-1 mg TiO_2/L), w/decreasing BCF with increasing TiO_2 concentrations	
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.)	*Oncorhynchus mykiss*, less than 50% mortality was observed at the highest test concentration (100 mg TiO2/L); *Leuciscus idus*, 48h $LC_0 \geq$ 1,000 mg/L; Cyprinodon variegatus, 96h LC_{50} > 240 <370 mg/L; *Phoxinus phoxinus*, 30-d $LC_0 \geq$ 1,000 mg/L; *Coregonus autumnalis migratorius*, 30-d LC_0 = 3 mg/L.	IUCLID: http://esis.jrc.ec.europa.eu/doc/IUCLID/data_sheets/13463677.pdf
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.)	*Mysidopsis almyra*, 96h LC_{50} >300 <400 mg/L; *Daphnia magna*, 30-d EC_0 = 3 mg/L, 30-d EC_{100} = 500 mg/L.	IUCLID: http://esis.jrc.ec.europa.eu/doc/IUCLID/data_sheets/13463677.pdf
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.)	*Pseudokirchnerella subcapitata*: 72 h EC_{50} = 16 mg/L (cell number),	ECHA (see link above)

Line	Data Type	Value	Reference
		72h NOEC = 1 mg/L (cell number), 72 h EC_{50} = 61 mg/L (growth rate), 72h NOEC = 1 mg/L (growth rate); *Skeletonema costatum*: 72 h EC_{50} >10,000 mg/L (growth rate), 72h NOEC = 5600 mg/L (growth rate).	
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.)	No inhibition of respiration of activated sludge at a concentration of up to 1000 mg/L.	ECHA (see link above)
5.4	Terrestrial Toxicity.		
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.)	Rat LD_{50} (oral) > 20,000 mg/kg; Rat LD_{50} (oral) > 10,000 mg/kg; Rat LD_{50} (oral) > 12,000 mg/kg; Hamster LD_{50} (Dermal) $\geq$ 10,000 mg/kg.	IUCLID: http://esis.jrc.ec.europa.eu/doc/IUCLID/data_sheets/13463677.pdf
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).	Crustacea (soil-dwelling woodlouse) *Porcellus scaber*, 3 d NOEC 1000 mg/kg diet test mat. TiO2 based on enzyme activity (catalase and glutathione-S-transferase) Non-sonicated,	ECHA (see link above)

Line	Data Type	Value	Reference
		3 d LOEC 2000 mg/kg diet test mat. TiO2 based on enzyme activity (catalase and glutathione-S-transferase) Non-sonicated, 3 d NOEC >= 3000 mg/kg diet test mat. TiO2 based on enzyme activity (catalase and glutathione-S-transferase) Sonicated.	
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 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		

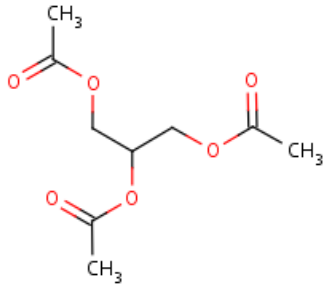
Line	Data Type	Value	Reference
	that contain confidential business information may be removed to a confidential appendix.		
9	List of Preparers.	Thomas Numbers, PE, CPEA, BCEE Senior Consultant (757) 645-7495 thomas.numbers@erm.com Kristen Schulz Senior Project Manager (513) 830-9041 kristen.schulz@erm.com ERM, Inc. 1011 East Main Street, Suite 227 Richmond, Virginia 23219	
10	References.		

Environmental Assessment Data Template for FDA Submissions

Triacetin
18 February 2016

Line	Data Type	Value	Reference
1	Name of applicant.	Philip Morris Products S.A.	
2	Address of applicant (correspondence).	Quai Jeanrenaud 3 2000 Neuchatel Switzerland	
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.	Triacetin	
4.1.2	Tradename(s).		
4.1.3	Chemical name.	1,2,3-triacetoxypropane; Glycerin triacetate; Glyceryl triacetate; EASTMAN" Triacetin; 1,2,3-Propanetriol triacetate; 1,2,3-Propanetriyl triacetate; Acetin, tri-; Enzactin; Fungacetin; Glycerin triacetate; Glycerol triacetate; Glyceryl triacetate; Glyped Kesscoflex TRA; Kodaflex Triacetin; Triacetin; Triacetina;	EPA SRS http://ofmpub.epa.gov/sor_internet/registry/substreg/searchandretrieve/advancedsearch/externalSearch.do?p_type=SRSITN&p_value=20933 ChemIDPlus http://chem.sis.nlm.nih.gov/chemidplus/ProxyServlet?objectHandle=DBMaint&actionHandle

Line	Data Type	Value	Reference
		Triacetylglycerol; Vanay	=default&nextPage=jsp/chemidlite/ResultScreen.jsp&TXTSUPERLISTID=0000102761
4.1.4	CAS number.	102-76-1	ESIS EPA SRS http://ofmpub.epa.gov/sor_internet/registry/substreg/searchandretrieve/advancedsearch/externalSearch.do?p_type=SRSITN&p_value=20933 ChemIDPlus http://chem.sis.nlm.nih.gov/chemidplus/ProxyServlet?objectHandle=DBMaint&actionHandle=default&nextPage=jsp/chemidlite/ResultScreen.jsp&TXTSUPERLISTID=0000102761
4.1.5	CAS index name.	1,2,3-Propanetriol, 1,2,3-triacetate	EPA SRS http://ofmpub.epa.gov/sor_internet/registry/substreg/searchandretrieve/advancedsearch/externalSearch.do?p_type=SRSITN&p_value=20933
4.2	Molecular formula.	$C_9H_{14}O_6$	ESIS EPA SRS http://ofmpub.epa.gov/sor_internet/registry/sub

Line	Data Type	Value	Reference
			streg/searchandretrieve/advancedsearch/externalSearch.do?p_type=SRSITN&p_value=20933 ChemIDPlus http://chem.sis.nlm.nih.gov/chemidplus/ProxyServlet?objectHandle=DBMaint&actionHandle=default&nextPage=jsp/chemidlite/ResultScreen.jsp&TXTSUPERLISTID=0000102761
4.3	Structure.		ChemIDPlus http://chem.sis.nlm.nih.gov/chemidplus/ProxyServlet?objectHandle=DBMaint&actionHandle=default&nextPage=jsp/chemidlite/ResultScreen.jsp&TXTSUPERLISTID=0000102761
5	Environmental Issues.		
5.1	Environmental Fate of Released Substance.		
5.1.1	Identification of substance of interest.		
5.1.2	Water solubility.	58 g/L at 25 °C	ECHA Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/15139
5.1.3	Dissociation constant(s).		
5.1.4	Octanol/water partition coefficients (k_{ow}).	Log Pow = 0.25	ECHA

Line	Data Type	Value	Reference
			Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/15139
5.1.5	Sorption and/or desorption properties (k_{oc}).	Koc = 8.55 Log Koc = 0.93 Estimated from log Kow	ECHA Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/15139
5.1.6	Vapor pressure and/or Henry's law constant.	H = 0 Pa ³/mol at 25 °C; VP = 0.331 Pa at 25 °C	ECHA Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/15139
5.1.7	UV/VIS absorption spectrum.		
5.1.8	Melting temperature.	-78 °C	ECHA Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/15139
5.1.9	Density.	1,156.2 kg/m³ at 25 °C	ECHA Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/15139
5.1.10	Hydrolysis.		
5.1.11	Aerobic biodegradation (including removal in sewage treatment plant).	Readily biodegradable (OECD Guideline 301 B)	ECHA Dissemination Portal: http://echa.euro

Line	Data Type	Value	Reference
			pa.eu/registration-dossier/-/registered-dossier/15139
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.		
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.)	*Oryzias latipes* 96 hour LC_{50} > 100 mg/L	ECHA Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/15139
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.)	*Daphnia magna* 48 hour EC_0 = 65 mg/L; EC_{50} = 380 mg/L; EC_{100} = 1,000 mg/L	ECHA Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/15139
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.)	*Daphnia magna* 21 day LC_{50} >94 mg/L; EC_{50} >94 mg/L; NOEC ≥94 mg/L; LOEC >94 mg/L	ECHA Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/15139
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.)	*Pseudokirchnerella subcapitata* 72 hour EC_{50} >940 mg/L (growth rate,	ECHA Dissemination Portal:

Line	Data Type	Value	Reference
		biomass); NOEC = 468 mg/L (growth rate, biomass)	http://echa.europa.eu/registration-dossier/-/registered-dossier/15139
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.)	*Pseudomonas putida* 18 hour NOEC >1,088 mg/L (growth inhibition)	ECHA Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/15139
5.4	Terrestrial Toxicity.		
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.)	LD_{50} rat (oral) >2,000 mg/kg bw 4 hour LC_{50} rat (inhalation) >1.721 mg/L air (maximum attainable concentration)	ECHA Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/15139
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.)	May cause an allergic skin reaction. No other toxicity observed at levels that would drive classification	ECHA Dissemination Portal: http://echa.europa.eu/registration-dossier/-/registered-dossier/15139
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).		

Line	Data Type	Value	Reference
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 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.	Thomas Numbers, PE, CPEA, BCEE Senior Consultant (757) 645-7495 thomas.numbers@erm.com Kristen Schulz Senior Project Manager (513) 830-9041 kristen.schulz@erm.com ERM, Inc.	

Line	Data Type	Value	Reference
		1011 East Main Street, Suite 227 Richmond, Virginia 23219	
10	References.		