

SCREENING-LEVEL HAZARD CHARACTERIZATION

Fatty Nitrogen Derived Amines Category

The High Production Volume (HPV) Challenge Program¹ was conceived as a voluntary initiative aimed at developing and making publicly available screening-level health and environmental effects information on chemicals manufactured in or imported into the United States in quantities greater than one million pounds per year. In the Challenge Program, producers and importers of HPV chemicals voluntarily sponsored chemicals; sponsorship entailed the identification and initial assessment of the adequacy of existing toxicity data/information, conducting new testing if adequate data did not exist, and making both new and existing data and information available to the public. Each complete data submission contains data on 18 internationally agreed to “SIDS” (Screening Information Data Set^{1,2}) endpoints that are screening-level indicators of potential hazards (toxicity) for humans or the environment.

The Environmental Protection Agency’s Office of Pollution Prevention and Toxics (OPPT) is evaluating the data submitted in the HPV Challenge Program on approximately 1400 sponsored chemicals by developing hazard characterizations (HCs). These HCs consist of an evaluation of the quality and completeness of the data set provided in the Challenge Program submissions. They are not intended to be definitive statements regarding the possibility of unreasonable risk of injury to health or the environment.

The evaluation is performed according to established EPA guidance^{2,3} and is based primarily on hazard data provided by sponsors; however, in preparing the hazard characterization, EPA considered its own comments and public comments on the original submission as well as the sponsor’s responses to comments and revisions made to the submission. In order to determine whether any new hazard information was developed since the time of the HPV submission, a search of the following databases was made from one year prior to the date of the HPV Challenge submission to the present: (ChemID to locate available data sources including Medline/PubMed, Toxline, HSDB, IRIS, NTP, ATSDR, IARC, EXTOXNET, EPA SRS, etc.), STN/CAS online databases (Registry file for locators, ChemAbs for toxicology data, RTECS, Merck, etc.) and Science Direct. OPPT’s focus on these specific sources is based on their being of high quality, highly relevant to hazard characterization, and publicly available.

OPPT does not develop HCs for those HPV chemicals which have already been assessed internationally through the HPV program of the Organization for Economic Cooperation and Development (OECD) and for which Screening Initial Data Set (SIDS) Initial Assessment Reports (SIAR) and SIDS Initial Assessment Profiles (SIAP) are available. These documents are presented in an international forum that involves review and endorsement by governmental authorities around the world. OPPT is an active participant in these meetings and accepts these documents as reliable screening-level hazard assessments.

¹ U.S. EPA. High Production Volume (HPV) Challenge Program; <http://www.epa.gov/chemrtk/index.htm>.

² U.S. EPA. HPV Challenge Program – Information Sources; <http://www.epa.gov/chemrtk/pubs/general/guidocs.htm>.

³ U.S. EPA. Risk Assessment Guidelines; <http://cfpub.epa.gov/ncea/raf/rafguid.cfm>.

These hazard characterizations are technical documents intended to inform subsequent decisions and actions by OPPT. Accordingly, the documents are not written with the goal of informing the general public. However, they do provide a vehicle for public access to a concise assessment of the raw technical data on HPV chemicals and provide information previously not readily available to the public.

Chemical Abstract Service Registry Number (CASRN)	23 Sponsored Chemicals 12 Supporting Chemicals (See Appendix for CASRN, Name and Structural Formula)
Chemical Abstract Index Name	
Structural Formula	
Summary	
<p>The 23 members of the fatty nitrogen-derived amines category are long-chain alkyl substituted amines used in commercial product mixtures. The category consists of primary alkylamines and alkyldiamines, dimethylalkylamines, dialkylmethylamines and dialkylamines, and trialkylamines. The primary alkylamines and alkyldiamines are solids at room temperature (except for CASRN 7173-62-8, which is a liquid), possessing low to moderate vapor pressure and low to moderate water solubility. The dialkylmethylamines are all liquids with low to moderate vapor pressure and low to moderate water solubility. The dialkylmethylamines and dialkylamines are solids (except for CASRN 7396-58-9, which is a liquid) with negligible to low vapor pressure and negligible to low water solubility. Finally, the trialkylamines are liquids with negligible to low vapor pressure; two (CASRNs 68814-95-9 and 61790-42-9) have negligible water solubility while the others (CASRNs 61791-31-9 and 61791-44-4) are expected to be dispersible in water.</p> <p>Volatilization is not expected to be an important fate process since the FND amines are weak bases that will exist as cations in the environment, and cations do not volatilize. Hydrolysis data were not available for any members of this category. Generally, amines are expected to hydrolyze extremely slowly under environmental conditions; however, these types of surfactants are generally not hydrolysable, according to the sponsor. The rate of atmospheric photooxidation is considered moderate to rapid for members of this category; however, this is not expected to be an important environmental fate process since these substances are not expected to exist in the vapor phase in the atmosphere. The overall weight of experimental evidence and read across from structurally similar compounds from these studies suggest that all members of the FND amines category have low persistence (P1). Most members of the FND amines category are expected to have low (B1) bioaccumulation potential (13/23, including all four trialkylamines), with 4/23 having a moderate (B2) rating and 6/23 having a high (B3) rating, 5/6 being primary alkylamines/alkyldiamines.</p> <p>Human Health Hazard <i>Subcategory I: Non-Hydroxylated FND Amines</i> The acute oral toxicity in rodents for the 21 members of this subcategory is low based on studies in nine sponsored chemicals in rats. The acute dermal toxicity in animal studies for this subcategory is also low based on studies of five sponsored chemicals in rabbits. Oral repeated-dose toxicity studies are available for one sponsored chemical (CASRN 4088-22-6) and three supporting chemicals (CASRNs 124-30-1, 3159-59-5/36505-83-6, and 61790-33-8). One dermal repeated-dose toxicity study is available for a sponsored chemical (CASRN 4088-22-6). In the 13-week oral gavage study with CASRN 4088-22-6 in rats, there was no NOAEL for systemic effects and the following effects were observed at the lowest tested dose of 117 mg/kg/day:</p>	

decreased body weight gain, organ weight changes, hematological changes and pathological changes in the intestine, lymph nodes and ovaries. In a one year study in dogs, CASRN 124-30-1 (supporting chemical) was administered via a capsule resulting in mortality, decreased body weight gain and pathological changes in the intestine at a dose of 15 mg/kg/day; the NOAEL for systemic toxicity was 3 mg/kg/day. The supporting chemical, CASRN 3159-59-5/36505-83-6, was tested in rats and dogs via the oral route. In the two-year dietary rat study, there was a decrease in body weight, clinical chemistry changes and pathological changes in the intestine and lymph node at 30 mg/kg/day; the NOAEL for systemic toxicity was 6 mg/kg/day. In the two-year gavage study in dogs, there were no effects observed; the NOAEL for systemic toxicity was 12 mg/kg/day (highest dose tested). In the only repeated-dose dermal study in the subcategory, rabbits were exposed to the sponsored chemical, CASRN 4088-22-6, daily for 13 weeks. Irritation was observed at the two doses used, resulting in no NOAEL for this local effect (lowest tested dose of 5 mg/kg/day). The NOAEL for systemic effects was 5 mg/kg/day, based on the following effects observed at 50 mg/kg/day: decreased body weight, slight changes in hematological parameters, and pathological changes in the liver and lymph nodes.

There were no reproductive toxicity studies in any of the 21 sponsored chemicals; however there were studies with two supporting chemicals which are used to read-across to the sponsored chemicals. In a dietary combined reproductive/developmental toxicity study with CASRN 61790-33-8, rats dosed with 150 mg/kg/day experienced implantation loss, decreased mating and fertility indices, increased precoital time interval and atrophy of corpora lutea; the NOAEL for reproductive toxicity was 50 mg/kg/day. In an oral one-generation reproductive toxicity study with CASRN 3159-59-5/36505-83-6 in rats, there were no effects on any reproductive parameters assessed; the NOAEL for reproductive toxicity was 30 mg/kg/day (highest dose tested).

Oral developmental toxicity studies were available with one sponsored chemical (CASRN 4088-22-6) and three supporting chemicals (CASRN 112-90-3, 3159-59-5/36505-83-6, and 61790-33-8). In a prenatal oral developmental toxicity study with rabbits using CASRN 4088-22-6, dams exhibited decreased weight gain at 250 mg/kg/day and above; the NOAEL for maternal toxicity was 50 mg/kg/day. Embryo lethality at 1000 mg/kg/day could not be discounted; the NOAEL for developmental toxicity was 250 mg/kg/day. The combined reproductive/developmental toxicity study with the supporting chemical CASRN 61790-33-8 in rats resulted in no NOAEL for maternal toxicity (based on decreased body weight at the lowest tested dose of 12.5 mg/kg/day) and a NOAEL of 12.5 mg/kg/day for developmental toxicity (based on decreased pup body weights at 50 mg/kg/day). There were two oral prenatal developmental toxicity studies, one with rats and one with rabbits, using the supporting chemical CASRN 112-90-3. In the rat study, maternal toxicity was observed at 40 mg/kg/day (clinical signs and a decrease in body weight); the NOAEL for maternal toxicity was 10 mg/kg/day. There was no developmental toxicity; the NOAEL for developmental toxicity was 80 mg/kg/day (highest dose tested). In the rabbit study, dams exhibited clinical signs and decreased body weight at 10 mg/kg/day; the NOAEL for maternal toxicity was 3 mg/kg/day. There was no developmental toxicity; the NOAEL for developmental toxicity was 30 mg/kg/day (highest dose tested). In two prenatal oral developmental toxicity studies in rats with the supporting chemical mixture (CASRN 3159-59-5/36505-83-6), different results were obtained. Taking the two studies together, maternal toxicity was observed at 30 mg/kg/day (decreased body weight); the

NOAEL for maternal toxicity was of 6 mg/kg/day. Unspecified malformations were seen in rat fetuses at 30 mg/kg/day; the NOAEL for developmental toxicity was of 6 mg/kg/day.

In vitro (using both bacteria and mammalian cells) evaluations of genetic toxicity (gene mutations and chromosomal aberrations) were conducted with three sponsored chemicals. *In vitro* data with the supporting chemicals were also for gene mutations (four chemicals) and chromosomal aberrations (one chemical); all results were negative. *In vivo* evaluations of chromosomal effects in one sponsored and three supporting chemicals also showed negative results. Unscheduled DNA synthesis was not induced in a study of one sponsored chemical. The available data in three sponsored chemicals suggest that non-hydroxylated FND amines are irritating to both skin and eyes.

No data gaps were identified under the HPV Challenge Program.

Subcategory II: Hydroxylated FND Amines

There are two chemicals (CASRN 61791-31-9 and 61791-44-4) in this subcategory for human health endpoints. With the exception of acute oral toxicity data, data were available for CASRN 61791-44-4. Acute oral toxicity of CASRN 61791-31-9 and 61791-44-4 in rats is low. Acute dermal toxicity of CASRN 61791-44-4 in rabbits is moderate. There were both oral and dermal repeated dose studies with CASRN 61791-44-4. Different results were obtained depending on the formulation tested (see text for details). Oral dietary studies were performed with rats (two) and dogs (one). In one 90-day rat study, there were gross and microscopic effects in the intestine and lymph nodes at 150 mg/kg/day; the NOAEL for systemic toxicity was 50 mg/kg/day. In the other 90-day rat study, the NOAEL was 12 mg/kg/day based on decreases in body weight gain and histopathological effects on the intestine and lymph nodes at 400 mg/kg/day. The dog 90-day study resulted in a NOAEL of 13 mg/kg/day based on clinical signs, decreased body weight and pathological changes in the intestine and lymph nodes at 40 mg/kg/day. There were three 28-day dermal toxicity studies in rabbits. Local effects (irritation) were observed at all doses tested, with no NOAEL for this effect (lowest dose tested was 40 mg/kg/day). There were no systemic effects observed up to the highest dose tested of 40 mg/kg/day, which is the NOAEL for systemic toxicity for the dermal studies in rabbits.

There were no reproductive/developmental toxicity data for either subcategory member. Gene mutations were not induced in two studies (bacterial and mammalian cells) with CASRN 61791-44-4 *in vitro*. CASRN 61791-44-4 induced chromosomal aberrations *in vitro* (with metabolic activation only), and results for chromosomal effects in an *in vivo* test were inconclusive. CASRN 61791-44-4 did not induce unscheduled DNA synthesis.

The reproductive and developmental toxicity endpoints were identified as data gaps under the HPV Challenge Program.

Hazard to the Environment

The typical 96-h LC₅₀ for fish with the supporting chemical, CASRN 112-90-3, is 0.11 mg/L and the typical 48-h EC₅₀ for aquatic invertebrates is 0.011 mg/L. The 96/72-h EC₅₀ values for aquatic plants are 0.03 mg/L and 0.04 mg/L for biomass and growth rate, respectively. For CASRN 61791-31-9, the 30-d fish chronic value is 0.0179 mg/L and the 21-d aquatic

invertebrates value is 0.14 mg/L.

No data gaps were identified under the HPV Challenge Program.

The sponsor, The Nitrogen Derivatives Panel Amines Task Group of the American Chemistry Council, submitted a Test Plan and Robust Summaries to EPA for the fatty nitrogen derived (FND) amines category on December 23, 2002. EPA posted the submission on the ChemRTK HPV Challenge website on January 23, 2003 (<http://www.epa.gov/oppt/chemrtk/pubs/summaries/amines/c14171tc.htm>). In the transmittal letter associated with the original submission, the sponsor indicated to EPA that a revision of the FND amines category would be submitted by December 31, 2003. In letters dated April 29 and July 10, 2003, the sponsor informed EPA of their plans to split the original submission into two separate submissions, an FND amines category and an FND ether amines category. Revised submissions were submitted to EPA on December 29, 2003. EPA posted the FND ether amines and FND amines submissions on the ChemRTK HPV Challenge website on March 25, 2004 and March 26, 2004, respectively. EPA posted comments on the revised FND ether amines category submission to the website on October 26, 2007. EPA did not comment on the revised FND amines category.

The Hazard Characterization for the FND ether amine category is being posted on the EPA website at the same time as this one because there is substantial overlap in the chemicals used in both categories. The original 2002 submission had 29 sponsored chemicals – the 23 in this submission plus six that were split off to form the FND ether amines category (all supporting information is available at the same URL used for this submission). Five of the seven supporting chemicals identified in the FND ether amines submission are either sponsored (three) or supporting (two) chemicals in this submission (identified with an asterisk in the list below).

The FND amines category consists of 23 sponsored substances and 12 supporting chemicals (see Appendix).

Category Justification

The members of the FND amines category are all aliphatic amines containing one or more long-chain alkyl groups. The sponsor's rationale for grouping these FND amines into a single category is based on the surfactant properties of the substances. These properties are expected to result in similar environmental fate and toxicological properties of the category members. The category members are nonetheless diverse in that they have primary, secondary and tertiary amines structures and span a broad range of molecular weights (185 – 752). While acknowledging the structural diversity in the FND amines category, the sponsor concludes that "there is no pattern of increasing or decreasing environmental fate or toxicity among these chemicals" but rather that "there is a consistency of response across the entire Category."

EPA agrees that available measured data and estimated values for the melting and boiling points, vapor pressure, partition coefficient and water solubility appear to be consistent with molecular size within and across structural types and hence support the grouping of the FND amines as a category. Data supplied for environmental fate endpoints for sponsored chemicals generally support the category, indicating similar susceptibility to and rates of degradation. Thus, for both physical-chemical and environmental fate properties, EPA does not believe it is necessary to divide the 23 sponsored chemicals into subcategories. The same is also true for environmental effect endpoints.

For assessment of human health hazards, however, the toxicological properties of the two dihydroxy derivatives (CASRN 61791-31-9 and 61791-44-4) may differ from the other category members, at least in longer-term studies, because these two substances are expected to be metabolized and excreted differently. In addition, they are expected to be more hydrophilic than the other category members. Therefore, EPA has indicated that, for human health effects, two subcategories be identified: Subcategory 1, Non-Hydroxylated FND Amines and Subcategory 2, Hydroxylated FND Amines. For the purposes of this hazard characterization, data may be read-across between only those members of a subcategory and not between subcategories. The distribution of subcategories is outlined in Table 1.

Table 1. Subcategories in the FND Amines Category	
HUMAN HEALTH HAZARD	ECOTOXICITY
<i>SPONSORED CHEMICALS</i>	
<p><i>Subcategory 1: Non-Hydroxylated Fatty Nitrogen Derived Amines</i></p> <ul style="list-style-type: none"> • CASRN 124-22-1 • CASRN 143-27-1 • CASRN 68037-91-2 • CASRN 68155-38-4 • CASRN 61790-18-9 • CASRN 68037-95-6 • CASRN 61791-55-7 • CASRN 7173-62-8 • CASRN 112-75-4 • CASRN 112-69-6* • CASRN 124-28-7* • CASRN 61788-95-2 • CASRN 61788-91-8 • CASRN 7396-58-9 • CASRN 67700-99-6 • CASRN 68153-95-7 • CASRN 4088-22-6 • CASRN 61788-63-4 • CASRN 68783-24-4 • CASRN 68814-95-9 • CASRN 61790-42-9 	<ul style="list-style-type: none"> • CASRN 124-22-1 • CASRN 143-27-1 • CASRN 68037-91-2 • CASRN 68155-38-4 • CASRN 61790-18-9 • CASRN 68037-95-6 • CASRN 61791-55-7 • CASRN 7173-62-8 • CASRN 112-75-4 • CASRN 112-69-6* • CASRN 124-28-7* • CASRN 61788-95-2 • CASRN 61788-91-8 • CASRN 7396-58-9 • CASRN 67700-99-6 • CASRN 68153-95-7 • CASRN 4088-22-6 • CASRN 61788-63-4 • CASRN 68783-24-4 • CASRN 68814-95-9 • CASRN 61790-42-9 • CASRN 61791-31-9* • CASRN 61791-44-4
<i>SUPPORTING CHEMICALS</i>	
<ul style="list-style-type: none"> • CASRN 61788-45-2 • CASRN 124-30-1 • CASRN 61788-46-3 • CASRN 61790-33-8 	<ul style="list-style-type: none"> • CASRN 112-90-3

Table 1. Subcategories in the FND Amines Category	
HUMAN HEALTH HAZARD	ECOTOXICITY
<ul style="list-style-type: none"> • CASRN 112-90-3* • CASRN 3151-59-5** • CASRN 112-18-5* • CASRN 61788-93-0 • CASRN 28061-69-0 • CASRN 61788-62-3 • CASRN 61789-79-5 • CASRN 61789-76-2 	
<p><i>Subcategory II: Hydroxylated Fatty Nitrogen Derived Amines</i></p> <ul style="list-style-type: none"> • CASRN 61791-31-9* • CASRN 61791-44-4 	

*Supporting chemicals submitted by the industry sponsors of the FND ether amine category that were used in the final FND ether amines hazard characterization.

** Also reported as a 1:1 mixture of 1-hexadecanamine, hydrofluoride and 9-octadecen-1-amine hydrofluoride (CASRN 36505-83-6).

Justification for Supporting Chemicals

Twelve non-sponsored chemicals were proposed by the submitter to provide support for this category.⁴ These supporting chemicals are structurally closely related to the FND amines sponsored chemicals. None of the supporting chemicals were used in evaluating the physical-chemical properties of the 23 sponsored chemicals because they did not provide data necessary to estimate or read-across to the sponsored chemicals. Eleven of the 12 supporting chemicals were used for the environmental fate endpoint (specifically biodegradation) – the one not used was CASRN 3151-59-5/36505-83-6 because there were no biodegradation data provided for this substance. For human health effect endpoints, only those supporting chemicals that provided more than just acute toxicity data were used (CASRN 112-90-3, 124-30-1, 3151-59-5/36505-83-6 mixture, 61788-46-3, 61790-33-8, and 112-18-5). EPA believes that the acute toxicity data available for the other four supporting chemicals (CASRN 61788-62-3, 61789-79-5, 61788-93-0 and 61788-45-2) - while useful – were not necessary for characterizing that endpoint for human health effects because there are ample data from sponsored chemicals for this endpoint.

For environmental effects, only one of the 12 supporting chemicals was used (CASRN 112-90-3) to fill the acute aquatic toxicity endpoints. The use of this chemical was based on its structure being sufficiently representative of the spectrum of structures among the 23 sponsored chemicals. In addition, the quality of the acute toxicity studies was high (i.e, use of measured concentrations).

CASRN 112-18-5 was assessed in the OECD HPV program at SIAM 11 (2001). The data are available for viewing at: <http://www.chem.unep.ch/irptc/sids/OECD/SIDS/112185.pdf>

⁴ These chemicals were removed from the original FND amines category because they are sponsored by the European Oleochemicals and Allied Products Group (APAG) under the International Council of Chemical Associations (ICCA) program

1. Chemical Identity

1.1 Identification and Purity

Appendix 1 provides the names and structures for all the sponsored (23) and supporting (12) chemicals in the category. Most (15/23 sponsored chemicals; 8/12 supporting chemicals) are mixtures for which a representative structure is presented in the Appendix. The following Table (“Text Table C”) is taken from p. 5 of the revised Test Plan submitted by the sponsor for the FND Amine category. This provides data on the composition of category members in terms of chain length and degree of unsaturation.

Text Table C: Chain Length and Degree of Unsaturation for Long-Chain Substituents in the FND Amines Category Chemicals

Identifier	Chain Length(s) or Average	Degree of Unsaturation
C8-C10 alkyl	9	None
Isodecyl	10	None
C9-C11 (C10 rich)	10	None
Dodecyl	12	None
C13 branched	13	None
C11-C14 (C13 rich)	13	None
Tetradecyl	14	None
Hexadecyl	16	None
C14-C18	Not specified	None
C12-C18	Not specified	None
C14-C18 and C16-C18 unsaturated	Not specified	Not specified
C16-C18 and C18-unsaturated	Not specified	Not specified
Octadecyl	18	None
Octadecenyl	18	1
Coco (coconut)	C6: 0-1%	None
	C8: 5-9%	None
	C10: 5-10%	None
	C12: 44-53%	None
	C14: 13-19%	None
	C16: 8-11%	None
	C18: 1-3%	None
	C16: 0-1%	1
C18: 5-8%	1	
C18: 1-3%	2	
Tallow, hydrogenated ¹	C14: 1-6%	None
	C16: 23-46%	None
	C18: 49-67%	None
Tallow	C14: 1-6%	None
	C16: 20-37%	None
	C18: 14-21%	None
	C16: 3-9%	1
	C18: 35-46%	1
	C18: 4-10%	2
	C18: 0-3%	3
Soya (soy bean)	C16: 7-11%	None
	C18: 2-7%	None
	C20: 0-2%	None
	C18: 20-30%	1
	C18: 43-56%	2
	C18: 8-14%	3

In addition, there are many different formulations that exist for the different sponsored/supporting chemical CASRNs. Table 2 provides a list (according to the information presented in the robust summaries and only for those substances used in this Hazard Characterization) of the formulations.

Table 2. Formulations of the FND Amines Category	
CASRN	FORMULATION
SPONSORED CHEMICALS	
112-75-4	Farmin DM40, Genamin 14R 302D, ADMA 4
112-69-6	Armeen DM16D, Farmin DM60, ADMA 6
124-28-7	Armeed DM18D, Farmin DM80, ADMA 8
61788-91-8	Armeen DMSD
4088-22-6	Genamin SH 301, E8220
61788-63-4	Armeen M2HT, B0390Adogen 243, Adogen 343
61791-44-4	Ethomeen T/12, 2EO, Varonic T-220, (POE) ₂₀ Tallowamine T-220D, Ethomeen 18/60, E1095.01, Varonic T-220D, Genamin S080, TAMET Benzoate
SUPPORTING CHEMICALS	
124-30-1	Genamin 18R 100D
61788-46-3	Armeen C, Armeen CD, Amine KK, Genamin C 100 D
61790-33-8	Genamin TA 100D, Armeen T, Genamin TA 100
112-18-5	Armeen DM12D, ADMA 2, Genamin LA 302D
3151-59-5 and 36505-83-6	Hetaflur
112-90-3	Oleylamine

1.2 Physical-Chemical Properties

The physical-chemical properties of the FND amines are summarized in Tables 3 through 5. Table 6 provides physical-chemical property data for the six supporting chemicals that are used in the human health and environmental effects sections of this hazard assessment. The structures are provided in the Appendix.

Conclusion: The members of the FND amines category are long-chain alkyl substituted amines found in commercial product mixtures. The category consists of primary alkylamines and alkyldiamines; dimethylalkylamines; dialkylmethylamines and dialkylamines; and trialkylamines (see the Appendix for attribution of chemicals to these groups). The primary alkylamines and alkyldiamines are solids at room temperature (except for CASRN 7173-62-8, which is a liquid), possessing low to moderate vapor pressure and low to moderate water solubility. The dialkylmethylamines are all liquids with low to moderate vapor pressure and low to moderate water solubility. The dialkylmethylamines and dialkylamines are solids (except for CASRN 7396-58-9, which is a liquid) with negligible to low vapor pressure and negligible to low water solubility. Finally, the trialkylamines are liquids with negligible to low vapor pressure; two (CASRN 68814-95-9 and 61790-42-9) have negligible water solubility while the others (CASRN 61791-31-9 and 61791-44-4) are expected to be dispersible in water.

Table 3. Physical-Chemical Properties of Fatty Nitrogen-Derived Amines: Sponsored Chemicals (1 of 3)¹								
Property	1-Dodecan-amine	1-Hexadecan-amine	Amines, C14-18-alkyl²	Amines, C14-18 and C16-18-unsatd. alkyl²	Amines, soya alkyl²	Amines, C16-18 and C18-unsatd. alkyl²	Amines, N-tallow alkyltri-methylenedi-²	1,3-Propanediamine, N1-(9Z)-9-octadecen-1-yl-
	Value	Value	Value	Value	Value	Value	Value	Value
CASRN	124-22-1	143-27-1	68037-91-2	68155-38-4	61790-18-9	68037-95-6	61791-55-7	7173-62-8
Molecular Weight	185	241	213 (typical) ²	239 (typical) ²	265 (typical) ²	241 (typical) ²	325 (typical) ²	325
Physical State	Solid/liquid ³	Solid ³	No data	No data	Solid, paste ³	Solid ³	Solid ³	Liquid ³
Melting Point	28.3°C (measured)	46.8°C (measured)	No data	No data	29.0°C (measured) ³	No data	No data	<25°C (liquid) ⁴
Boiling Point	259°C (measured)	322.5°C (measured) ⁵ ; 330°C (measured) ⁶	291.2°C (measured, typical) ⁵	>300°C (estimated) ⁷	>300°C (estimated) ⁷	322.5°C (measured, typical) ⁵ ; 330°C (measured, typical) ⁶	>300°C (estimated, typical) ⁷	>300°C (estimated) ⁷
Vapor Pressure	8.05×10 ⁻³ mm Hg (measured) ⁵	1.33×10 ⁻⁴ mm Hg (measured) ⁵	9.74×10 ⁻⁴ mm Hg (measured, typical) ⁵	2.2×10 ⁻⁴ mm Hg (estimated) ⁷	1.3×10 ⁻⁴ mm Hg (estimated) ⁷	1.33×10 ⁻⁴ mm Hg (measured, typical) ⁵	4.9×10 ⁻⁷ mm Hg (estimated, typical) ⁷	4.9×10 ⁻⁷ mm Hg (estimated) ⁷
Dissociation Constant (pK _a)	10.63 (measured) ⁵	10.61 (measured) ⁵	10.62 (measured, typical) ⁵	10 (estimated) ⁸	10 (estimated) ⁸	10.6 (measured, typical) ⁵	8.7–11 (estimated) ⁸	11 (estimated) ⁸
Henry's Law Constant	2.5×10 ⁻⁵ atm-m ³ /mol (estimated) ⁷	5.3×10 ⁻⁴ atm-m ³ /mol (estimated) ⁷	3.0×10 ⁻⁴ atm-m ³ /mol (estimated) ⁷	4.7×10 ⁻⁴ atm-m ³ /mol (estimated) ⁷	7.2×10 ⁻⁴ atm-m ³ /mol (estimated) ⁷	5.3×10 ⁻³ atm-m ³ /mol (estimated) ⁷	7.8×10 ⁻⁵ atm-m ³ /mol (estimated) ⁷	3.3×10 ⁻⁷ atm-m ³ /mol (estimated) ⁷

Table 3. Physical-Chemical Properties of Fatty Nitrogen-Derived Amines: Sponsored Chemicals (1 of 3)¹

Property	1-Dodecan-amine	1-Hexadecan-amine	Amines, C14-18-alkyl ²	Amines, C14-18 and C16-18-unsatd. alkyl ²	Amines, soya alkyl ²	Amines, C16-18 and C18-unsatd. alkyl ²	Amines, N-tallow alkyltri-methylenedi- ²	1,3-Propanediamine, N1-(9Z)-9-octadecen-1-yl-
	Value	Value	Value	Value	Value	Value	Value	Value
Water Solubility	78 mg/L (measured) ^{5,9}	0.31 mg/L (estimated) ⁷	1.4 mg/L (estimated) ⁷	0.76 mg/L (estimated) ⁷	0.13 mg/L (estimated) ⁷	0.31 mg/L (estimated) ⁷	0.037 mg/L (estimated, typical) ⁷	0.037 mg/L (estimated) ⁷
Log K _{ow}	4.8 (estimated) ⁷	6.7 (estimated) ⁷	5.8 (estimated) ⁷	6.5 (estimated) ⁷	7.3 (estimated) ⁷	6.7 (estimated) ⁷	7.5 (estimated) ⁷	7.5 (estimated) ⁷

¹American Chemistry Council. 2003. Revised Robust Summary and Test Plan for Fatty Nitrogen-derived Amines Category. Available online at <http://www.epa.gov/chemrtk/pubs/summaries/amines/c14171tc.htm> as of July 15, 2010.

² Estimated data provided are based on the typical representative structure; see Appendix for detailed information on the structures.

³ Visek, K. 2003. Amines, Fatty. Kirk-Othmer Encyclopedia of Chemical Technology. John Wiley & Sons, Inc. Article online posting date: August 15, 2003.

⁴ Estimated based on melting point data.

⁵ SRC. 2010. The Physical Properties Database (PHYSPROP). SRC: Syracuse, NY. Available online at <http://www.srcinc.com/what-we-do/free-demos.aspx> as of July 16, 2010.

⁶ Beilstein search. 2010.

⁷ U.S. EPA. 2010. Estimation Programs Interface Suite™ for Microsoft® Windows, v4.00. U.S. Environmental Protection Agency, Washington, DC, USA. Available online at <http://www.epa.gov/opptintr/exposure/pubs/episuitedl.htm> as of July 12, 2010.

⁸ SPARC Online Calculator. 2008. Version 4.2. Available online at <http://ibmlc2.chem.uga.edu/sparc> as of July 21, 2010.

⁹ A measured water solubility value of 2 g/L provided by the sponsor was determined to be semi-quantitative and is not in good agreement with other measured data.

Table 4. Physical-Chemical Properties of Fatty Nitrogen-Derived Amines: Sponsored Chemicals (2 of 3)¹

Property	1-Tetradecan-amine, N,N-dimethyl-	1-Hexadecan-amine, N,N-dimethyl-	1-Octadecanamine, N,N-dimethyl-	Amines, (hydrogenated tallow alkyl) dimethyl ²	Amines, dimethylsoya alkyl ²	Amines, tri-C8-10-alkyl ²	Amines, tris(hydrogenated tallow alkyl) ²	Ethanol, 2,2'-iminobis-, N-coco alkyl derivs. ²
	Value	Value	Value	Value	Value	Value	Value	Value
CASRN	112-75-4	112-69-6	124-28-7	61788-95-2	61788-91-8	68814-95-9	61790-42-9	61791-31-9
Molecular Weight	241	270	298	298 (typical) ²	294 (typical) ²	382 (typical) ²	774 (typical) ²	273 (typical) ²
Physical State	Liquid ³	Liquid ³	Liquid ³	Liquid ³	Liquid ³	Liquid ³	No data	Liquid ⁴
Melting Point	-6°C (measured) ³	8°C (measured) ³ ; 12°C (measured) ⁵	22.9°C (measured)	22.9°C (measured)	<25°C (liquid) ⁶	<25°C (liquid)	No data	-5°C (measured) ⁴
Boiling Point	159–161°C at 11 mm Hg (measured) ⁵ ; 289–291°C (extrapolated) ⁷	147°C at 2 mm Hg (measured) ⁵ ; 319°C (extrapolated) ⁷	205–208°C at 16 mm Hg (measured) ⁵ ; 332–335°C (extrapolated) ⁷	205–208°C at 16 mm Hg (measured, typical) ⁵ ; 332–335°C (extrapolated, typical) ⁷	>300°C (estimated) ⁸	>300°C (estimated) ⁸	>300°C (estimated) ⁸	179–183°C at 2 mm Hg (measured, typical) ⁵ ; 358–363°C (extrapolated, typical) ⁷
Vapor Pressure	2.2×10 ⁻³ mm Hg (estimated) ⁷	3.3×10 ⁻⁴ mm Hg (estimated) ⁷	1.4×10 ⁻⁴ mm Hg (estimated) ⁷	1.4×10 ⁻⁴ mm Hg (estimated typical) ⁷	3.5×10 ⁻⁵ mm Hg (estimated) ⁸	2.7×10 ⁻⁷ mm Hg (estimated) ⁸	<1×10 ⁻¹⁰ mm Hg (estimated) ⁸	2.3×10 ⁻⁵ mm Hg (estimated, typical) ⁷
Dissociation Constant (pK _a)	7.1 (estimated) ¹⁰	7.1 (estimated) ¹⁰	7.5 (estimated) ¹⁰	7.5 (estimated) ¹⁰	9.5 (estimated) ¹⁰	9.2 (estimated) ¹⁰	7.2 (estimated) ¹⁰	6.2 (estimated) ¹⁰
Henry's Law Constant	1.5×10 ⁻³ atm-m ³ /mol (estimated) ⁸	2.6×10 ⁻³ atm-m ³ /mol (estimated) ⁸	4.5×10 ⁻³ atm-m ³ /mol (estimated) ⁸	4.5×10 ⁻³ atm-m ³ /mol (estimated) ⁸	3.5×10 ⁻³ atm-m ³ /mol (estimated) ⁸	3.3×10 ⁻² atm-m ³ /mol (estimated) ⁸	69 atm-m ³ /mol (estimated) ⁸	1.9×10 ⁻⁹ atm-m ³ /mol (estimated) ⁸

Table 4. Physical-Chemical Properties of Fatty Nitrogen-Derived Amines: Sponsored Chemicals (2 of 3)¹

Property	1-Tetradecan-amine, N,N-dimethyl-	1-Hexadecan-amine, N,N-dimethyl-	1-Octadecanamine, N,N-dimethyl-	Amines, (hydrogenated tallow alkyl) dimethyl ²	Amines, dimethylsoya alkyl ²	Amines, tri-C8-10-alkyl ²	Amines, tris(hydrogenated tallow alkyl) ²	Ethanol, 2,2'-iminobis-, N-coco alkyl derivs. ²
	Value	Value	Value	Value	Value	Value	Value	Value
Water Solubility	0.98 mg/L (estimated) ⁸	0.10 mg/L (estimated) ⁸	0.44 mg/L (measured) ⁹	0.44 mg/L (measured, typical) ⁹	0.02 mg/L (estimated) ⁸	8.5×10 ⁻⁶ mg/L (estimated) ⁸	<1×10 ⁻¹⁰ mg/L (estimated) ⁸	Dispersible ⁴
Log K _{ow}	6.4 (estimated) ⁸	7.4 (estimated) ⁸	8.4 (estimated) ⁸	8.4 (estimated) ⁸	8.0 (estimated) ⁸	11 (estimated) ⁸	25 (estimated) ⁸	Not applicable ¹¹

¹American Chemistry Council. 2003. Revised Robust Summary and Test Plan for Fatty Nitrogen-derived Amines Category. Available online at <http://www.epa.gov/chemrtk/pubs/summaries/amines/c14171tc.htm> as of July 15, 2010.

² Estimated data provided are based on the typical representative structure; see Appendix for detailed information on the structures.

³ Visek, K. 2003. Amines, Fatty. Kirk-Othmer Encyclopedia of Chemical Technology. John Wiley & Sons, Inc. Article online posting date: August 15, 2003.

⁴ Ash, M; Ash, I. 2000. Industrial Sufactants, Electronic Handbook 2000. Synapse Information Resources: Endicott, NY.

⁵ Beilstein search. 2010.

⁶ Estimated based on physical state at room temperature.

⁷ NOMO5. 1987. Programs to Enhance PC-Gems Estimates of Physical Properties for Organic Compounds. The Mitre Corp.

⁸ U.S. EPA. 2010. Estimation Programs Interface Suite™ for Microsoft® Windows, v4.00. U.S. Environmental Protection Agency, Washington, DC, USA. Available online at <http://www.epa.gov/opptintr/exposure/pubs/episuitedl.htm> as of July 12, 2010.

⁹ Chemicals Inspection and Testing Institute. 1996. Biodegradation and Bioaccumulation Data of Existing Chemicals Based on the CSCL Japan. Japan Chemical Industry Ecology - Toxicology and Information Center. ISBN 4-89074-101-1, pg. 2–36.

¹⁰ SPARC Online Calculator. 2008. Version 4.2. Available online at <http://ibmlc2.chem.uga.edu/sparc/> as of July 19, 2010.

¹¹ Due to dispersibility, log Kow cannot be reliably measured or estimated. Source: Toll, J; Sijm, D. 2000. Estimating properties of surface active chemicals. In: Handbook of Property Estimation for Chemicals. Boethling, RS; Mackay, D; eds. Chapter 17. Lewis Publishers: Boca Raton, FL pp. 419-446.

Table 5. Physical-Chemical Properties of Fatty Nitrogen-Derived Amines: Sponsored Chemicals (3 of 3)¹

Property	1-Decanamine, N-decyl-N- methyl-	Amines, di-C14- 18-alkylmethyl ²	Amines, di- C12-18-alkyl ²	1-Octadecanamine, N-methyl-N- octadecyl-	Amines, bis(hydrogenated tallow alkyl)methyl ²	Amines, ditallow alkyl ²	Ethanol, 2,2'- iminobis-, N-tallow alkyl derivs. ²
	Value	Value	Value	Value	Value	Value	Value
CASRN	7396-58-9	67700-99-6	68153-95-7	4088-22-6	61788-63-4	68783-24-4	61791-44-4
Molecular Weight	312	480 (typical) ²	438 (typical) ²	536 (typical) ²	536 (typical) ²	518 (typical) ²	356 (typical) ²
Physical State	Liquid ³	No data	No data	Solid ³	Solid ³	Solid ³	No data
Melting Point	-6.3°C (measured) ³	No data	No data	48–49°C (measured) ⁴	38°C (measured) ³	55.0°C (measured) ³	No data
Boiling Point	140–145°C at 1–2 mm Hg (measured) ² ; 326°C (extrapolated) ⁶	>300°C (estimated) ⁷	>300°C (estimated) ⁷	252–259°C at 0.05 mm Hg (measured) ⁵ ; 541–550°C (extrapolated) ⁶	252–259°C at 0.05 mm Hg (measured, typical) ⁵ ; 541–550°C (extrapolated, typical) ⁶	>300°C (estimated) ⁷	230–232°C at 1 mm Hg (measured, typical) ⁵ ; 439–441°C (extrapolated, typical) ⁶
Vapor Pressure	1.9×10 ⁻⁴ mm Hg (estimated) ⁶	1.9×10 ⁻⁸ mm Hg (estimated) ⁷	3.63×10 ⁻⁹ mm Hg (estimated) ⁷	1.3×10 ⁻⁹ mm Hg (estimated) ⁷	1.3×10 ⁻⁹ mm Hg (estimated) ⁷	8.2×10 ⁻¹⁰ mm Hg (estimated) ⁷	<1×10 ⁻¹⁰ mm Hg (estimated) ⁷
Dissociation Constant (pK _a)	8.6 (estimated) ⁸	7.1 (estimated) ⁸	11 (estimated) ⁸	7.1 (estimated) ⁸	7.1 (estimated) ⁸	11 (estimated) ⁸	8.0 (estimated) ⁸
Henry's Law Constant	6.0×10 ⁻³ atm-m ³ /mol (estimated) ⁷	5.8×10 ⁻² atm-m ³ /mol (estimated) ⁷	4.6×10 ⁻² atm-m ³ /mol (estimated) ⁷	0.56 atm-m ³ /mol (estimated) ⁷	0.56 atm-m ³ /mol (estimated) ⁷	0.20 atm-m ³ /mol (estimated) ⁷	9.4×10 ⁻⁹ atm-m ³ /mol (estimated) ⁷

Table 5. Physical-Chemical Properties of Fatty Nitrogen-Derived Amines: Sponsored Chemicals (3 of 3)¹

Property	1-Decanamine, N-decyl-N-methyl-	Amines, di-C14-18-alkylmethyl ²	Amines, di-C12-18-alkyl ²	1-Octadecanamine, N-methyl-N-octadecyl-	Amines, bis(hydrogenated tallow alkyl)methyl ²	Amines, ditallow alkyl ²	Ethanol, 2,2'-iminobis-, N-tallow alkyl derivs. ²
	Value	Value	Value	Value	Value	Value	Value
Water Solubility	3.3×10 ⁻³ mg/L (estimated) ⁷	2.6×10 ⁻⁷ mg/L (estimated) ⁷	4.6×10 ⁻⁸ mg/L (estimated) ⁷	<1×10 ⁻¹⁰ mg/L (estimated) ⁷	0.29 mg/L (measured) ⁹ ; <1×10 ⁻¹⁰ mg/L (estimated) ⁷	<1×10 ⁻¹⁰ mg/L (estimated) ⁷	Dispersible ¹⁰
Log K _{ow}	8.9 (estimated) ⁷	13 (estimated) ⁷	14 (estimated) ⁷	17 (estimated) ⁷	3.15 (measured) ⁹ ; 17 (estimated) ⁷	16 (estimated) ⁷	Not applicable ¹¹

¹American Chemistry Council. 2003. Revised Robust Summary and Test Plan for Fatty Nitrogen-Derived Amines Category. Available online at <http://www.epa.gov/chemrtk/pubs/summaries/amines/c14171tc.htm> as of July 15, 2010.

² Estimated data provided are based on the typical representative structure; see Appendix for detailed information on the structures.

³ Visek, K. 2003. Amines, Fatty. Kirk-Othmer Encyclopedia of Chemical Technology. John Wiley & Sons, Inc. Article online posting date: August 15, 2003.

⁴ Aldrich Chemical Company. 2010. Handbook of Fine Chemicals and Laboratory Equipment, Catalog, p. 1539.

⁵ Beilstein search. 2010.

⁶ NOMO5. 1987. Programs to Enhance PC-Gems Estimates of Physical Properties for Organic Compounds. The Mitre Corp.

⁷ U.S. EPA. 2010. Estimation Programs Interface Suite™ for Microsoft® Windows, v4.00. U.S. Environmental Protection Agency, Washington, DC, USA. Available online at <http://www.epa.gov/opptintr/exposure/pubs/episuitedl.htm> as of July 12, 2010.

⁸ SPARC Online Calculator. 2008. Version 4.2. Available online at <http://ibmlc2.chem.uga.edu/sparc/> as of July 19, 2010.

⁹ The sponsor indicated that there was an apparent concentration-dependent partitioning of the test substance; the reported log K_{ow} was based on the lowest concentration tested.

¹⁰ Ash, M; Ash, I. 2000. Industrial Sufactants, Electronic Handbook 2000. Synapse Information Resources: Endicott, NY.

¹¹ Due to dispersibility, log Kow cannot be reliably measured or estimated. Source: Toll, J; Sijm, D. 2000. Estimating properties of surface active chemicals. In: Handbook of Property Estimation for Chemicals. Boethling, RS; Mackay, D; eds. Chapter 17. Lewis Publishers: Boca Raton, FL pp. 419-446.

Table 6. Physical-Chemical Properties of Fatty Nitrogen-Derived Amines: Supporting Chemicals¹

Property	9-Octadecen-1-amine, (9Z)-	1-Octadecanamine	1-Hexadecanamine, hydrofluoride	Amines, coco alkyl ²	Amines, tallow alkyl ²	1-Dodecanamine, N,N-dimethyl- ³
	Value	Value	Value	Value	Value	Value
CASRN	112-90-3	124-30-1	3151-59-5	61788-46-3	61790-33-8	112-18-5
Molecular Weight	267	270	262	185 (typical) ²	268 (typical) ²	213
Physical State	Liquid ³	Solid ³	No data	Liquid ³	Solid ³	Liquid ⁴
Melting Point	21°C (measured)	52.9°C (measured)	No data	16.0°C (measured) ³	34–40°C (measured); 25–30°C (measured)	-15°C (measured) ⁴
Boiling Point	335°C (measured)	346.8°C (measured)	>300°C (estimated) ⁴	259°C (measured, typical) ⁵	200–230°C (measured – too low, may be at reduced pressure) >300 (estimated) ⁵	260°C (measured) ⁹
Vapor Pressure	3.0×10 ⁻⁴ mm Hg (estimated) ⁶	9.0×10 ⁻⁶ mm Hg (measured)	6.7×10 ⁻⁴ mm Hg (estimated) ⁴	8.05×10 ⁻³ mm Hg (measured, typical) ⁵	<1 mm Hg (measured) 3×10 ⁻⁴ mm Hg (estimated) ⁵	2.2×10 ⁻² mm Hg (estimated) ⁷
Dissociation Constant (pK _a)	10.4 (estimated) ⁷	10.6 (measured)	No data	10.6 (measured, typical) ⁵	10.4 (estimated) ⁷	7.5 (estimated) ¹⁰
Henry's Law Constant	8.2×10 ⁻⁴ atm-m ³ /mol (estimated) ⁴	9.4×10 ⁻⁴ atm-m ³ /mol (estimated) ⁴	1.8×10 ⁻² atm-m ³ /mol (estimated) ⁴	2.5×10 ⁻⁵ atm-m ³ /mol (estimated) ⁴	8.2×10 ⁻⁴ atm-m ³ /mol (estimated) ⁴	8.2×10 ⁻⁴ atm-m ³ /mol (estimated) ⁸

Table 6. Physical-Chemical Properties of Fatty Nitrogen-Derived Amines: Supporting Chemicals¹

Property	9-Octadecen-1-amine, (9Z)-	1-Octadecanamine	1-Hexadecanamine, hydrofluoride	Amines, coco alkyl ²	Amines, tallow alkyl ²	1-Dodecanamine, N,N-dimethyl- ³
	Value	Value	Value	Value	Value	Value
Water Solubility	0.08 mg/L (estimated) ⁴	2.9×10 ⁻² mg/L (estimated) ⁴	Dispersible ⁸	78 mg/L (measured, typical) ⁵	0.08 mg/L (estimated) ⁴	9.3 mg/L (estimated) ⁸
Log K _{ow}	7.5 (estimated) ⁴	7.7 (estimated) ⁴	Not applicable ⁸	4.8 (estimated) ⁴	7.5 (estimated) ⁴	5.4 (estimated) ⁸

¹American Chemistry Council. 2003. Revised Robust Summary and Test Plan for Fatty Nitrogen-derived Amines Category. Available online at <http://www.epa.gov/chemrtk/pubs/summaries/amines/c14171tc.htm> as of July 15, 2010.

² Estimated data provided are based on the typical representative structure; see Appendix for detailed information on the structures.

³ Visek, K. 2003. Amines, Fatty. Kirk-Othmer Encyclopedia of Chemical Technology. John Wiley & Sons, Inc. Article online posting date: August 15, 2003.

⁴ U.S. EPA. 2010. Estimation Programs Interface Suite™ for Microsoft® Windows, v4.00. U.S. Environmental Protection Agency, Washington, DC, USA. Available online at <http://www.epa.gov/opptintr/exposure/pubs/episuitedi.htm> as of July 12, 2010.

⁵ SRC. 2010. The Physical Properties Database (PHYSPROP). SRC: Syracuse, NY. Available online at <http://www.srcinc.com/what-we-do/free-demos.aspx> as of July 16, 2010.

⁶ NOMO5. 1987. Programs to Enhance PC-Gems Estimates of Physical Properties for Organic Compounds. The Mitre Corp.

⁷ SPARC Online Calculator. 2008. Version 4.2. Available online at <http://ibmlc2.chem.uga.edu/sparc> as of July 21, 2010.

⁸ This chemical may be dispersible as a worst case scenario. Therefore, log K_{ow} cannot be reliably measured or estimated. Source: Tolls, J; Sijm, D. 2000. Estimating properties of surface active chemicals. In: Handbook of Property Estimation for Chemicals. Boethling, RS; Mackay, D; eds. Chapter 17. Lewis Publishers: Boca Raton, FL. pp. 419–446.

2. General Information on Exposure

2.1 Production Volume and Use Pattern

The FND amines category chemicals had an aggregated production and/or import volume in the United States between 129.5 million pounds and 534 million pounds in calendar year 2005.

- CASRN 112-69-6: 10 to <50 million pounds;
- CASRN 112-75-4: 10 to <50 million pounds;
- CASRN 124-22-1: 1 to <10 million pounds;
- CASRN 124-28-7: 10 to <50 million pounds;
- CASRN 143-27-1: 500,000 pounds to <1 million pounds;
- CASRN 4088-22-6: 1 to <10 million pounds;
- CASRN 7173-62-8: 1 to <10 million pounds;
- CASRN 7396-58-9: 10 to <50 million pounds;
- CASRN 61788-63-4: 50 to <100 million pounds;
- CASRN 61788-91-8: 500,000 pounds to <1 million pounds;
- CASRN 61788-95-2: 1 to <10 million pounds;
- CASRN 61790-18-9: 1 to <10 million pounds;
- CASRN 61790-42-9: < 500,000 pounds;
- CASRN 61791-31-9: 10 to <50 million pounds;
- CASRN 61791-44-4: 1 to <10 million pounds;
- CASRN 61791-55-7: 1 to <10 million pounds;
- CASRN 67700-99-6: 10 to <50 million pounds;
- CASRN 68153-95-7: 500,000 pounds to <1 million pounds;
- CASRN 68155-38-4: 10 to <50 million pounds;
- CASRN 68783-24-4: < 500,000 pounds;
- CASRN 68814-95-9: 1 to <10 million pounds;

CASRN 68037-91-2 and 68037-95-6 were not reported under the 2006 Inventory Update Rule (IUR).

CASRN 112-69-6:

Non-confidential information in the IUR indicated that the industrial processing and uses of the chemical include all other chemical product and preparation manufacturing as intermediates and surface active agents; other basic organic chemical manufacturing, pesticide and other agricultural chemical manufacturing, soap and cleaning compound manufacturing, general warehousing and storage and other chemical and allied products merchant wholesalers as intermediates; all other chemical product and preparation manufacturing as process regulators, other than polymerization or vulcanization processes. Non-confidential commercial and consumer uses of this chemical include “other.”

CASRN 112-75-4:

Non-confidential information in the IUR indicated that the industrial processing and uses of the chemical include all other chemical product and preparation manufacturing as intermediates and surface active agents; other basic organic chemical manufacturing, pesticide and other agricultural chemical manufacturing, and soap and cleaning compound manufacturing as intermediates; petroleum refineries as corrosion inhibitors and anti-scaling agents; general warehousing and storage as intermediates and not readily obtainable (NRO). Non-confidential commercial and consumer uses of this chemical include "other."

CASRN 124-22-1 and 61788-63-4:

Non-confidential information in the IUR indicated that the industrial processing and uses of the chemicals include other basic organic chemical manufacturing as surface active agents and intermediates; other nonmetallic mineral mining and quarrying and synthetic dye and pigment manufacturing as surface active agents. No commercial and consumer uses were reported for these chemicals.

CASRN 124-28-7:

Non-confidential information in the IUR indicated that the industrial processing and uses of the chemical include all other chemical product and preparation manufacturing as surface active agents; other basic organic chemical manufacturing and other chemical and allied products merchant wholesalers as intermediates. Non-confidential commercial and consumer uses of this chemical include "other."

CASRN 143-27-1:

Non-confidential information in the IUR indicated that the industrial processing and uses of the chemical include other basic organic chemical manufacturing as intermediates. Commercial and consumer uses are claimed confidential.

CASRN 4088-22-6 and 68814-95-9:

Industrial processing and uses of these chemicals are claimed confidential. No commercial and consumer users were reported.

CASRN 7173-62-8:

Non-confidential information in the IUR indicated that the industrial processing and uses of the chemical include other basic organic chemical manufacturing as surface active agents, intermediates and "other"; other petroleum and coal products manufacturing, plate work and fabricated structural product manufacturing, soap and cleaning compound manufacturing, and support activities for mining as surface active agents. Non-confidential commercial and consumer uses of this chemical include "other."

CASRN 7396-58-9:

Non-confidential information in the IUR indicated that the industrial processing and uses of the chemical include all other chemical product and preparation manufacturing as surface active agents and process regulators, other than polymerization or vulcanization processes; pesticide and other agricultural chemical manufacturing as intermediates. Non-confidential commercial and consumer uses of this chemical include wood and wood furniture.

CASRN 61788-91-8 and 61788-95-2:

Non-confidential information in the IUR indicated that the industrial processing and uses of the chemicals include other basic organic chemical manufacturing as surface active agents and intermediates. No commercial and consumer uses were reported for these chemicals.

CASRN 61790-18-9:

Non-confidential information in the IUR indicated that the industrial processing and uses of the chemical include other basic organic chemical manufacturing as surface active agents and intermediates; other petroleum and coal products manufacturing, support activities for mining and synthetic dyes and pigment manufacturing as surface active agents. No commercial and consumer uses were reported.

CASRN 61790-42-9 and 68783-24-4:

No industrial processing and uses and commercial and consumer uses were reported for these chemicals.

CASRN 61791-31-9:

Non-confidential information in the IUR indicated that the industrial processing and uses of the chemical include other basic organic chemical manufacturing as surface active agents and intermediates; asphalt paving, roofing and saturated materials manufacturing, paper mills, pesticide and other agricultural chemical manufacturing, support activities for mining, synthetic dye and pigment manufacturing, and soap and cleaning compound manufacturing as surface active agents. Non-confidential commercial and consumer uses of the chemical include soaps and detergents.

CASRN 61791-44-4:

Non-confidential information in the IUR indicated that the industrial processing and uses of the chemical include other basic organic chemical manufacturing as surface active agents and intermediates; asphalt paving, roofing and saturated materials manufacturing, other petroleum and coal products manufacturing, and support activities for mining as surface active agents. No commercial and consumer uses were reported.

CASRN 61791-55-7:

Non-confidential information in the IUR indicated that the industrial processing and uses of the chemical include other basic organic chemical manufacturing as surface active agents and intermediates; asphalt paving, roofing and saturated materials manufacturing, other nonmetallic mineral mining and quarrying, other petroleum and coal products manufacturing, and support activities for mining as surface active agents. No commercial and consumer uses were reported.

CASRN 67700-99-6, 68153-95-7 and 68155-38-4:

Industrial processing and uses, and commercial and consumer uses for these chemicals are claimed confidential.

2.2 Environmental Exposure and Fate

The environmental fate properties are provided in Tables 7 through 12. The structures are provided in the Appendix.

The members of the fatty nitrogen-derived amines category are expected to possess low mobility in soil; however, CASRNs 124-22-1, 68814-95-9 and 61790-42-9 possess moderate mobility in soil. Experimental biodegradation data are available for 11/23 sponsored chemicals and 11/12 supporting chemicals (see tables). These data were used to extrapolate to the other members for which no data were available.

In Table 7, acceptable data are available for 3/8 sponsored primary alkylamines and alkyldiamines: CASRNs 124-22-1, 143-27-1), and 68037-95-6. All were found to be readily biodegradable according to OECD Guideline 301D (closed bottle test), with 55, 85, and 85% biodegradation after 28 days, respectively. Inherent biodegradability results from OECD Guideline 302B (Zahn-Wellens test) of CASRN 61791-55-7 do not allow a prediction on the biodegradability due to the high adsorption in activated sludge. In Table 8, five closely related supporting chemicals were all found to be either inherently biodegradable or readily biodegradable according to OECD guidelines.

For the dimethylalkylamines (Table 9), five sponsored chemicals and three supporting chemicals are presented. Three sponsored chemicals (CASRNs 112-69-6, 61788-95-2 and 61788-91-8) were all considered readily biodegradable. A fourth (CASRN 124-28-7) was reported to be not readily biodegradable (49% in 29 days) but was estimated to be inherently biodegradable based on the results of a modified Sturm test (OECD 301B) and readily biodegradable (72% in 4 weeks) by the modified MITI test (OECD 301C). A determination of the biodegradability of the fifth sponsored chemical (CASRN 112-75-4) using OECD Guideline 301D was not deemed adequate due to results that were inconsistent with other, related chemicals. Thus, the available data with the other sponsored chemicals plus the supporting chemicals also reported in Table 7 suggest that CASRN 112-75-4 is readily biodegradable.

Biodegradation data are available for only one dimethylalkylamine/dialkylamine sponsored chemical (CASRN 61788-63-4); and it was found to be readily biodegradable using a closed bottle test (OECD 301D) and a modified Sturm assay (in compliance with Method C5 of the European Commission of Communities 84/449/CEE), achieving >100% biodegradation after 28 days (97.3% pure test substance) and 75% BOD after 28 days (purity not specified), respectively (Table 10). However, data were found for three supporting chemicals (Table 11) which indicate that these substances are not persistent in the environment.

In Table 12, the trialkylamines (CASRNs 61791-31-9 and 61791-44-4) were found readily biodegradable by OECD 301D closed bottle test, achieving 61 and 52% degradation in 28 days, respectively; ethanol, 2,2'-iminobis-, N-tallow alkyl derivs. (98% purity) was classified as readily biodegradable because biodegradation proceeded rapidly after an initial lag of 15 days. This information is read-across to the other sponsored chemicals in this group.

Conclusion: Volatilization is not expected to be an important fate process since the FND amines are weak bases that will exist as cations in the environment, and cations do not volatilize. Hydrolysis data were not available for any members of this category. Generally, amines are expected to hydrolyze extremely slowly under environmental conditions; however, these types of surfactants are generally not hydrolysable, according to the sponsor. The rate of atmospheric photooxidation is considered moderate to rapid for members of this category; however, this is not expected to be an important environmental fate process since these substances are not expected to exist in the vapor phase in the atmosphere. The overall weight of experimental evidence and read across from structurally similar compounds from these studies suggest that all members of the FND amines category have low persistence (P1). As shown in the tables, most members of the FND amines category are expected to have low (B1) bioaccumulation potential (13/23, including all four trialkylamines), with 4/23 having a moderate (B2) rating and 6/23 having a high (B3) rating; with 5/6 being primary alkylamines/alkyldiamines.

Table 7. Environmental Fate Characteristics of Fatty Nitrogen-Derived Amines: Primary Alkylamines and Alkyldiamines¹								
Property	SPONSORED CHEMICAL 1-Dodecan-amine	SPONSORED CHEMICAL 1-Hexadecan-amine	SPONSORED CHEMICAL Amines, C14-18-alkyl²	SPONSORED CHEMICAL Amines, C14-18 and C16-18-unsatd. alkyl²	SPONSORED CHEMICAL Amines, soya alkyl²	SPONSORED CHEMICAL Amines, C16-18 and C18-unsatd. alkyl²	SPONSORED CHEMICAL Amines, N-tallow alkyltrimethyl-enedi-²	SPONSORED CHEMICAL 1,3-Propanediamine, N1-(9Z)-9-octadecen-1-yl-
	Value	Value	Value	Value	Value	Value	Value	Value
CASRN	124-22-1	143-27-1	68037-91-2	68155-38-4	61790-18-9	68037-95-6	61791-55-7	7173-62-8
Photodegradation Half-life	2.8 hours (estimated) ³	2.5 hours (estimated) ³	2.6 hours (estimated) ³	1.2 hours (estimated) ³	0.80 hours (estimated) ³	2.5 hours (estimated) ³	0.4 hours (estimated) ³	0.67 hours (estimated) ³
Hydrolysis Half-life	Stable							
Biodegradation	55% in 28 days (readily biodegradable)	85% in 28 days (readily biodegradable) ⁴	No data (RA) Readily Biodegradable	No data (RA) Readily Biodegradable	No data (RA) Readily Biodegradable	85% in 28 days (readily biodegradable) ⁴	Inadequate Data ⁵ (RA) Readily Biodegradable	No data (RA) Readily Biodegradable
Bioaccumulation Factor	BAF = 900 (estimated) ³	BAF = 2.7×10 ⁴ (estimated) ³	BAF = 2.7×10 ³ (estimated) ³	BAF = 3.6×10 ⁴ (estimated) ³	BAF = 3.6×10 ⁵ (estimated) ³	BAF = 2.7×10 ⁴ (estimated) ³	BAF = 1.3 (estimated) ³	BAF = 9.6×10 ⁵ (estimated) ³
Log K _{oc}	3.7 (estimated) ³	4.8 (estimated) ³	4.3 (estimated) ³	4.8 (estimated) ³	5.3 (estimated) ³	4.8 (estimated) ³	10 (estimated) ³	5.9 (estimated) ³
Fugacity (Level III Model) ³								
Air (%)	0.6	0.6	0.7	0.1	<0.1	0.6	<0.1	<0.1
Water (%)	22.3	13.8	15.7	14.5	13.0	13.8	18	8.1
Soil (%)	73.5	67.7	75.7	65.0	53.3	67.7	82	39.0
Sediment (%)	3.7	17.9	8.0	20.4	33.7	17.9	<0.1	52.8

Table 7. Environmental Fate Characteristics of Fatty Nitrogen-Derived Amines: Primary Alkylamines and Alkyldiamines¹								
Property	SPONSORED CHEMICAL 1-Dodecan-amine	SPONSORED CHEMICAL 1-Hexadecan-amine	SPONSORED CHEMICAL Amines, C14-18-alkyl²	SPONSORED CHEMICAL Amines, C14-18 and C16-18-unsatd. alkyl²	SPONSORED CHEMICAL Amines, soya alkyl²	SPONSORED CHEMICAL Amines, C16-18 and C18-unsatd. alkyl²	SPONSORED CHEMICAL Amines, N-tallow alkyltrimethyl-enedi-²	SPONSORED CHEMICAL 1,3-Propanediamine, N1-(9Z)-9-octadecen-1-yl-
	Value	Value	Value	Value	Value	Value	Value	Value
Persistence ⁶	P1 (low)	P1 (low)	P1 (low)	P1 (low)	P1 (low)	P1 (low)	P1 (low)	P1 (low)
Bio-accumulation ⁶	B1 (low)	B3 (high)	B2 (moderate)	B3 (high)	B3 (high)	B3 (high)	B1 (low)	B3 (high)

¹American Chemistry Council. 2003. Revised Robust Summary and Test Plan for Fatty Nitrogen-Derived Amines Category. Available online at <http://www.epa.gov/chemrtk/pubs/summaries/amines/c14171tc.htm> as of July 15, 2010.

² Estimated data provided are based on the typical representative structure; see Appendix for detailed information on the structures.

³ U.S. EPA. 2010. Estimation Programs Interface Suite™ for Microsoft® Windows, v4.00. U.S. Environmental Protection Agency, Washington, DC, USA. Available online at <http://www.epa.gov/opptintr/exposure/pubs/episuitedl.htm> as of July 12, 2010.

⁴ van Ginkel, CG. 1995. Biodegradability of Cationic Surfactants. In: Biodegradation of Surfactants. Karsa, DR; Porter, MR; eds. Glasgow, UK: Blackie, pp. 183-203.

⁵ Inherent biodegradability results from the OECD Guideline 302B test do not allow a prediction of the biodegradability of this chemical due to its high adsorption in activated sludge.

⁶ Federal Register. 1999. Category for Persistent, Bioaccumulative, and Toxic New Chemical Substances. *Federal Register* 64, Number 213 (November 4, 1999) pp. 60194–60204.

RA = Read Across.

Property	SUPPORTING CHEMICAL 9-Octadecen-1-amine, (9Z)-	SUPPORTING CHEMICAL 1-Octadecanamine	SUPPORTING CHEMICAL Amines, hydrogenated tallow alkyl ²	SUPPORTING CHEMICAL Amines, coco alkyl ²	SUPPORTING CHEMICAL Amines, tallow alkyl ²
CASRN	112-90-3	124-30-1	61788-45-2	61788-46-3	61790-33-8
Photodegradation Half-life	1.2 hours (estimated) ³	2.4 hours (estimated) ³	2.4 hours (estimated) ³	2.8 hours (estimated) ³	1.2 hours (estimated) ³
Hydrolysis Half-Life	Stable				
Biodegradation	66% in 28 days (not readily biodegradable) ⁴ ; >60% in 12 days (inherently biodegradable)	70% in 28 days (readily biodegradable); >60% in 12 days (inherently biodegradable)	75% in 28 days (readily biodegradable)	56% in 28 days (readily biodegradable) ⁵ ; 91.1% as CO ₂ in 28 days (readily biodegradable) ⁶	56% in 28 days (not readily biodegradable); 73% in 28 days (inherently biodegradable)
Bioaccumulation Factor	BAF = 2.1×10 ⁵ (estimated) ³	BAF = 1.1×10 ⁵ (estimated) ³	BAF = 1.1×10 ⁵ (estimated) ³	BAF = 900 (estimated) ³	BAF = 2.1×10 ⁵ (estimated) ³
Log K _{oc}	5.3 (estimated) ³	5.3 (estimated) ³	5.3 (estimated) ³	3.7 (estimated) ³	5.3 (estimated) ³
Fugacity (Level III Model) ³					
Air (%)	0.1	0.4	0.4	0.6	0.1
Water (%)	13.9	15.3	15.3	22.3	13.9
Soil (%)	57.8	61.2	61.2	73.5	57.8
Sediment (%)	28.2	23.1	23.1	3.7	28.2
Persistence ⁷	P1 (low)	P1 (low)	P1 (low)	P1 (low)	P1 (low)
Bio-accumulation ⁷	B3 (high)	B3 (high)	B3 (high)	B1 (low)	B3 (high)

¹American Chemistry Council. 2003. Revised Robust Summary and Test Plan for Fatty Nitrogen-Derived Amines Category. Available online at <http://www.epa.gov/chemrtk/pubs/summaries/amines/c14171tc.htm> as of July 15, 2010.

² Supporting chemicals. Estimated data provided are based on the typical representative structure; see Appendix for detailed information on the structures.

³ U.S. EPA. 2010. Estimation Programs Interface Suite™ for Microsoft® Windows, v4.00. U.S. Environmental Protection Agency, Washington, DC, USA. Available online at <http://www.epa.gov/opptintr/exposure/pubs/episuitd.htm> as of July 12, 2010.

⁴ 60% biodegradation needs to be achieved within a 10-day window following the initial 10% degradation for the substance to be considered readily biodegradable.

⁵ Sponsor stated that the test substance was readily biodegradable. However, pass/fail criteria for a Closed Bottle Test (OECD Guideline 301D) is 60% in 28 days.

⁶ Study was a variant of the OECD Closed Bottle Test using a raw sewage inoculum. The sponsor stated that the test substance was readily biodegradable.

⁷ Federal Register. 1999. Category for Persistent, Bioaccumulative, and Toxic New Chemical Substances. *Federal Register* 64, Number 213 (November 4, 1999) pp. 60194–60204.

Table 9. Environmental Fate Characteristics of Fatty Nitrogen-Derived Amines: Dimethylalkylamines¹

Property	SPONSORED CHEMICAL 1-Tetradecan-amine, N,N-dimethyl-	SPONSORED CHEMICAL 1-Hexadecan-amine, N,N-dimethyl-	SPONSORED CHEMICAL 1-Octadecan-amine, N,N-dimethyl-	SPONSORED CHEMICAL Amines, (hydrogenated tallow alkyl) dimethyl ²	SPONSORED CHEMICAL Amines, dimethylsoya alkyl ²	SUPPORTING CHEMICAL Octadecen-1-amine, N,N-dimethyl- ³	SUPPORTING CHEMICAL 1-Dodecanamine, N,N-dimethyl- ³	SUPPORTING CHEMICAL Amines, coco alkyldimethyl ^{2,3}
	Value	Value	Value	Value	Value	Value	Value	Value
CASRN	112-75-4	112-69-6	124-28-7	61788-95-2	61788-91-8	28061-69-0	112-18-5	61788-93-0
Photodegradation Half-life ⁴	1.3 hours (estimated)	1.3 hours (estimated)	1.3 hours (estimated)	1.3 hours (estimated)	0.62 hours (estimated)	1.0 hours (estimated)	1.4 hours (estimated)	1.4 hours (estimated)
Hydrolysis Half-life	Stable					Stable		
Biodegradation	Inadequate Data ⁵ (RA) Readily Biodegradable	59% in 28 days (readily biodegradable); 100% in 28 days (readily biodegradable)	49% in 29 days (inherently biodegradable); 72% in 4 weeks (readily biodegradable) ⁶	58% in 28 days (readily biodegradable)	98% in 28 days (readily biodegradable)	50% in 28 days and 59% in 70 days (biodegradable) ⁷	67% in 28 days (readily biodegradable); 72% in 29 days (readily biodegradable)	81% in 28 days (readily biodegradable)
Bioaccumulation Factor ⁴	BAF = 430 (estimated)	BAF = 950 (estimated)	BAF = 1,400 (estimated)	BAF = 1,400 (estimated)	BAF = 8,600 (estimated)	BAF = 1,300 (estimated)	BAF = 280 (estimated)	BAF = 280 (estimated)
Log K _{oc} ⁴	4.3 (estimated)	4.8 (estimated)	5.3 (estimated)	5.3 (estimated)	5.3 (estimated)	5.3 (estimated)	3.8 (estimated)	3.8 (estimated)
Fugacity (Level III Model) ⁴								
Air (%)	0.2	0.2	0.1	0.1	<0.1	0.1	0.5	0.5
Water (%)	9.7	10.7	14.6	14.6	10.8	13.1	16.8	16.8
Soil (%)	80.9	72.5	71.9	71.9	66.5	70.9	79.8	79.8
Sediment (%)	9.2	16.7	13.3	13.3	22.7	15.9	2.9	2.9
Persistence ⁸	P1 (low)	P1 (low)	P1 (low)	P1 (low)	P1 (low)	P1 (low)	P1 (low)	P1 (low)

Table 9. Environmental Fate Characteristics of Fatty Nitrogen-Derived Amines: Dimethylalkylamines¹

Property	SPONSORED CHEMICAL 1-Tetradecan-amine, N,N-dimethyl-	SPONSORED CHEMICAL 1-Hexadecan-amine, N,N-dimethyl-	SPONSORED CHEMICAL 1-Octadecan-amine, N,N-dimethyl-	SPONSORED CHEMICAL Amines, (hydrogenated tallow alkyl) dimethyl ²	SPONSORED CHEMICAL Amines, dimethylsoya alkyl ²	SUPPORTING CHEMICAL Octadecen-1-amine, N,N-dimethyl- ³	SUPPORTING CHEMICAL 1-Dodecanamine, N,N-dimethyl- ³	SUPPORTING CHEMICAL Amines, coco alkyldimethyl ^{2,3}
	Value	Value	Value	Value	Value	Value	Value	Value
Bio-accumulation ⁸	B1 (low)	B1 (low)	B2 (moderate)	B2 (moderate)	B3 (high)	B2 (moderate)	B1 (low)	B1 (low)

¹American Chemistry Council. 2003. Revised Robust Summary and Test Plan for Fatty Nitrogen-Derived Amines Category. Available online at <http://www.epa.gov/chemrtk/pubs/summaries/amines/c14171tc.htm> as of July 15, 2010.

² Estimated data provided are based on the typical representative structure; see Appendix for detailed information on the structures.

³ Supporting chemicals.

⁴ U.S. EPA. 2010. Estimation Programs Interface Suite™ for Microsoft® Windows, v4.00. U.S. Environmental Protection Agency, Washington, DC, USA. Available online at <http://www.epa.gov/opptintr/exposure/pubs/episuitedl.htm> as of July 12, 2010.

⁵ Although there is a guideline study (OECD 301D) that reports <2% degradation after 28 days, a determination of the biodegradability could not be reached due to results that were inconsistent with related chemicals; it is not considered representative of the biodegradation of this chemical.

⁶ National Institute of Technology and Evaluation. 2002. Biodegradation and Bioaccumulation of the Existing Chemical Substances under the Chemical Substances Control Law. Available online at http://www.safe.nite.go.jp/english/kizon/KIZON_start_hazkizon.html as of August 10, 2010.

⁷ Test substance did not meet the criteria for ready biodegradability in OECD Guideline 301D (closed bottle test); however, the sponsor states that the test substance should be classified as biodegradable.

⁸ Federal Register. 1999. Category for Persistent, Bioaccumulative, and Toxic New Chemical Substances. *Federal Register* 64, Number 213 November 4, 1999) pp. 60194–60204.

RA = read across

Table 10. Environmental Fate Characteristics of Fatty Nitrogen-Derived Amines : Dimethylalkylamines and Dialkylamines¹						
Property	SPONSORED CHEMICAL 1-Decanamine, N-decyl-N-methyl-	SPONSORED CHEMICAL Amines, di-C14-18-alkylmethyl²	SPONSORED CHEMICAL Amines, di-C12-18-alkyl²	SPONSORED CHEMICAL 1-Octadecanamine, N-methyl-N-octadecyl-	SPONSORED CHEMICAL Amines, bis(hydrogenated tallow alkyl)methyl²	SPONSORED CHEMICAL Amines, ditallow alkyl²
	Value	Value	Value	Value	Value	Value
CASRN	7396-58-9	67700-99-6	68153-95-7	4088-22-6	61788-63-4	68783-24-4
Photodegradation Half-life	1.2 hours (estimated) ³	1.0 hours (estimated) ³	1.1 hours (estimated) ³	1.0 hours (estimated) ³	1.0 hours (estimated) ³	0.5 hours (estimated) ³
Hydrolysis Half-life	Stable					
Biodegradation	No data (RA) Readily Biodegradable	No data (RA) Readily Biodegradable	No data (RA) Readily Biodegradable	No data (RA) Readily Biodegradable	100% in 28 days (readily biodegradable); 75% in 28 days (readily biodegradable)	No data (RA) Readily Biodegradable
Bioaccumulation Factor	BAF = 1,500 (estimated) ³	BAF = 3 (estimated) ³	BAF = 83 (estimated) ³	BAF = 0.95 (estimated) ³	BAF = 0.95 (estimated) ³	BAF = 1.2 (estimated) ³
Log K _{oc}	5.6 (estimated) ³	8.7 (estimated) ³	8.2 (estimated) ³	9.8 (estimated) ³	9.8 (estimated) ³	9.8 (estimated) ³
Fugacity (Level III Model) ³						
Air (%)	0.2	0.1	0.2	<0.1	<0.1	<0.1
Water (%)	22.6	17.0	23.7	17	17	18
Soil (%)	70.5	82.9	76.1	83	83	82
Sediment (%)	6.7	<0.1	<0.1	<0.1	<0.1	<0.1
Persistence ⁴	P1 (low)	P1 (low)	P1 (low)	P1 (low)	P1 (low)	P1 (low)
Bio-accumulation ⁴	B2 (moderate)	B1 (low)	B1 (low)	B1 (low)	B1 (low)	B1 (low)

¹American Chemistry Council. 2003. Revised Robust Summary and Test Plan for Fatty Nitrogen-Derived Amines Category. Available online at <http://www.epa.gov/chemrtk/pubs/summaries/amines/c14171tc.htm> as of July 15, 2010.

² Estimated data provided are based on the typical representative structure; see Appendix for detailed information on the structures.

³ U.S. EPA. 2010. Estimation Programs Interface Suite™ for Microsoft® Windows, v4.00. U.S. Environmental Protection Agency, Washington, DC, USA. Available online at <http://www.epa.gov/opptintr/exposure/pubs/episuitedi.htm> as of July 12, 2010.

⁴ Federal Register. 1999. Category for Persistent, Bioaccumulative, and Toxic New Chemical Substances. *Federal Register* 64, Number 213 (November 4, 1999) pp. 60194–60204.
RA = Read Across

Table 11. Environmental Fate Characteristics of Fatty Nitrogen-Derived Amines: Dimethylalkylamines and Dialkylamines¹			
Property	SUPPORTING CHEMICAL Amines, dicoco alkyl²	SUPPORTING CHEMICAL Amines, dicoco alkylmethyl²	SUPPORTING CHEMICAL Amines, bis(hydrogenated tallow alkyl)²
CASRN	61789-76-2	61788-62-3	61789-79-5
Photodegradation Half-life	1.1 hours (estimated) ³	1.1 hours (estimated) ³	1.0 hours (estimated) ³
Hydrolysis Half-life	Stable		
Biodegradation	20% in 28 days (not readily biodegradable) ⁴	82% in 28 days (readily biodegradable)	16% in 28 days (not readily biodegradable) ⁵
Bioaccumulation Factor	BAF = 2.2×10^4 (estimated) ³	BAF = 420 (estimated) ³	BAF = 1.0 (estimated) ³
Log K _{oc}	6.7 (estimated) ³	6.6 (estimated) ³	9.8 (estimated) ³
Fugacity (Level III Model) ³			
Air (%)	0.2	0.1	0.1
Water (%)	24.1	17.8	17.0
Soil (%)	74.2	80.8	82.9
Sediment (%)	1.5	1.3	<0.1
Persistence ⁶	P1 (low)	P1 (low)	P1 (low)
Bioaccumulation ⁶	B3 (high)	B1 (low)	B1 (low)

¹American Chemistry Council. 2003. Revised Robust Summary and Test Plan for Fatty Nitrogen-Derived Amines Category. Available online at <http://www.epa.gov/chemrtk/pubs/summaries/amines/c14171tc.htm> as of July 15, 2010.

² Supporting chemicals. Estimated data provided are based on the typical representative structures; see Appendix for detailed information on the structures.

³ U.S. EPA. 2010. Estimation Programs Interface Suite™ for Microsoft® Windows, v4.00. U.S. Environmental Protection Agency, Washington, DC, USA. Available online at <http://www.epa.gov/opptintr/exposure/pubs/episuitedl.htm> as of July 12, 2010.

⁴ The purity of the test substance was 87.8%. The sponsor states that this test result is inconsistent with expected results based on similar chemicals; adsorption may have had an impact on the bioavailability of the test material since these types of substances are known to adsorb to solids.

⁵ The sponsor states that due to inconsistency with related chemicals, it is possible that the solubility of the test substance was inadequate for biodegradation using this method (OECD Guideline 301F, Respirometric method).

⁶ Federal Register. 1999. Category for Persistent, Bioaccumulative, and Toxic New Chemical Substances. *Federal Register* 64, Number 213 (November 4, 1999) pp. 60194–60204.

Table 12. Environmental Fate Characteristics of Fatty Nitrogen-Derived Amines: Trialkylamines¹

Property	SPONSORED CHEMICAL Amines, tri-C8-10-alkyl ²	SPONSORED CHEMICAL Amines, tris(hydrogenated tallow alkyl) ²	SPONSORED CHEMICAL Ethanol, 2,2'-iminobis-, N-coco alkyl derivs. ²	SPONSORED CHEMICAL Ethanol, 2,2'-iminobis-, N-tallow alkyl derivs. ²
	Value	Value	Value	Value
CASRN	68814-95-9	61790-42-9	61791-31-9	61791-44-4
Photodegradation Half-life	1.0 hours (estimated) ³	0.8 hours (estimated) ³	1.1 hours (estimated) ³	0.7 hours (estimated) ³
Hydrolysis Half-life	Stable			
Biodegradation	No data (RA) Readily Biodegradable	No data (RA) Readily Biodegradable	61% in 28 days (readily biodegradable)	52% in 28 days (readily biodegradable) ⁴
Bioaccumulation Factor	BAF = 320 (estimated) ³	BAF = 0.89 (estimated) ³	BAF = 21 (estimated) ³	BAF = 97 (estimated) ³
Log K _{oc}	6.9 (estimated) ³	14 (estimated) ³	2.2 (estimated) ³	3.8 (estimated) ³
Fugacity (Level III Model) ³				
Air (%)	0.2	<0.1	<0.1	0.1
Water (%)	24.4	16	22.1	23.3
Soil (%)	74.9	84	77.7	73.3
Sediment (%)	0.6	<0.1	0.2	3.4
Persistence ⁵	P1 (low)	P1 (low)	P1 (low)	P1 (low)
Bioaccumulation ⁵	B1 (low)	B1 (low)	B1 (low)	B1 (low)

¹American Chemistry Council. 2003. Revised Robust Summary and Test Plan for Fatty Nitrogen-Derived Amines Category. Available online at <http://www.epa.gov/chemrtk/pubs/summaries/amines/c14171tc.htm> as of July 15, 2010.

² Estimated data provided are based on the typical representative structure; see Appendix for detailed information on the structures.

³ U.S. EPA. 2008. Estimation Programs Interface Suite™ for Microsoft® Windows, v3.20. United States Environmental Protection Agency, Washington, DC, USA. Available online at <http://www.epa.gov/opptinr/exposure/pubs/episuite.htm> as of August 10, 2010.

⁴ The sponsor classified the test substance as readily biodegradable because biodegradation proceeded rapidly after an initial lag of 15 days.

⁵ Federal Register. 1999. Category for Persistent, Bioaccumulative, and Toxic New Chemical Substances. *Federal Register* 64, Number 213 (November 4, 1999) pp. 60194–60204.
RA = Read Across

3. Human Health Hazard

The human health data are summarized in Tables 13 to 16. The tables also indicate where data for tested category members are read-across (RA) to untested members of the category.

Acute Oral Toxicity

Subcategory I: Non-Hydroxylated FND Amines

Dodecylamine (CASRN 124-22-1)

Wistar rats (5/sex/dose) were administered dodecylamine via gavage at 2000 mg/kg and observed for 14 days. There were no mortalities.

LD₅₀ > 2000 mg/kg

N-Tallow alkyltrimethylenediamines (CASRN 61791-55-7)

Sprague-Dawley rats (5/sex/dose) were administered amines, N-tallow alkyltrimethylenedi- in arachis oil via gavage at 5000 mg/kg and observed for 14 days. One male and one female died.

LD₅₀ > 5000 mg/kg

N,N-Dimethyl-1-tetradecanamine (CASRN 112-75-4)

(1) CD strain rats (5/sex/dose) were administered N,N-dimethyl-1-tetradecanamine (“Farmin DM40”) in corn oil via gavage at 500 or 2000 mg/kg and observed for 14 days. Mortalities occurred at 2000 mg/kg (2/5). The LD₅₀ was calculated based on the slope of the dose-response curve.

LD₅₀ = 2116 mg/kg

(2) Wistar rats (5 females/dose; 5 males at 1400 mg/kg) were administered N,N-dimethyl-1-tetradecanamine (“Genamin 14R 302D”) in sesame oil via gavage at 1250, 1400 or 1600 mg/kg and observed for 14 days. Mortalities occurred in females at all dose levels; 20, 80 and 100% at 1250, 1400 and 1600 mg/kg.

LD₅₀ = 1320 mg/kg

(3) Wistar rats (10 males/dose) were administered N,N-dimethyl-1-tetradecanamine (“ADMA 4”) via gavage at 300, 600, 1220 or 5000 mg/kg and observed for 14 days. Mortalities occurred at 600 (2/10), 1220 (9/10) and 5000 (10/10) mg/kg. This study is a TSCATS submission and can be retrieved by typing in the CASRN at the following link: <http://www.srcinc.com/what-we-do/databaseforms.aspx?id=384>.

LD₅₀ = 720 mg/kg

N,N-Dimethyl-1-hexadecanamine (CASRN 112-69-6)

(1) Albino rats (5/sex/dose) were administered N,N-dimethyl-1-hexadecanamine (“Armeen DM16D”) via gavage at 0.50, 0.75, 1.0, 2.0, 4.0 or 8.0 mL/kg (the first four dose levels diluted in 10% gum Arabic and the highest two not diluted) and observed for 14 days. Mortality was 100% at 2, 4 and 8 mL/kg; 90% at 1 mL/kg; 20% at 0.75 and 10% at 0.5 mL/kg. The LD₅₀ value was 0.80 mL/kg.

LD₅₀ = 641 mg/kg [calculated using a density of 0.801 g/mL]

(2) Sprague-Dawley rats (5/sex/dose) were administered N,N-dimethyl-1-hexadecanamine via gavage at 2000 mg/kg and observed for 14 days. Mortalities occurred at 2000 mg/kg (three males and one female).

LD₅₀ > 2000 mg/kg (combined)

(3) CD rats (5/sex/dose) were administered N,N-dimethyl-1-hexadecanamine (“Farmin DM60”) in corn oil via gavage at 500 or 2000 mg/kg and observed for 14 days. No animals died at 500 mg/kg, but all animals died at 2000 mg/kg.

LD₅₀ = 1015 mg/kg (combined)

(4) Wistar rats (10 males/dose) were administered N,N-dimethyl-1-hexadecanamine (“ADMA 6”) via gavage at 150, 300, 600, 1220 and 5000 mg/kg and observed for 14 days. Mortalities occurred at all doses above 150 mg/kg: 300 (1/10), 600 (4/10) and all animals (10/10) at the highest two doses. This study is a TSCATS submission and can be retrieved by typing in the CASRN at the following link: <http://www.srcinc.com/what-we-do/databaseforms.aspx?id=384> .

LD₅₀ = 620 mg/kg (males)

N,N-Dimethyl-1-octadecanamine (CASRN 124-28-7)

(1) Albino rats (5/sex/dose) were administered N,N-dimethyl-1-octadecanamine (“Armeen DM18D”) via gavage at 0.5, 0.75, 1.0, 2.0, 4.0 or 8.0 mL/kg (the first four dose levels diluted in 10% gum Arabic and the highest two levels were not diluted) and observed for 14 days.

Mortalities occurred at ≥ 0.75 mL/kg. Mortality was 100% at 2, 4 and 8 mL/kg; 70% at 1 mL/kg; 50% at 0.75 and 0% at 0.5 mL/kg. The LD₅₀ value was 0.78 mL/kg.

LD₅₀ = 624 mg/kg [calculated using a density of 0.8 g/mL]

(2) Sprague-Dawley rats (5/sex/dose) were administered N,N-dimethyl-1-octadecanamine (“Farmin DM80”) in corn oil via gavage at 500 or 2000 mg/kg and observed for 14 days. Mortalities occurred at the highest dose (2/5 males and 2/5 females). The LD₅₀ value was calculated using Probit analysis.

LD₅₀ = 2116 mg/kg (combined)

Amines, hydrogenated tallow alkyl dimethyl (CASRN 61788-95-2)

Sprague-Dawley rats (5/sex/dose) were administered amines, hydrogenated tallow alkyl dimethyl in arachis oil via gavage at 2000 mg/kg and observed for 14 days. One male and one female died.

LD₅₀ > 2000 mg/kg

Amines, dimethylsoya alkyl (CASRN 61788-91-8)

Albino rats (5/sex/dose) were administered amines, dimethylsoya alkyl (“Armeen DMSD”) in gum arabic (except for two highest dose groups, which were given with no vehicle) via gavage at 0.5, 0.75, 1.0, 2.0, 4.0 or 8.0 mL/kg and observed for 14 days. Mortalities occurred at ≥ 0.75 mL/kg; 0, 30 and 80% at 0.5, 0.75 and 1 mL/kg, respectively and 100% at 2, 4 and 8 mL/kg. The LD₅₀ was 0.835 mL/kg.

LD₅₀ = 835 mg/kg [based on the density of chemical ~ 1 g/mL]

1-Octadecanamine, N-methyl-N-octadecyl (CASRN 4088-22-6)

(1) Wistar rats (5/sex/dose) were administered 1-octadecanamine, N-methyl-N-octadecyl (“Genamin SH 301”) in sesame oil via gavage at 2000 mg/kg and observed for 14 days. No mortalities occurred.

LD₅₀ > 2000 mg/kg

(2) Sprague-Dawley rats (5/sex/dose) were administered 1-octadecanamine, N-methyl-N-octadecyl (“E8220”) via gavage at 5000 mg/kg and observed for 14 days. No mortalities occurred.

LD₅₀ > 5000 mg/kg

Dihydrogenated tallow methylamine (CASRN 61788-63-4)

(1) Sprague-Dawley rats (5/sex/dose) were administered dihydrogenated tallow methylamine (“Armeen M2HT”) in methyl cellulose via gavage at 5.0 g/kg and observed for 14 days. No mortalities occurred.

LD₅₀ > 5000 mg/kg

(2) Sprague-Dawley rats (5/sex/dose) were administered dihydrogenated tallow methylamine (“B0390Adogen 243”) in mineral oil via gavage at 15 g/kg and observed for 14 days. No mortalities occurred.

LD₅₀ > 15000 mg/kg

Octadecylamine (CASRN 124-30-1, supporting chemical)

Wistar rats (5/sex/dose) were administered octadecylamine (“Genamin 18 R 100D”) in sesame oil via gavage at 2000 mg/kg and observed for 14 days. One mortality occurred at 2000 mg/kg.

LD₅₀ > 2000 mg/kg

Coco alkyl amines (CASRN 61788-46-3, supporting chemical)

(1) Wistar rats (5/sex/dose) were administered coco alkyl amines (“Armeen C”) in arachis oil via gavage at doses ranging from 0.5 to 2.0 g/kg and observed for 14 days. Mortalities occurred at all dose levels and it was 11, 20, 40 and 100% at 0.5, 1, 1.5 and 2 g/kg, respectively.

LD₅₀ = 1300 mg/kg (combined)

(2) In two studies, Sprague-Dawley albino rats (5/sex/dose) were administered coco alkyl amines (“Armeend CD”) in distilled water via gavage at doses between 1.8 and 6.0 g/kg and observed for 14 days. Mortalities occurred at ≥ 2.56 g/kg in the first test and no mortalities occurred in the second test at 6.0 g/kg.

LD₅₀ = 2040 – > 6000 mg/kg

Tallow alkyl amines (CASRN 61790-33-8, supporting chemical)

(1) Wistar rats (5/sex/dose) were administered tallow alkyl amines (“Genamin TA 100D”) in sesame oil via gavage at 2000 mg/kg (females and males) or 2500 mg/kg (males only) and observed for 14 days. One male in each treated groups died and no females died.

LD₅₀ > 2000 mg/kg

(2) WISW–SPF TNO rats (5/sex/dose) were administered tallow alkyl amines (“Armeen T”) at 1.5, 2.5, 3.5 and 5.0 mL/kg and observed for 14 days. Mortalities occurred at all dose levels and was 20, 50, 70 and 100% at 1.5, 2.5, 3.5 and 5.0 mL/kg. The LD₅₀ was 2.4 mL/kg.

LD₅₀ = 1944 mg/kg (combined) [calculated using a density of 0.81 g/mL]

Cis-9-Octadecenylamine (CASRN 112-90-3, supporting chemical)

Sprague-Dawley rats (5/sex/dose) were administered *cis*-9-octadecenylamine via gavage at 200, 500, 1000 or 2000 mg/kg and observed for 14 days. Mortalities occurred at 200 and ≥ 1000 mg/kg and it was 10%, 0%, 20% and 70% at 200, 500, 1000 and 2000 mg/kg, respectively.

LD₅₀ = 1689 mg/kg (combined)

N,N-Dimethyl-1-dodecanamine (CASRN 112-18-5, supporting chemical)

(1) Male Wistar rats (10 dose) were administered N,N-dimethyl-1-dodecanamine (“Armeen DM12D”) via gavage at doses of 0.60 – 5.0 g/kg and observed for 14 days. Mortalities occurred at ≥ 0.96 g/kg and it was 0, 30, 70, 100 and 100% at 0.6, 0.96, 1.54, 2.47, and 5.0 g/kg.

LD₅₀ = 1220 mg/kg

(2) Male Wistar rats (10 dose) were administered N,N-dimethyl-1-dodecanamine (“ADMA 2”) in either Mazola oil or no vehicle via gavage at doses of 0.072 – 5.0 g/kg and observed for 14 days. Mortalities occurred at ≥ 0.30 g/kg and it was 0, 20, 60, and 100% at 0.072, 0.3, 1.22 and 5.0 g/kg, respectively.

LD₅₀ = 790 mg/kg

Subcategory II: Hydroxylated FND Amines

N-Coco alkyl derivatives of 2,2'-iminobis ethanol (CASRN 61791-31-9)

Wistar rats (3/sex/dose) were administered N-coco alkyl derivatives of 2,2'-iminobis ethanol via gavage at 5.0, 6.3, 7.01, 7.94 or 10.0 g/kg and observed for 14 days. Mortalities occurred at all doses: 1/6 at 5.0 g/kg; 3/6 at both 6.3 and 7.01 g/kg; 4/6 at 7.94 g/kg; and 6/6 at 10.0 g/kg.

LD₅₀ ~ 6300 mg/kg

N-Tallow alkyl derivatives of 2,2'-iminobis ethanol (CASRN 61791-44-4)

Six studies show the variation in acute oral toxicity that is likely due to formulated product and/or vehicle used.

(1) Sprague-Dawley rats (1 – 3/sex/dose) were administered N-tallow alkyl derivatives of 2,2'-iminobis ethanol (“Ethomeen T/12”) in methyl cellulose via gavage at doses ranging from 0.8 to 5.0 g/kg and observed for 14 days. Mortalities occurred at ≥ 1.26 g/kg.

LD₅₀ = 1200 mg/kg (females) and 1500 mg/kg (males)

(2) Sprague-Dawley rats (5/sex/dose) were administered N-tallow alkyl derivatives of 2,2'-iminobis ethanol (“2EO”) in arachis oil via gavage at a dose of 2000 mg/kg and observed for 14 days. There were no mortalities.

LD₅₀ > 2000 mg/kg

(3) Albino Sprague-Dawley rats (5/sex/dose) were administered N-tallow alkyl derivatives of 2,2'-iminobis ethanol (“Varonic T-220”) via gavage at doses ranging from 0.547 to 1.071 g/kg

and observed for 14 days. Mortalities occurred at ≥ 0.765 g/kg; 0, 40, 50 and 80% at 0.547, 0.765, 0.918 and 1.071 g/kg, respectively.

LD₅₀ = 890 mg/kg

(4) Albino Sprague-Dawley rats (5/sex/dose) were administered N-tallow alkyl derivatives of 2,2'-iminobis ethanol ("Varonic T-220") via gavage at doses ranging from 160 to 6250 mg/kg and observed for 14 days. Mortalities occurred at ≥ 400 mg/kg; 0, 20, 80, 100 and 100% at 160, 400, 1000, 2500 and 6250 mg/kg, respectively.

LD₅₀ = 630 mg/kg

(5) Albino Sprague-Dawley rats (5/sex/dose) were administered N-tallow alkyl derivatives of 2,2'-iminobis ethanol ("POE)₂₀ Tallowamine T-220D") via gavage at doses ranging from 0.69 to 1.36 g/kg and observed for 14 days. Mortalities occurred at ≥ 0.97 g/kg; 0, 20, 50, and 90% at 0.69, 0.97, 1.17 and 1.36 g/kg, respectively.

LD₅₀ = 1150 mg/kg

(6) Albino Sprague-Dawley rats (5/sex/dose) were administered N-tallow alkyl derivatives of 2,2'-iminobis ethanol ("Ethomeen 18/60") in distilled water via gavage at a dose of 15.0 g/kg and observed for 14 days. There were two mortalities (one male and one female).

LD₅₀ > 15,000 mg/kg

Acute Inhalation Toxicity

Subcategory I: Non-Hydroxylated FND Amines

Coco alkyl amines (CASRN 61788-46-3, supporting chemical)

Male Sprague-Dawley rats (10/dose) were exposed to coco alkyl amines ("Armeen C") via whole-body inhalation at vapor concentrations of 0.063 and 0.099 mg/L for one hour and were observed for 14 days. There were no mortalities.

LC₅₀ > 0.099 mg/L (one hour exposure)

Subcategory II: Hydroxylated FND Amines

N-Tallow alkyl derivatives of 2,2'-iminobis ethanol (CASRN 61791-44-4)

Sprague-Dawley rats (5/sex/dose) were exposed to N-tallow alkyl derivatives of 2,2'-iminobis ethanol via whole body inhalation at an aerosol concentration of 0.6 mg/L (generated by heating) for four hours and were observed for 14 days. There were no mortalities.

LC₅₀ > 0.6 mg/L

Acute Dermal Toxicity

Subcategory I: Non-Hydroxylated FND Amines

N,N-Dimethyl-1-tetradecanamine (CASRN 112-75-4)

New Zealand White rabbits (4/dose) (number per sex not stated) were administered N,N-dimethyl-1-tetradecanamine ("ADMA 4") via the dermal route at 2680, 5200, 10,200 or 20,000 mg/kg under occluded conditions for 24 hours and observed for 14 days. Skin abrasions were made on half of the animals. Mortalities occurred at all dose levels: 2680 mg/kg (1/4), 5200

(2/4) and all animals (4/4) at the highest two dose levels. (TSCATS: <http://www.srcinc.com/what-we-do/databaseforms.aspx?id=384>)

LD₅₀ = 4400 mg/kg

N,N-Dimethyl-1-hexadecanamine (CASRN 112-69-6)

New Zealand White rabbits (4/dose) (sex not stated) were administered N,N-dimethyl-1-hexadecanamine (“Armeen DM16D”, undiluted) via the dermal route at 4.0, 6.0 or 8.0 mL/kg under occluded conditions for 24 hours and observed for 14 days. Mortalities occurred at all doses; 50, 75 and 100% at 4, 6 and 8 mL/kg, respectively. The LD₅₀ value was 4.29 mL/kg.

LD₅₀ ~ 3432 mg/kg [calculated using a density of 0.8 g/mL]

N,N-Dimethyl-1-octadecanamine (CASRN 124-28-7)

(1) New Zealand White rabbits (4/dose) (sex not stated) were administered N,N-dimethyl-1-octadecanamine (“Armeen DM18D”, undiluted) via the dermal route at 4, 6 or 8 mL/kg under occluded conditions for 24 hours and observed for 14 days. Mortalities occurred at all doses; 50, 75 and 100% at 4, 6 and 8 mL/kg, respectively. The LD₅₀ value was 4.29 mL/kg.

LD₅₀ ~ 3432 mg/kg [calculated using a density of 0.8 g/mL]

(2) New Zealand White rabbits (4/dose) (sex not stated) were administered N,N-dimethyl-1-octadecanamine (“ADMA 8”) via the dermal route at 1000, 4000 or 16,000 mg/kg under occluded conditions for 24 hours and observed for 14 days. Mortalities occurred at the mid (1/4) and high (3/4) dose levels. (TSCATS: <http://www.srcinc.com/what-we-do/databaseforms.aspx?id=384>)

LD₅₀ = 8000 mg/kg

Amines, dimethylsoya alkyl (CASRN 61788-91-8)

New Zealand White rabbits (4/dose) (sex not stated) were administered amines, dimethylsoya alkyl (“Armeen DMSD”, undiluted) via the dermal route at 2, 4 or 8 mL/kg under occluded conditions for 24 hours and observed for 14 days. Mortalities occurred at ≥ 4 mL/kg; 0, 75, 100% at 2, 4, 8 mL/kg, respectively. The LD₅₀ value was 3.0 mL/kg.

LD₅₀ ~ 2400 mg/kg [calculated using a density of 0.8 g/mL]

1-Octadecanamine, N-methyl-N-octadecyl (CASRN 4088-22-6)

New Zealand White rabbits (3/sex/dose) were administered 1-octadecanamine, N-methyl-N-octadecyl (“E8220”, undiluted/wax-like solid) via the dermal route at 2 g/kg under occluded conditions for 24 hours and observed for 14 days. The skin on half of the animals was abraded. Mortalities occurred at 2 g/kg (one male and one female).

LD₅₀ > 2000 mg/kg

Coco alkyl amines (CASRN 61788-46-3, supporting chemical)

(1) In two rabbit studies, New Zealand White rabbits (3/sex/dose) were administered coco alkyl amines (“Armeen CD”, undiluted) via the dermal route at 2.0 mL/kg under occluded conditions for 24 hours and observed for 14 days. One male and two females per group had their skin abraded for the study. No mortalities occurred in either the abraded or intact animals in one study and one intact male died in the second study (the latter was considered not treatment-related).

LD₅₀ > 2000 mg/kg [density of chemical is ~ 1 g/mL]

(2) Sprague-Dawley rats (2/sex/dose) were administered coco alkyl amines (“Amine KK”) via the dermal route at doses of 500 (neat substance) or 2000 (in distilled water) mg/kg under occluded conditions for 24 hours and observed for 14 days. No mortalities occurred.

LD₅₀ > 2000 mg/kg

N,N-Dimethyl-1-dodecanamine (CASRN 112-18-5, supporting chemical)

New Zealand White rabbits (4/dose) (females and males; number per sex not stated) were administered N,N-dimethyl-1-dodecanamine (“ADMA 2”) via the dermal route at 20.0, 10.2, 5.2 or 2.68 g/kg under occluded conditions for 24 hours and observed for 14 days. Abrasions were made on half the animals. Mortalities occurred at all dose levels; 50, 25, 100 and 100% at 2.68, 5.20, 10.2 and 20.0 g/kg, respectively.

LD₅₀ ~ 5000 mg/kg

Subcategory II: Hydroxylated FND Amines

N-Tallow alkyl derivatives of 2,2'-iminobis ethanol (CASRN 61791-44-4)

In four different studies, New Zealand White rabbits (3/sex/dose) were administered N-tallow alkyl derivatives of 2,2'-iminobis ethanol via the dermal route at 2 mL/kg (undiluted) under occluded conditions for 24 hours and observed for 14 days. Three different formulations were used: Varonic T-220D, Varonic T-220 (two studies; one of which had half the animals exposed to a 50% dilution of the test material) and Ethomeen 18/60. In all studies, half the animals had their skin abraded and the other half had intact skin. Mortalities occurred in only one of the two studies with Varonic T-220 (4/6 animals died – all in undiluted groups and no difference between intact and abraded skin). For the purposes of this hazard characterization, the LD₅₀ will be conservatively estimated to be the only dose level tested.

LD₅₀ ~ 1600 mg/kg [one study only; calculated using a density of 0.8 g/mL]

Repeated-Dose Toxicity

Subcategory I: Non-Hydroxylated FND Amines

1-Octadecanamine, N-methyl-N-octadecyl (CASRN 4088-22-6)

(1) Sprague-Dawley CD rats (20/sex/dose) were administered 1-octadecanamine, N-methyl-N-octadecyl daily for 13 weeks via the diet. Original doses were 0, 0.15, 0.5 and 1.5% w/w, but after 4 weeks, the doses were adjusted to 0, 0.15, 0.4 and 1.0% w/w due to marked depression of body weight gain at the high dose. Mean doses over weeks 1 – 13 were 117, 343 or 936 mg/kg/day (males) and 139, 406 or 1076 mg/kg/day (females). There were no mortalities. Alopecia was observed in the high-dose group. Body weight gains of rats in all dosed groups were lower than controls (but statistically significant only at the mid and high doses). Food consumption and food conversion efficiency were decreased at the high dose. The absolute weights of most organs (no specific information provided) were decreased in the high (males and females) and mid (males) dose groups. Relative weights of liver, testes, kidneys and lungs were increased in all treated groups (no specific information provided). Significant increased leukocyte counts and reductions in hemoglobin concentration were seen in all dosed groups. Significant reductions in packed cell volume were seen in the mid- and high-dose groups. Accumulation of histiocytes with foamy cytoplasm was found in all dose groups in the lamina propria of the jejunum, in the mesenteric lymph nodes and to a lesser extent in other tissues. Degenerative changes were also seen in the lymph nodes at the high dose and some animals

(doses unclear) had peritonitis. In the ovaries, foamy interstitial cells were detected in all dosed groups.

LOAEL ~ 117 mg/kg/day (based on decrease body weight gain, increased weights of liver, testes, kidneys and lungs, hematologic changes, accumulation of histiocytes with foamy cytoplasm in jejunum and lymph nodes and foamy interstitial cells in the ovaries)

NOAEL = Not established

(2) New Zealand White rabbits (5/sex/dose) were administered 1-octadecanamine, N-methyl-N-octadecyl once daily, 5 days/week, for 13 weeks via dermal application. Doses were 0 (carrier control), 5 or 50 mg/kg/day. The test material (and vehicle control – polyethylene glycol) were applied to non-abraded skin with a syringe and left for seven hours before removal (presence of a covering was not noted in the summary). Clinical observations included skin sensitivity to touch and raised vesicles at the exposure site. Group mean body weight of the 50 mg/kg/day group was reduced compared to controls. Skin irritation was present in both dose groups, with a higher severity at the high dose level. In addition to the reduction in body weight, other, mild systemic effects observed at the high dose group were: decreased hemoglobin concentration, red blood cell count and packed cell volume (females); pathological changes in the liver (increased incidence of intralobular leukocyte foci) and the presence of epithelioid cells in the mesenteric lymph node.

LOAEL (systemic) = 50 mg/kg/day (based on decreased body weight, slight changes in hematology parameters, and pathological changes in the liver and lymph node)

NOAEL (systemic) = 5 mg/kg/day

LOAEL (local) = 5 mg/kg/day (based on skin irritation, skin sensitivity to touch and raised vesicles at the exposure site)

NOAEL (local) = Not established

Octadecylamine (CASRN 124-30-1, supporting chemical)

Mongrel dogs (3/dose) (male and female number per group not specified) were administered octadecylamine (containing 20% hexadecylamine) once daily, 5 days/week for 1 year via a capsule administered orally at doses of 0, 0.6, 3.0 or 15.0 mg/kg/day. One dog treated with 15 mg/kg/day of the test substance died after 22 weeks of treatment. Weight gains were smaller in the 15 mg/kg/day group than controls. No significant hematological effects considered to be treatment-related were observed. Pale staining was observed in the tips of the villi of the small intestinal mucosa of two dogs treated with 15 mg/kg/day and sinuses of the mesenteric lymph nodes were filled with pale foamy histiocytes. No significant changes in organ characteristics were observed.

LOAEL = 15 mg/kg/day (based on mortality, decreased weight gain and intestinal pathological changes)

NOAEL = 3 mg/kg/day

Hexadecylamine hydrofluoride (CASRN3151-59-5) and 9-Octadecen-1-amine hydrofluoride (CASRN 36505-83-6) (a 1:1 mixture, supporting chemical)

(1) Long-Evans rats (70/sex/dose) were administered the test substance (“Hetaflur”) via the diet at doses of 1.2, 6 and 30 mg/kg/day continuously for two years. There were two control groups (further explanation not provided in the robust summary). The following effects were observed in the high dose group only (except where noted): significant decrease in body weight and food

consumption (both sexes); changes in a variety of clinical chemistry values (decreases in serum glutamic pyruvic transaminase (females), alkaline phosphatase (females, also females in mid-dose group), total protein (females), calcium (males and females), cholesterol (males) and triglycerides (males and females); increases in relative liver and adrenal (males) and kidney (females) weights and decreases in absolute liver (both sexes) and kidney (males) weights. No such effects were reported for the low and mid dose groups. The description of histopathological damage was extensive, but the dose levels were not always stated. Ankylosis (stiffness of joints) occurred in a few animals at each dose. Enlarged mesenteric lymph nodes and yellow discoloration of the small intestine were observed, with incidence dependent on dose (but no details were presented on numbers seen at each dose). Reticuloendothelial cell hypertrophy and/or hyperplasia were also observed, with no information on which doses resulted in these effects. Reproductive organs were examined histologically.

LOAEL ~ 30 mg/kg/day (based on decreased body weight, changes in various clinical chemistry parameters and histopathological changes in the small intestine and lymph nodes)

NOAEL ~ 6 mg/kg/day

(2) Beagle dogs (six/sex/dose) were administered the test substance (“Hetaflur”) via gavage at doses of 1.2, 6 and 12 mg/kg/day for two years. The high dose was 30 mg/kg/day for the first five weeks, with a two-week interlude before dosing with the new high dose of 12 mg/kg/day. For the first five weeks, dogs experienced excessive salivation before and after dosing, diarrhea and emesis. Other than the effects noted for the first five weeks at 30 mg/kg/day, there were no other effects observed at any dose on body weight, food consumption, hematology, clinical chemistry (except for decreased protein levels in females), organ weight/histopathology (including the reproductive organs) for the remainder of the two year study.

NOAEL = 12 mg/kg/day (highest dose tested)

Amines, tallow alkyl (CASRN 61790-33-8, supporting chemical)

Sprague-Dawley rats (5/sex/dose) were administered amines, tallow alkyl (“Genamin TA 100D”) once daily for 28 days via gavage at doses of 0, 12.5, 50 or 150 mg/kg/day. One mortality occurred in the 50 mg/kg/day group and five mortalities occurred in the 150 mg/kg/day group. Significant decreases in body weights, body weight gains and food consumption were shown in groups treated with 50 and 150 mg/kg/day. Salivation (all animals in the mid- and high-dose groups) and piloerection (all animals at the high dose group and females only at the mid-dose group) were observed. A variety of hematology and clinical chemistry differences were observed between treated and control groups. Decreases in the following parameters were seen in one or both sexes at both the mid and high doses (unless noted): mean corpuscular volume (MCV), bilirubin, albumin/globulin ratio, total protein/, creatinine (high dose only), cholesterol (high dose only) and blood glucose (high dose only). Increases in the following were also seen in one or both sexes at the mid and high doses (unless noted): ALAT activity, white blood cells, platelets, prothrombin time, red blood cells, ASAT (high dose only), GGT (high dose only) and BUN (high dose only). The only hematology/clinical chemistry findings observed in the low dose group were decreased MCV in females and increased ALAT and decreased potassium and bilirubin in males. In the high dose group, absolute weights of liver and kidneys (males only) and heart and thymus (both sexes) were decreased. Again in the high dose group, the relative weights were increased in the following organs: brain, adrenals and liver (both sexes); kidney (females); and testes and epididymides (males). In the mid-dose group, the

absolute liver and kidney weights were decreased in males and the relative kidney weight was increased in females. Histological changes at 12.5, 50 and 150 mg/kg/day included histiocytosis (with vacuolization of histiocytes) in both the small intestine and the lymph nodes in both sexes. Additional histopathological changes were at the mid and high dose level in the liver (necrosis), lungs (inflammation), and thymus (depletion of lymphocytes).

LOAEL = 12.5 mg/kg/day (based on changes in hematology and clinical chemistry and histopathological effects in the small intestine and lymph nodes)

NOAEL = Not established

Subcategory II: Hydroxylated FND Amines

N-Tallow alkyl derivatives of 2,2'-iminobis ethanol (CASRN 61791-44-4)

(1) Wistar SPF rats (17 rats/sex/high dose and 25/sex/all other doses) were administered N-tallow alkyl derivatives of 2,2'-iminobis ("Ethomeen T/12") daily for 90 days via the diet at concentrations of 0, 170, 500, 1500 or 4500 ppm (approximately 0, 15, 50, 150 or 450 mg/kg/day). Seven of the high dose rats were sacrificed at intervals up to 6 weeks from the beginning of the test. There were no mortalities. High dose rats lost hair and generally were lethargic throughout the study. No clinical observations were noted in rats at any other dietary level. Body weight gain was inhibited at 450 mg/kg/day and partly inhibited at 150 mg/kg/day. The palatability of the diet (basis not indicated) was decreased at 150 and 450 mg/kg/day. No hematological abnormalities were detected at any dose. No significant differences were seen between treated and control group organ weights. Gross macroscopic observations at necropsy were seen only at 450 mg/kg/day and consisted of yellow coloration of the stomach and bowel contents and thickening and yellow coloration of the mucosa of the small intestine and the regional mesenteric nodes. Microscopic findings observed in high and mid-dose animals were engorgement of the villi and lamina propria of the small intestine with swollen foamy macrophages. Similar macrophages were present in Peyer's patches and in regional lymph nodes.

LOAEL ~ 150 mg/kg/day (based on gross and microscopic effects on the small intestinal and lymph nodes)

NOAEL ~ 50 mg/kg/day

(2) CrI:CD(SD)BR rats (20/sex/dose) were administered N-tallow alkyl derivatives of 2,2'-iminobis ethanol ("E1095.01") daily for 13 weeks via the diet at concentrations of 0.001, 0.015, or 0.5% in feed (approximate doses of 0, 0.8, 12 or 400 mg/kg/day). One death (control female) and a high incidence of hair loss across all groups were not considered treatment related. Body weight gain was slightly reduced at the mid (males only) and high (males and females) levels. There were no effects on food consumption or biologically significant differences in hematology or organ weights between treatment and control groups. Histiocytosis in the jejunum and mesenteric lymph nodes at 400 mg/kg/day was the only treatment-related histopathological finding.

LOAEL ~ 400 mg/kg/day (based on reduced body weight gain and histopathologic effects on the small intestine and lymph nodes)

NOAEL ~ 12 mg/kg/day

(3) Beagle dogs (4/dose, distribution by sex not indicated) were administered N-tallow alkyl derivatives of 2,2'-iminobis ethanol ("Ethomeen T/12") via the diet at doses of 0, 13, 40 or 120

mg/kg/day for 90 days. No deaths occurred. Vomiting of the meal was seen in dogs at 40 and 120 mg/kg/day, but not at 13 mg/kg/day. Treatment of the 120 mg/kg/day group was discontinued after 5 – 6 weeks due to poor health and the loss of approximately 20% of body weight. Mid-dose males showed a decrease in body weight (significance not provided). At 120 mg/kg/day, females showed hypochromic anemia and males showed slight elevation in blood urea and serum alkaline phosphate. No treatment-related findings were noted for urinalysis and no gross lesions were observed. Increased incidences of foamy macrophages in the small intestine and regional lymph nodes were found at 40 and 120 mg/kg/day.

LOAEL ~ 40 mg/kg/day (based on decreased body weight [males] and pathological changes in the small intestine and regional lymph nodes)

NOAEL ~ 13 mg/kg/day

(4) New Zealand White rabbits (5/sex/dose) were administered N-tallow alkyl derivatives of 2,2'-iminobis ethanol ("Varonic T-220D") dermally at doses of 0 or 2% w/v (40 mg/kg/day) 5 days/week for 4 weeks. Distilled water was used as the vehicle and skin was prepared by clipping and abrasion before each application (which was done with a syringe and gentle rubbing with a glass rod and left for seven hours). Abrasion was discontinued if skin became fissured. In addition to body weight and hematology, only liver and kidney weights were obtained.

Reproductive organs and skin were examined histologically; it is not clear which other organs were examined microscopically. Dermal irritation was most severe in Week 2, during which all groups exhibited moderate to severe erythema and edema, slight to moderate atonia, slight to marked desquamation, moderate coriaceousness and slight to severe fissuring of the exposure sites. No dermal irritation was observed in the control group. No significant differences in individual body or organ weights of treated rabbits relative to the control rabbits were observed. No treatment-related changes in hematological values were observed. Histologically, mild to moderate hyperplasia of the epidermis and mild inflammatory changes of the outer dermis were observed at the exposure sites of treated animals (specific groups not noted).

LOAEL (local) ~ 40 mg/kg/day (only dose tested)

NOAEL (systemic) ~ 40 mg/kg/day (only dose tested)

(5) New Zealand albino rabbits (5/sex/dose) were administered N-tallow alkyl derivatives of 2,2'-iminobis ("Varonic T-220") dermally at doses of 0 or 10% w/v (reduced to 2% w/v after two treatments due to severe skin reactions; 200 mg/kg/day reduced to 40 mg/kg/day) 5 days/week for 4 weeks. Although initially the skin was abraded, once the concentration dropped, abrading the skin discontinued. In addition to body weight and hematology, liver and kidney were weighed. Several tissues, including skin, were examined histologically. The test substance produced severe irritation (erythema to edema, atonia, desquamation) and a high sheen appearance following the sloughing of eschar tissue during the course of the study. Body weight losses were seen in 6 of 10 treated animals by the end of week 1, after which steady weight gain was noted. Anorexia was noted in three animals. Those same three animals, along with two others, displayed signs of rales (histopathology showed signs of focal inflammatory respiratory tract disease). No biologically significant, treatment-related effects on hematology were observed in the treated animals. Additionally, necropsy confirmed treatment-related cutaneous morphological alterations. Females exhibited decreased kidney weight.

LOAEL (local) ~ 40 mg/kg/day (only dose tested)

NOAEL (systemic) ~ 40 mg/kg/day (only dose tested)

(6) There were four dermal toxicity studies presented in the HPV submission. The two summarized above are 28-day studies. A 90-day study was terminated after 17 days and so is not presented here. In that study, rabbits were exposed (shaved, intact skin) to either 0.1 or 0.5% of the test substance (N-tallow alkyl derivatives of 2,2'-iminobis ethanol) in distilled water for seven hours after each application. After 17 days, five (1/10 low dose, 4/10 high dose) treated animals and one control had died or were sacrificed. The decision to stop the study was based on moderate/marked skin irritation that precluded an assessment of systemic toxicity because of the likely effect the irritation would have on absorption. In addition to the terminated 90-day study, one 28-day study is not presented because it resulted in excessive numbers of deaths that precluded evaluation of treatment-related effects.

Reproductive Toxicity

Subcategory I: Non-Hydroxylated FND Amines

Tallow alkyl amines (CASRN 61790-33-8, supporting chemical)

In a reproductive/developmental screening test, Sprague-Dawley Crl:CD(SD)BR rats (10/sex/dose) were administered tallow alkyl amines ("Genamin TA 100") in sesame oil via gavage at doses of 0, 12.5, 50 or 150 mg/kg/day for a 14 day pre-mating period and throughout mating, gestation and up to day 3 of lactation for females (~ 54 days); and through the pre-mating and mating periods for males (28 days). One mortality per sex was observed in the 50 mg/kg/day group and 50% mortality occurred in both sexes at 150 mg/kg/day; all were considered treatment-related. Clinical signs were observed at high (salivation, hunched posture, incidental soft stools and piloerection) and mid (salivation) doses. A dose-related decrease in pre-mating body weight gains was observed in the 50 and 150 mg/kg/day groups (all animals) and it was also seen in all doses in females during gestation. A decrease in gestational and lactational body weights was observed in females in the mid and high, and low and mid dose groups, respectively. Food consumption was decreased in both sexes at 50 and 150 mg/kg/day. Females in the 50 and 150 mg/kg/day groups also had decreased food consumption during gestation. At 150 mg/kg/day, the mating index (43% vs. 100% in controls) and fertility index (33% vs. 100% in controls) were decreased and the pre-coital interval (13.5 days vs. 2.3 days in controls) was increased. Implantation loss was 100% at 150 mg/kg/day. Gestation duration in the high dose females was also affected (no specifics provided). Males at 150 mg/kg/day showed increased relative weights of epididymis and testes (and decreased absolute weight of epididymis) and tubular degeneration with decreased spermatogenesis in the testes was seen in one male. Atrophy of corpora lutea was seen in 8 of 10 females at 150 mg/kg/day.

LOAEL (parental toxicity) = 12.5 mg/kg/day (based on decreased body weight during gestation)

NOAEL (parental toxicity) = Not established

LOAEL (reproductive toxicity) = 150 mg/kg/day (based on implantation loss, decreased mating and fertility indices, increased pre-coital time, atrophy of corpora lutea)

NOAEL (reproductive toxicity) = 50 mg/kg/day

9-Octadecen-1-amine, hydrofluoride (CASRN 3151-59-5, supporting chemical) and 9-octadecen-1-amine, hydrofluoride (CASRN 36505-83-6, supporting chemical), 1:1 mixture

In a one-generation study, Long-Evans rats (10 males and 20 females/group) were administered a 1:1 mixture of 9-octadecen-1-amine, hydrofluoride and 9-octadecen-1-amine, hydrofluoride (“Hetaflur”) in methylcellulose via gavage at doses of 0, 1.2, 6.0 or 30.0 mg/kg/day for a 60-day (males) or 15-day (females) pre-mating period and throughout mating, gestation and lactation for females. Half of the females were sacrificed on gestation day 13 and examined for the evidence and status of embryos. The other half were allowed to deliver and the pups were followed through lactation day 21. A decrease in mean body weight gain was observed in males in the high-dose group when compared to the control group. There were no adverse effects on the following parameters: mortality, female body weight gain or overall weight, mating performance, estrous cycles, pregnancy rates, lengths of gestation, intrauterine deaths, implantation efficiencies, implantation number per litter size or gross pathology results.

NOAEL (parental toxicity) = 30 mg/kg/day (highest dose tested)

NOAEL (reproductive toxicity) = 30 mg/kg/day (highest dose tested)

Subcategory II: Hydroxylated FND Amines

No data available for this endpoint.

Developmental Toxicity

Subcategory I: Non-Hydroxylated FND Amines

1-Octadecanamine, N-methyl-N-octadecyl- (CASRN 4088-22-6)

Pregnant New Zealand White rabbits (16/dose) were administered 1-octadecanamine, N-methyl-N-octadecyl- in corn oil via gavage at doses of 0, 50, 250 or 1000 mg/kg/day for days 6 through 18 of gestation. At 250 and 1000 mg/kg/day, maternal body weight gain was significantly lower during days 12 through 18 of gestation. No treatment-related effects were found on pregnancy rate, mortality, abortions or gestation length. There was a high post-implantation loss seen in the high dose group, but it was not significant given the unusually high loss observed in controls. No treatment-related effects were found on fetal size, fetal sex or mortalities; however, slight reductions in fetal weight at 250 and 1000 mg/kg/day were observed. The robust summary states that possible embryo lethality at 1000 mg/kg/day cannot be disregarded.

LOAEL (maternal toxicity) = 250 mg/kg/day (based on decreased weight gain during gestation)

NOAEL (maternal toxicity) = 50 mg/kg/day

LOAEL (developmental toxicity) = 1000 mg/kg/day (based on possible embryo lethality)

NOAEL (developmental toxicity) = 250 mg/kg/day

Tallow alkyl amines (CASRN 61790-33-8, supporting chemical)

In a reproductive/developmental screening test describe above, Sprague-Dawley Crl:CD(SD)BR rats (10/sex/group) were administered tallow alkyl amines (“Genamin TA 100”) in sesame oil via gavage at doses of 0, 12.5, 50 or 150 mg/kg/day (protocol, systemic and reproductive effects described previously). There were no litters in the high dose group. Pup body weights were decreased in the mid-dose group. There were no treatment-related effects on the sex ratio, viability index, survival or visible abnormalities for the 12.5 and 50 mg/kg/day groups.

LOAEL (maternal toxicity) = 12.5 mg/kg/day (based on decreased body weight during gestation)

NOAEL (maternal toxicity) = Not established

LOAEL (developmental toxicity) = 50 mg/kg/day (decreased pup body weight)

NOAEL (developmental toxicity) = 12.5 mg/kg/day

Cis-9-Octadecenylamine (CASRN 112-90-3, supporting chemical)

(1) Pregnant Sprague-Dawley rats (28/dose) were administered cis-9-octadecenylamine (“Oleylamine”) in corn oil via gavage at doses of 0, 10, 40 or 80 mg/kg/day for days 6 through 15 of gestation. Clinical signs (rales, salivation, soft stools, diarrhea, few/abnormal colored feces, fecal/urine staining and unkempt appearance) of toxicity were observed in the 40 and 80 mg/kg/day dose groups. High dose animals also presented emaciation, rough coat, and dark red material around the eyes/nose/mouth. Dose-dependent body weight losses or reduced weight gain, and reduction in food consumption, occurred during the treatment period in the 40 and 80 mg/kg/day dose groups. No other maternal effects were noted, including no effects on the gastrointestinal tract. There were no effects on any fetal parameter evaluated (fetal external, visceral or skeletal examinations).

LOAEL (maternal toxicity) = 40 mg/kg/day (based on clinical signs, decreased body weight)

NOAEL (maternal toxicity) = 10 mg/kg/day

NOAEL (developmental toxicity) = 80 mg/kg/day (highest dose tested)

(2) New Zealand White rabbits (22 artificially-inseminated females/group) were administered cis-9-octadecenylamine (“Oleylamine”) in corn oil via gavage at doses of 0, 3, 10 or 30 mg/kg/day for days 6 through 18 of gestation. Two females died in the high-dose group. Clinical signs (irritation of the lips and chin, labored breathing and rales) of toxicity were observed at 10 and 30 mg/kg/day. Dose-dependent body weight losses or reduced gains and reduced food consumption occurred at the 10 and 30 mg/kg/day groups (significant only in the high dose group). There were no effects on the gastrointestinal tract of the does. There were no treatment-related effects on the fetuses examined.

LOAEL (maternal toxicity) = 10 mg/kg/day (based on clinical signs, reduced body weight)

NOAEL (maternal toxicity) = 3 mg/kg/day

NOAEL (developmental toxicity) = 30 mg/kg/day (highest dose tested)

9-Octadecen-1-amine, hydrofluoride (CASRN 3151-59-5, supporting chemical) and 9-octadecen-1-amine, hydrofluoride (CASRN 36505-83-6, supporting chemical), 1:1 mixture

(1) Pregnant Long-Evans rats (20/dose) were administered 9-octadecen-1-amine, hydrofluoride and 9-octadecen-1-amine, hydrofluoride, 1:1 mixture (“Hetaflur”) in methylcellulose via gavage at doses of 0, 1.2, 6.0 and 30.0 mg/kg/day for days 6 through 15 of gestation. No adverse effects were found on maternal body weight, pregnancy rate, mortality, abortions, gestation length, implantation efficiency or resorptions. No treatment-related effects were found on fetal survival, size, sex ratio or incidence of ossification. There were sporadic malformations seen in the treated groups (total incidence was 0, 0.6, 0.5, and 3.1% in control, low, mid and high dose, respectively). No other information was provided in the robust summary.

NOAEL (maternal toxicity) = 30 mg/kg/day (highest dose tested)

LOAEL (developmental toxicity) = 30 mg/kg/day (based on unspecified malformations)

NOAEL (developmental toxicity) = 6 mg/kg/day

(2) To clarify the results of the study described above in which sporadic fetal malformations were observed, the same test substance was administered under identical conditions as those described above. In this study, there was a significant decrease in the mean weight gains of the high-dose group dams. No other adverse effects were found on pregnancy rate, mortality, gestation length, implantation efficiency or resorptions. No treatment-related effects were found on fetal size, fetal sex, incidence of ossification, incidence of malformations or mortalities. Specific incidence data were not provided.

LOAEL (maternal toxicity) = 30 mg/kg/day (based on body weight)

NOAEL (maternal toxicity) = 6 mg/kg/day

NOAEL (developmental toxicity) = 30 mg/kg/day (highest dose tested)

(3) Pregnant Long-Evans rats (20/dose) were administered 9-octadecen-1-amine, hydrofluoride and 9-octadecen-1-amine, hydrofluoride, 1:1 mixture (“Hetaflur”) in methylcellulose via gavage at doses of 0, 1.2, 6.0 and 30.0 mg/kg/day from gestation day 15 through lactation day 21. As a Segment III test, does were allowed to deliver and the offspring were followed through lactation. No significant adverse effects were found on maternal body weight (there was a slight reduction in body weight gain in high dose does only during lactation), pregnancy rate, mortality, gestation length, implantation efficiency or resorptions, live-birth index, postnatal viability, sex ratios or soft-tissue malformations. No significant treatment-related effects were found on fetal size (there was reduced mean fetal weights in all treated groups on lactation day 0, but not statistically significant compared with controls), fetal sex, incidence of ossification, incidence of malformations or mortalities. EPA considers this study of limited utility because dosing does not capture organogenesis in its entirety.

NOAEL (maternal toxicity) = 30 mg/kg/day (highest dose tested)

NOAEL (developmental toxicity) = 30 mg/kg/day (highest dose tested)

Subcategory II: Hydroxylated FND Amines

No data available for this endpoint.

Genetic Toxicity – Gene Mutation

In vitro

Subcategory I: Non-Hydroxylated FND Amines

Salmonella typhimurium assays were performed with three sponsored chemicals (CASRN 112-75-4, 112-69-6 and 124-28-7), however in each case only two bacterial strains were tested. The guidelines require at least five different *Salmonella* strains (or four *Salmonella* strains and one *E. coli* strain) since each strain identifies a different type of possible mutation. Therefore, for the purposes of the US HPV Challenge Program, these data were considered inadequate for this endpoint.

Hexadecylamine (CASRN 143-27-1)

Hexadecylamine was tested in *Salmonella typhimurium* strains TA97, TA98, TA100 and TA1535 at concentrations of 0.3, 1.0, 3.0, 10, 33, 66 or 100 µg/plate, with and without metabolic activation. Both positive and negative controls were used. Cytotoxicity was not noted. Control responses were not provided.

CASRN 143-27-1 was not mutagenic in this assay.

1-Octadecanamine, N-methyl-N-octadecyl (CASRN 4088-22-6)

1-Octadecanamine, N-methyl-N-octadecyl (“Genamin SH 301”) was tested in *Salmonella typhimurium* strains TA98, TA100, TA1535, TA1537 and TA1538 and *Escherichia coli* strain WP2uvrA at concentrations of 4, 20, 100, 500, 2500 and 5000 µg/plate with and without metabolic activation. Both positive and negative controls were used. Cytotoxicity was not observed at any concentration. Control responses were not provided.

CASRN 4088-22-6 was not mutagenic in these assays.

Dihydrogenated tallow methylamine (CASRN 61788-63-4)

(1) Dihydrogenated tallow methylamine (“Adogen 343”) was tested in *Salmonella typhimurium* strains TA98, TA100, TA1535, TA1537 and TA1538 at concentrations of 0.33, 1.0, 3.3, 10, 33 and 100 µg/plate with and without metabolic activation. Both positive and negative controls were used. Cytotoxicity was observed at concentrations greater than or equal to 10 µg/plate. Precipitate was observed at all concentrations. Control responses were not provided.

CASRN 61788-63-4 was not mutagenic in this assay.

(2) Dihydrogenated tallow methylamine (“Adogen 343”) was tested in L5178Y TK+/1 mouse lymphoma cells at concentrations of 0.33, 1.0, 3.3, 10, 33 and 100 µg/plate with and without metabolic activation. Both positive and negative controls were used. Cytotoxicity was observed at 1 µL/mL without and 10 µL/mL in with metabolic activation (data assumed to have been in a dose-range finding study since the units are different). Control responses were not provided.

CASRN 61788-63-4 was not mutagenic in this assay.

1-Octadecyl amine (CASRN 124-30-1, supporting chemical)

(1) 1-Octadecyl amine was tested in *Salmonella typhimurium* strains TA97, TA98, TA100 and TA1535 at concentrations of 0, 100, 333, 1000 or 6666 µg/plate with and without metabolic activation. Both positive and negative controls were used. Evidence of cytotoxicity was not noted; but precipitate was observed at 333 and 1000 µg/plate (no mention of 6666 µg/plate). Positive control responses were as expected.

CASRN 124-30-1 was not mutagenic in this assay.

(2) 1-Octadecyl amine (“Genamine 18 R 100 D”) was tested in *Salmonella typhimurium* strains TA98, TA100, TA1535, TA1537 and TA1538 and *Escherichia coli* strain WP2uvrA at concentrations of 0, 4, 20, 100, 500, 2500 or 10,000 µg/plate (experiment 1) and concentrations of 0, 4, 20, 100, 500, 2500 and 5000 µg/plate (experiment 2), with and without metabolic activation. Both positive and negative controls were used in each study. Cytotoxicity occurred at 100 µg/plate and there was a visible precipitate at concentrations of 500 µg/plate and higher. Control responses were not provided.

CASRN 124-30-1 was not mutagenic in this assay.

Coco alkyl amine (CASRN 61788-46-3, supporting chemical)

Coco alkyl amine (“Genamin C 100 D”) was tested in *Salmonella typhimurium* strains TA98, TA100, TA1535, TA1537 and TA1538 and *Escherichia coli* strain WP2uvrA at concentrations of 0.16, 0.8, 4, 20, 100, 500, 2500 or 10,000 µg/plate with and without metabolic activation. Both positive and negative controls were used in each study. Cytotoxicity was observed at concentrations > 20 µg/plate with *Salmonella typhimurium* and > 100 µg/plate with *Escherichia coli*. Control responses were not provided.

CASRN 61788-46-3 was not mutagenic in these assays.

Tallow alkyl amine (CASRN 61790-33-8, supporting chemical)

Tallow alkyl amine (“Genamin TA 100 D”) was tested in *Salmonella typhimurium* strains TA98, TA100, TA1535, TA1537 and TA1538 and *Escherichia coli* strain WP2uvrA at concentrations of 0.16 – 10,000 µg/plate with and without metabolic activation. Both positive and negative controls were used in each study. Cytotoxicity was observed at concentrations ≥ 20 µg/plate. Control responses were not provided.

CASRN 61790-33-8 was not mutagenic in these assays.

Cis-9-octadecenylamine (CASRN 112-90-3, supporting chemical)

(1) In a reverse mutation assay, cis-9-octadecenylamine was tested in *Salmonella typhimurium* strains TA98, TA100, TA1535, TA1537 and TA1538 at concentrations of 0.2, 1, 5, 10 and 15 µg/plate without metabolic activation and 2, 10, 25, 50 and 100 µg/plate with metabolic activation. Both positive and negative controls were used in each study. Cytotoxicity was observed at concentrations of 100 µg/plate with activation and ≥ 15 µg/plate without activation (based on a previous study). Control responses were not provided.

CASRN 112-90-3 was not mutagenic in these assays.

(2) Cis-9-octadecenylamine was tested in Chinese hamster ovary cells in an HGPRT mutation assay at concentrations of 0.1 – 2 nL/mL (without metabolic activation, first assay) and 5 – 9 nL/mL (with metabolic activation, first assay); and 1 – 2.5 nL/mL (without metabolic activation, second assay in duplicate) and 7 – 10 nL/mL (with metabolic activation, second assay in duplicate). Both positive and negative controls were used in each study. No mutagenic activity was induced by cis-9-octadecenylamine in any strain. Cytotoxicity was observed at 2.5 nL/mL in the absence of activation and at 10.0 nL/mL in the presence of activation. In these three assays, an increase in mutant frequency was observed on two occasions, but were not reproduced in the other two assays (i.e., at the highest dose of 2 nL/mL without activation and 9 nL/mL with activation in the first assay, but not in the other two; and in one assay at a concentration not stated, but apparently not reproduced in the other two assays). Control responses were not provided.

CASRN 112-90-3 was not mutagenic in this assay.

(3) Cis-9-octadecenylamine was tested in L5178Y TK+/- mouse lymphoma cells at concentrations of 0.13 – 0.32 nL/mL [without activation] or 1.2 – 13 nL/mL [with activation] (first assay); of 0.13 – 1.8 nL/mL [without activation] or 1.3 – 13 nL/mL [with activation] (second assay); and 0.2 - 1 nL/mL [without activation] or 1.5 – 11.0 nL/mL [with activation] (third [confirmatory] assay). Both positive and negative controls were used in each study.

Cytotoxicity was observed in each assay at concentrations greater than or equal to the highest concentration tested. Control responses were not provided.

CASRN 112-90-3 was not mutagenic in this assay.

Subcategory II: Hydroxylated FND Amines

N-Tallow alkyl derivatives of 2,2'-iminobis ethanol (CASRN 61791-44-4)

(1) N-Tallow alkyl derivatives of 2,2'-iminobis ethanol ("Genamin S080") was tested in *Salmonella typhimurium* strains TA98, TA100, TA1535, TA1537 and TA1538 at concentrations of 0.0008, 0.02, 0.04 and 0.08 µg/plate with and without metabolic activation. Both positive and negative controls were used. Slight cytotoxicity was observed at 0.1 µL/plate in a dose-range-finding study. Control responses were not provided.

CASRN 61791-44-4 was not mutagenic in this assay.

(2) N-Tallow alkyl derivatives of 2,2'-iminobis ethanol ("TAMET Benzoate") was tested in *Salmonella typhimurium* strains TA98, TA100, TA1535, TA1537 and TA1538 at concentrations of 2.0, 10, 50, 100 and 200 µg/plate with and without metabolic activation. Both positive and negative controls were used. Slight cytotoxicity was observed at 305 µg/plate in a dose-range finding study. Control responses were not provided.

CASRN 61791-44-4 was not mutagenic in this assay.

(3) N-Tallow alkyl derivatives of 2,2'-iminobis ethanol ("Varonic T-220") was tested in *Salmonella typhimurium* strains TA98, TA100, TA1535, TA1537 and TA1538 at concentrations of 0.0008, 0.004, 0.002, 0.04 and 0.08 µL/plate with and without metabolic activation. Both positive and negative controls were used. There was no cytotoxicity. Control responses were not provided.

CASRN 61791-44-4 was not mutagenic in this assay.

(4) N-tallow alkyl derivatives of 2,2'-iminobis ethanol ("Varonic T-220") was tested in L5178Y TK+/- mouse lymphoma cells at concentrations of 0.33, 1.0, 3.3, 10, 33 and 100 µg/plate with and without metabolic activation. Both positive and negative controls were used. Complete cytotoxicity was observed at 0.1 µL/mL (equivalent to 100 µg/mL) without and 10 µL/mL (equivalent to 10000 µg/mL) with metabolic activation. Control responses were not provided.

CASRN 61791-44-4 was not mutagenic in this assay.

Genetic Toxicity – Chromosomal Aberrations

In vitro

Subcategory I: Non-Hydroxylated FND Amines

Cis-9-Octadecenylamine (CASRN 112-90-3, supporting chemical)

(1) Cis-9-octadecenylamine was tested in Chinese hamster ovary cells at concentrations of 0.05, 0.15, 0.5, 1.5 and 5.0 nL/mL without metabolic activation and 0.2, 0.6, 2.0, 6.0 and 20.0 nL/mL with metabolic activation. Both positive and negative controls were used in each study. Cytotoxicity was observed at 5.0 nL/mL without metabolic activation and 20.0 nL/mL with metabolic activation. Control responses were not provided.

CASRN 112-90-3 did not increase the number of chromosomal aberrations in this assay.

Subcategory II: Hydroxylated FND Amines

N-Tallow alkyl derivatives of 2,2'-iminobis ethanol (CASRN 61791-44-4)

N-Tallow alkyl derivatives of 2,2'-iminobis ethanol ("Varonic T-220") was tested in Chinese hamster ovary cells at concentrations of 0.005 – 0.03 µL/mL (without activation) and 0.05 – 0.3 µL/mL (with activation). Both positive and negative controls were used. Cytotoxic concentrations were > 0.01 and > 0.03 µL/mL for the without and with metabolic activation assays, respectively. Controls responded appropriately.

CASRN 61791-44-4 induced chromosomal aberrations with metabolic activation, and did not induce chromosomal aberrations without metabolic activation in this assay

In vivo

Subcategory I: Non-Hydroxylated FND Amines

N,N-Dimethyl-1-dodecanamine (CASRN 112-18-5, supporting chemical)

In an erythrocyte micronucleus test, HsdWin:NMRI mice (5/sex/group) were administered N,N-dimethyl-1-dodecanamine ("Genamin LA 302D") in sesame oil via gavage at doses of 120, 400 or 1200 mg/kg daily for two days (total of two doses). Both positive and negative controls were used. The robust summary states that 6/10 mice died prematurely in the high dose group, but they were replaced and the new animals survived. Controls responded appropriately.

CASRN 112-18-5 did not increase the number of micronucleated cells in this assay.

Tallow alkyl amine (CASRN 61790-33-8, supporting chemical)

Tallow alkyl amine (in sesame oil) was administered to Sprague-Dawley rats (5/sex/group) in a single dose of 2000 mg/kg by gavage in a rat micronucleus test in bone marrow cells. Both positive and negative controls were used. One male died at 48 hours. Genotoxic effects were not observed in the test group. Control responses were appropriate.

CASRN 61790-33-8 did not increase the number of micronucleated cells in this assay.

Cis-9-Octadecenylamine (CASRN 112-90-3, supporting chemical)

ICR mice (5/sex/group) were administered cis-9-octadecenylamine (in corn oil) at doses of 500, 2500 or 5000 mg/kg via gavage in a cytogenetics assay. Both positive and negative controls were used. One female died prematurely. Control responses were appropriate.

CASRN 112-90-3 did not increase the number of chromosome aberrations in this assay.

Subcategory II: Hydroxylated FND Amines

N-Tallow alkyl derivatives of 2,2'-iminobis ethanol (CASRN 61791-44-4)

(1) Sprague-Dawley rats (5/sex/group) were administered N-tallow alkyl derivatives of 2,2'-iminobis ethanol ("Varonic T-220") in water by gavage at doses of 39, 130 or 390 mg/kg/day daily for five days in a cytogenicity study. Both positive and negative controls were used. Controls responded appropriately.

CASRN 61791-44-4 did not induce chromosome aberrations in this assay.

(2) In an erythrocyte micronucleus test, CD1 mice (15/sex/group) were administered N-tallow alkyl derivatives of 2,2'-iminobis ethanol ("15% TAMET solution with 5% H₃PO₄ in water") via gavage at a single dose of 10860 mg/kg/day. Five mice/sex were sacrificed at 24, 48 and 72 hours. Both positive and negative controls were used. One treated male died. Although there

were no biologically significant increases in the number of micronucleated polychromatic erythrocytes, there was apparent toxicity to the bone marrow. Because of this toxicity in the bone marrow, three dose levels should have been employed – in accordance with OECD/OCSPP guidelines for this assay. Controls responded appropriately.

CASRN 61791-44-4 did not increase the number of micronucleated cells in this assay, but the result is considered inconclusive.

Genetic Toxicity – Other

In vitro

Subcategory I: Non-Hydroxylated FND Amines

Dihydrogenated tallow methylamine (CASRN 61788-63-4)

In an unscheduled DNA synthesis test, dihydrogenated tallow methylamine (“Adogen 343”) was tested in Sprague-Dawley hepatocyte primary cell cultures at concentrations of 32.1, 41.7, 54.2, 70.4, 91.6, 119.0, 154.8, 201.2, 261.5 and 340 µg/mL. Both positive and negative controls were used. Cytotoxicity was observed only at the highest concentration (340 ug/mL). Controls responded appropriately.

CASRN 61788-63-4 did not induce unscheduled DNA synthesis in this assay.

Subcategory II: Hydroxylated FND Amines

N-Tallow alkyl derivatives of 2,2'-iminobis ethanol (CASRN 61791-44-4)

In two studies of unscheduled DNA synthesis tests, N-tallow alkyl derivatives of 2,2'-iminobis ethanol (“Varonic T-220”) was tested in Sprague-Dawley hepatocyte primary cell cultures at ten concentrations between $0.035 \times 10^{-4} - 1.0 \times 10^{-4}$ µL/mL (experiment 1) and an unspecified number of concentrations between $0.008 \times 10^{-4} - 0.23 \times 10^{-4}$ µL/mL (experiment 2). Both positive and negative controls were used in each study. Due to excessive toxicity – and questionable UDS results - in the first experiment, the second test was conducted. Overall, cytotoxicity was observed at $\geq 0.052 \times 10^{-4}$ µL/mL. Controls responded appropriately.

CASRN 61791-44-4 did not induce unscheduled DNA synthesis in this assay.

Additional Information

Skin Irritation

Subcategory I: Non-Hydroxylated FND Amines

N,N-Dimethyl-1-hexadecanamine (CASRN 112-69-6)

New Zealand White rabbits (6/dose) were administered N,N-dimethyl-1-hexadecanamine (“ADMA 6”) on shaved skin at a dose of 0.5 grams and the skin was occluded for 4 hours. After four hours, the covering was removed, the area washed with water and the animals were examined at that time and then at 24 and 48 hours. Corrosivity and skin irritation (moderate to severe erythema and edema) was observed at 48 hours (but not @ 4 or 24 hours) following exposure in 5/6 animals. This study is a TSCATS submission and can be retrieved by typing in the CASRN at the following link: <http://www.srcinc.com/what-we-do/databaseforms.aspx?id=384>.

CASRN 112-69-6 was corrosive to rabbit skin in this assay.

N,N-Dimethyl-1-tetradecanamine (CASRN 112-75-4)

New Zealand White rabbits (6/dose) were administered N,N-dimethyl-1-tetradecanamine (“ADMA 2”) on shaved skin at a dose of 0.5 ml and the skin was occluded for 4 hours. After four hours, the covering was removed, the area washed with water and the animals were examined at that time and then at 24 and 48 hours. No corrosivity or skin irritation was observed following exposure. This study is a TSCATS submission and can be retrieved by typing in the CASRN at the following link: <http://www.srcinc.com/what-we-do/databaseforms.aspx?id=384>. **CASRN 112-75-4 was not irritating to rabbit skin in this assay.**

N,N-Dimethyl-1-octadecanamine (CASRN 124-28-7)

New Zealand White rabbits (6/dose) were administered N,N-dimethyl-1-octadecanamine (“ADMA 8”) on shaved skin at a dose of 0.5 mL and the skin was occluded for 4 hours. After four hours, the covering was removed, the area washed with water and the animals were examined at that time and then at 24 and 48 hours. Corrosivity and skin irritation (moderate to severe erythema and edema) was observed at 24 and 48 hours (but not @ 4 hours) following exposure in all six animals. This study is a TSCATS submission and can be retrieved by typing in the CASRN at the following link: <http://www.srcinc.com/what-we-do/databaseforms.aspx?id=384>. **CASRN 124-28-7 was corrosive to rabbit skin in this assay.**

Eye Irritation

Subcategory I: Non-Hydroxylated FND Amines

N,N-Dimethyl-1-hexadecanamine (CASRN 112-69-6)

New Zealand White rabbits (6/dose) were administered N,N-dimethyl-1-hexadecanamine (“ADMA 6”) at 0.1 mL in one eye and the other eye served as the control. Animals were evaluated at 24, 48 and 72 hours following dosing. The study in rabbits showed irritation following exposure. This study is a TSCATS submission and can be retrieved by typing in the CASRN at the following link: <http://www.srcinc.com/what-we-do/databaseforms.aspx?id=384>. **CASRN 112-69-6 was irritating to rabbit eyes in this assay.**

N,N-Dimethyl-1-tetradecanamine (CASRN 112-75-4)

New Zealand White rabbits (6/dose) were administered N,N-dimethyl-1-tetradecanamine (“ADMA 4”) at 0.1 mL in one eye and the other eye served as the control. Animals were evaluated at 24, 48 and 72 hours following dosing. The study in rabbits showed irritation following exposure. This study is a TSCATS submission and can be retrieved by typing in the CASRN at the following link: <http://www.srcinc.com/what-we-do/databaseforms.aspx?id=384>. **CASRN 112-75-4 was irritating to rabbit eyes in this assay.**

N,N-Dimethyl-1-octadecanamine (CASRN 124-28-7)

New Zealand White rabbits (6/dose) were administered N,N-dimethyl-1-octadecanamine (“ADMA 8”) at 0.1 mL in one eye and the other eye served as the control. Animals were evaluated at 24, 48 and 72 hours following dosing. The study in rabbits showed irritation following exposure. This study is a TSCATS submission and can be retrieved by typing in the CASRN at the following link: <http://www.srcinc.com/what-we-do/databaseforms.aspx?id=384>. **CASRN 124-28-7 was irritating to rabbit eyes in this assay.**

Conclusion:

Subcategory I: Non-Hydroxylated FND Amines

The acute oral toxicity in rodents for the 21 members of this subcategory is low based on studies in nine sponsored chemicals in rats. The acute dermal toxicity in animal studies for this subcategory is also low based on studies of five sponsored chemicals in rabbits. Oral repeated-dose toxicity studies are available for one sponsored chemical (CASRN 4088-22-6) and three supporting chemicals (CASRNs 124-30-1, 3159-59-5/36505-83-6, and 61790-33-8). One dermal repeated-dose toxicity study is available for a sponsored chemical (CASRN 4088-22-6). In the 13-week oral gavage study with CASRN 4088-22-6 in rats, there was no NOAEL for systemic effects and the following effects were observed at the lowest tested dose of 117 mg/kg/day: decreased body weight gain, organ weight changes, hematological changes and pathological changes in the intestine, lymph nodes and ovaries. In a one year study in dogs, CASRN 124-30-1 (supporting chemical) was administered via a capsule resulting in mortality, decreased body weight gain and pathological changes in the intestine at a dose of 15 mg/kg/day; the NOAEL for systemic toxicity was 3 mg/kg/day. The supporting chemical, CASRN 3159-59-5/36505-83-6, was tested in rats and dogs via the oral route. In the two-year dietary rat study, there was a decrease in body weight, clinical chemistry changes and pathological changes in the intestine and lymph node at 30 mg/kg/day; the NOAEL for systemic toxicity was 6 mg/kg/day. In the two-year gavage study in dogs, there were no effects observed; the NOAEL for systemic toxicity was 12 mg/kg/day (highest dose tested). In the only repeated-dose dermal study in the subcategory, rabbits were exposed to the sponsored chemical, CASRN 4088-22-6, daily for 13 weeks. Irritation was observed at the two doses used, resulting in no NOAEL for this local effect (lowest tested dose of 5 mg/kg/day). The NOAEL for systemic effects was 5 mg/kg/day, based on the following effects observed at 50 mg/kg/day: decreased body weight, slight changes in hematological parameters, and pathological changes in the liver and lymph nodes.

There were no reproductive toxicity studies in any of the 21 sponsored chemicals; however there were studies with two supporting chemicals which are used to read-across to the sponsored chemicals. In a dietary combined reproductive/developmental toxicity study with CASRN 61790-33-8, rats dosed with 150 mg/kg/day experienced implantation loss, decreased mating and fertility indices, increased precoital time interval and atrophy of corpora lutea; the NOAEL for reproductive toxicity was 50 mg/kg/day. In an oral one-generation reproductive toxicity study with CASRN 3159-59-5/36505-83-6 in rats, there were no effects on any reproductive parameters assessed; the NOAEL for reproductive toxicity was 30 mg/kg/day (highest dose tested).

Oral developmental toxicity studies were available with one sponsored chemical

(CASRN 4088-22-6) and three supporting chemicals (CASRN 112-90-3, 3159-59-5/36505-83-6, and 61790-33-8). In a prenatal oral developmental toxicity study with rabbits using CASRN 4088-22-6, dams exhibited decreased weight gain at 250 mg/kg/day and above; the NOAEL for maternal toxicity was 50 mg/kg/day. Embryo lethality at 1000 mg/kg/day could not be discounted; the NOAEL for developmental toxicity was 250 mg/kg/day. The combined reproductive/developmental toxicity study with the supporting chemical CASRN 61790-33-8 in rats resulted in no NOAEL for maternal toxicity (based on decreased body weight at the lowest tested dose of 12.5 mg/kg/day) and a NOAEL of 12.5 mg/kg/day for developmental toxicity (based on decreased pup body weights at 50 mg/kg/day). There were two oral prenatal developmental toxicity studies, one with rats and one with rabbits, using the supporting chemical CASRN 112-90-3. In the rat study, maternal toxicity was observed at 40 mg/kg/day (clinical signs and a decrease in body weight); the NOAEL for maternal toxicity was 10 mg/kg/day. There was no developmental toxicity; the NOAEL for developmental toxicity was 80 mg/kg/day (highest dose tested). In the rabbit study, dams exhibited clinical signs and decreased body weight at 10 mg/kg/day; the NOAEL for maternal toxicity was 3 mg/kg/day. There was no developmental toxicity; the NOAEL for developmental toxicity was 30 mg/kg/day (highest dose tested). In two prenatal oral developmental toxicity studies in rats with the supporting chemical mixture (CASRN 3159-59-5/36505-83-6), different results were obtained. Taking the two studies together, maternal toxicity was observed at 30 mg/kg/day (decreased body weight); the NOAEL for maternal toxicity was of 6 mg/kg/day. Unspecified malformations were seen in rat fetuses at 30 mg/kg/day; the NOAEL for developmental toxicity was of 6 mg/kg/day.

In vitro (using both bacteria and mammalian cells) evaluations of genetic toxicity (gene mutations and chromosomal aberrations) were conducted with three sponsored chemicals. *In vitro* data with the supporting chemicals were also for gene mutations (four chemicals) and chromosomal aberrations (one chemical); all results were negative. *In vivo* evaluations of chromosomal effects in one sponsored and three supporting chemicals also showed negative results. Unscheduled DNA synthesis was not induced in a study of one sponsored chemical. The available data in three sponsored chemicals suggest that non-hydroxylated FND amines are irritating to both skin and eyes.

Subcategory II: Hydroxylated FND Amines

There are two chemicals (CASRN 61791-31-9 and 61791-44-4) in this subcategory for human health endpoints. With the exception of acute oral toxicity data, data were available for CASRN 61791-44-4. Acute oral toxicity of CASRN 61791-31-9 and 61791-44-4 in rats is low. Acute dermal toxicity of CASRN 61791-44-4 in rabbits is moderate. There were both oral and dermal repeated dose studies with CASRN 61791-44-4. Different results were obtained depending on the formulation tested (see text for details). Oral dietary studies were performed with rats (two) and dogs (one). In one 90-day rat study, there were gross and microscopic effects in the intestine and lymph nodes at 150 mg/kg/day; the NOAEL for systemic toxicity was 50 mg/kg/day. In the other 90-day rat study, the NOAEL was 12 mg/kg/day based on decreases in body weight gain and histopathological effects on the intestine and lymph nodes at 400 mg/kg/day. The dog 90-day study resulted in a NOAEL of 13 mg/kg/day based on clinical signs, decreased body weight and pathological changes in the intestine and lymph nodes at

40 mg/kg/day. There were three 28-day dermal toxicity studies in rabbits. Local effects (irritation) were observed at all doses tested, with no NOAEL for this effect (lowest dose tested was 40 mg/kg/day). There were no systemic effects observed up to the highest dose tested of 40 mg/kg/day, which is the NOAEL for systemic toxicity for the dermal studies in rabbits.

There were no reproductive/developmental toxicity data for either subcategory member. Gene mutations were not induced in two studies (bacterial and mammalian cells) with CASRN 61791-44-4 *in vitro*. CASRN 61791-44-4 induced chromosomal aberrations *in vitro* (with metabolic activation only), and results for chromosomal effects in an *in vivo* test were inconclusive. CASRN 61791-44-4 did not induce unscheduled DNA synthesis.

Table 13. Summary Table of the Screening Information Data Set as Submitted under the U.S. HPV Challenge Program – Human Health Data

<i>Subcategory 1: Non-Hydroxylated FND Amines</i>													
Endpoints	Dodecyl-amine (124-22-1)	Hexadecyl-amine (143-27-1)	N-(9Z)-octadecenyl-1,3-propane-diamine (7173-62-8)	C14 – 18-alkyl amines (68037-91-2)	C16 – 18 and C18-unsaturated alkyl amines (68037-95-6)	C14 – 18 and C16 – 18-unsaturated alkyl amines (68155-38-4)	Soya alkyl amines (61790-18-9)	N,N-Dimethyl-1-hexadecan-amine (112-69-6)	N,N-Dimethyl-1-tetradecan-amine (112-75-4)	N,N-Dimethyl-1-octadecan-amine (124-28-7)	N-Tallow alkyltri-methylene-diamines (61791-55-7)	Dimethyl soya alkyl amines (61788-91-8)	(Hydrogenated tallow alkyl)di-methyl amines (61788-95-2)
SPONSORED CHEMICALS													
Acute Oral Toxicity LD₅₀ (mg/kg)	> 2000	No Data 620 (RA)	No Data 620 (RA)	No Data 620 (RA)	No Data 620 (RA)	No Data 620 (RA)	No Data 620 (RA)	620 - >2000 ¹	720 - 2116 ¹	624 - 2116 ¹	> 5000	835	> 2000
Acute Dermal Toxicity LD₅₀ (mg/kg)	No Data > 2000 (RA)	No Data > 2000 (RA)	No Data > 2000 (RA)	No Data > 2000 (RA)	No Data > 2000 (RA)	No Data > 2000 (RA)	No Data > 2000 (RA)	3432	4400	3432-8000 ¹	No Data > 2000 (RA)	2400	No Data > 2000 (RA)
Repeated-Dose Toxicity Oral (mg/kg/day) NOAEL/LOAEL (systemic)	No Data NOAEL = Not Established LOAEL = 12.5 (RA)	No Data NOAEL = Not Established LOAEL = 12.5 (RA)	No Data NOAEL = Not Established LOAEL = 12.5 (RA)	No Data NOAEL = Not Established LOAEL = 12.5 (RA)	No Data NOAEL = Not Established LOAEL = 12.5 (RA)	No Data NOAEL = Not Established LOAEL = 12.5 (RA)	No Data NOAEL = Not Established LOAEL = 12.5 (RA)	No Data NOAEL = Not Established LOAEL = 12.5 (RA)	No Data NOAEL = Not Established LOAEL = 12.5 (RA)	No Data NOAEL = Not Established LOAEL = 12.5 (RA)	No Data NOAEL = Not Established LOAEL = 12.5 (RA)	No Data NOAEL = Not Established LOAEL = 12.5 (RA)	No Data NOAEL = Not Established LOAEL = 12.5 (RA)
Repeated-Dose Toxicity Dermal (mg/kg/day) NOAEL/LOAEL (systemic)	No Data NOAEL = 5 LOAEL = 50 (RA)	No Data NOAEL = 5 LOAEL = 50 (RA)	No Data NOAEL = 5 LOAEL = 50 (RA)	No Data NOAEL = 5 LOAEL = 50 (RA)	No Data NOAEL = 5 LOAEL = 50 (RA)	No Data NOAEL = 5 LOAEL = 50 (RA)	No Data NOAEL = 5 LOAEL = 50 (RA)	No Data NOAEL = 5 LOAEL = 50 (RA)	No Data NOAEL = 5 LOAEL = 50 (RA)	No Data NOAEL = 5 LOAEL = 50 (RA)	No Data NOAEL = 5 LOAEL = 50 (RA)	No Data NOAEL = 5 LOAEL = 50 (RA)	No Data NOAEL = 5 LOAEL = 50 (RA)
Reproductive Toxicity Oral (mg/kg/day) NOAEL/LOAEL Reproductive Toxicity	No Data NOAEL = 50 LOAEL = 150 (RA)	No Data NOAEL = 50 LOAEL = 150 (RA)	No Data NOAEL = 50 LOAEL = 150 (RA)	No Data NOAEL = 50 LOAEL = 150 (RA)	No Data NOAEL = 50 LOAEL = 150 (RA)	No Data NOAEL = 50 LOAEL = 150 (RA)	No Data NOAEL = 50 LOAEL = 150 (RA)	No Data NOAEL = 50 LOAEL = 150 (RA)	No Data NOAEL = 50 LOAEL = 150 (RA)	No Data NOAEL = 50 LOAEL = 150 (RA)	No Data NOAEL = 50 LOAEL = 150 (RA)	No Data NOAEL = 50 LOAEL = 150 (RA)	No Data NOAEL = 50 LOAEL = 150 (RA)

Table 13. Summary Table of the Screening Information Data Set as Submitted under the U.S. HPV Challenge Program – Human Health Data

<i>Subcategory 1: Non-Hydroxylated FND Amines</i>													
Endpoints	Dodecyl-amine (124-22-1)	Hexadecyl-amine (143-27-1)	N-(9Z)-octadecenyl-1,3-propane-diamine (7173-62-8)	C14 – 18-alkyl amines (68037-91-2)	C16 – 18 and C18-unsaturated alkyl amines (68037-95-6)	C14 – 18 and C16 – 18-unsaturated alkyl amines (68155-38-4)	Soya alkyl amines (61790-18-9)	N,N-Dimethyl-1-hexadecan-amine (112-69-6)	N,N-Dimethyl-1-tetradecan-amine (112-75-4)	N,N-Dimethyl-1-octadecan-amine (124-28-7)	N-Tallow alkyltri-methylene-diamines (61791-55-7)	Dimethyl soya alkyl amines (61788-91-8)	(Hydrogenated tallow alkyl)di-methyl amines (61788-95-2)
Developmental Toxicity Oral (mg/kg/day) NOAEL/LOAEL	No Data (rat)	No Data (rat)	No Data (rat)	No Data (rat)	No Data (rat)	No Data (rat)	No Data (rat)	No Data (rat)	No Data (rat)	No Data (rat)	No Data (rat)	No Data (rat)	No Data (rat)
Maternal Toxicity	NOAEL = 6 LOAEL = 30	NOAEL = 6 LOAEL = 30	NOAEL = 6 LOAEL = 30	NOAEL = 6 LOAEL = 30	NOAEL = 6 LOAEL = 30	NOAEL = 6 LOAEL = 30	NOAEL = 6 LOAEL = 30	NOAEL = 6 LOAEL = 30	NOAEL = 6 LOAEL = 30	NOAEL = 6 LOAEL = 30	NOAEL = 6 LOAEL = 30	NOAEL = 6 LOAEL = 30	NOAEL = 6 LOAEL = 30
Developmental Toxicity	NOAEL = 6 LOAEL = 30 (RA)	NOAEL = 6 LOAEL = 30 (RA)	NOAEL = 6 LOAEL = 30 (RA)	NOAEL = 6 LOAEL = 30 (RA)	NOAEL = 6 LOAEL = 30 (RA)	NOAEL = 6 LOAEL = 30 (RA)	NOAEL = 6 LOAEL = 30 (RA)	NOAEL = 6 LOAEL = 30 (RA)	NOAEL = 6 LOAEL = 30 (RA)	NOAEL = 6 LOAEL = 30 (RA)	NOAEL = 6 LOAEL = 30 (RA)	NOAEL = 6 LOAEL = 30 (RA)	NOAEL = 6 LOAEL = 30 (RA)
Genetic Toxicity – Gene Mutation In vitro	No Data Negative (RA)	Negative	No Data Negative (RA)	No Data Negative (RA)	No Data Negative (RA)	No Data Negative (RA)	No Data Negative (RA)	No Data Negative (RA)	No Data Negative (RA)	No Data Negative (RA)	No Data Negative (RA)	No Data Negative (RA)	No Data Negative (RA)
Genetic Toxicity – Chromosomal Aberrations In vitro	–	–	–	–	–	–	–	–	–	–	–	–	–
Genetic Toxicity – Chromosomal Aberrations In vivo	No Data Negative (RA)	No Data Negative (RA)	No Data Negative (RA)	No Data Negative (RA)	No Data Negative (RA)	No Data Negative (RA)	No Data Negative (RA)	No Data Negative (RA)	No Data Negative (RA)	No Data Negative (RA)	No Data Negative (RA)	No Data Negative (RA)	No Data Negative (RA)
Genetic Toxicity – Other Unscheduled DNA synthesis In vitro	No Data Negative (RA)	No Data Negative (RA)	No Data Negative (RA)	No Data Negative (RA)	No Data Negative (RA)	No Data Negative (RA)	No Data Negative (RA)	No Data Negative (RA)	No Data Negative (RA)	No Data Negative (RA)	No Data Negative (RA)	No Data Negative (RA)	No Data Negative (RA)

Table 13. Summary Table of the Screening Information Data Set as Submitted under the U.S. HPV Challenge Program – Human Health Data

<i>Subcategory 1: Non-Hydroxylated FND Amines</i>													
Endpoints	Dodecyl-amine (124-22-1)	Hexadecyl-amine (143-27-1)	N-(9Z)-octadecenyl-1,3-propane-diamine (7173-62-8)	C14 – 18-alkyl amines (68037-91-2)	C16 – 18 and C18-unsaturated alkyl amines (68037-95-6)	C14 – 18 and C16 – 18-unsaturated alkyl amines (68155-38-4)	Soya alkyl amines (61790-18-9)	N,N-Dimethyl-1-hexadecan-amine (112-69-6)	N,N-Dimethyl-1-tetradecan-amine (112-75-4)	N,N-Dimethyl-1-octadecan-amine (124-28-7)	N-Tallow alkyltri-methylene-diamines (61791-55-7)	Dimethyl soya alkyl amines (61788-91-8)	(Hydrogenated tallow alkyl)di-methyl amines (61788-95-2)
Additional Information													
Skin irritation	—	—	—	—	—	—	—	Positive	Negative	Positive	—	—	—
Eye irritation	—	—	—	—	—	—	—	Positive	Positive	Positive	—	—	—

Measured data in bold text; (RA) = Read Across; — indicates that endpoint was not addressed for this substance

¹ A range is presented due to different responses depending on the formulation used. Please see appropriate text for individual values.

Table 14. Summary Table of the Screening Information Data Set as Submitted under the U.S. HPV Challenge Program – Human Health Data

<i>Subcategory 1: Non-Hydroxylated FND Amines</i>								
Endpoints	N-Methyl-N-octadecyl-1-octadecanamine (4088-22-6)	Dihydrogenated tallow methylamine (61788-63-4)	Di-C14 – 18-alkylmethyl amines (67700-99-6)	Di-C12 – 18-alkyl amines (68153-95-7)	Ditalow alkyl amines (68783-24-4)	N-Decyl-N-methyl-1-decanamine (7396-58-9)	Tri-C8 – 10-alkyl amines (68814-95-9)	Tris(hydrogenated tallow alkyl) amines (61790-42-9)
SPONSORED CHEMICALS								
Acute Oral Toxicity LD ₅₀ (mg/kg)	> 2000, >5000 ¹	> 5000, >15,000 ¹	No Data 620 (RA)	No Data 620 (RA)	No Data 620 (RA)	No Data 620 (RA)	No Data 620 (RA)	No Data 620 (RA)
Acute Dermal Toxicity LD ₅₀ (mg/kg)	> 2000	No Data > 2000 (RA)	No Data > 2000 (RA)	No Data > 2000 (RA)	No Data > 2000 (RA)	No Data > 2000 (RA)	No Data > 2000 (RA)	No Data > 2000 (RA)
Repeated-Dose Toxicity Oral (mg/kg/day) NOAEL/LOAEL	(rat) NOAEL = Not established LOAEL = 117	No Data NOAEL = Not Established LOAEL = 12.5 (RA)	No Data NOAEL = Not Established LOAEL = 12.5 (RA)	No Data NOAEL = Not Established LOAEL = 12.5 (RA)	No Data NOAEL = Not Established LOAEL = 12.5 (RA)	No Data NOAEL = Not Established LOAEL = 12.5 (RA)	No Data NOAEL = Not Established LOAEL = 12.5 (RA)	No Data NOAEL = Not Established LOAEL = 12.5 (RA)
Repeated-Dose Toxicity Dermal (mg/kg/day) NOAEL/LOAEL	(rabbit) NOAEL = 5 LOAEL = 50	No Data NOAEL = 5 LOAEL = 50 (RA)	No Data NOAEL = 5 LOAEL = 50 (RA)	No Data NOAEL = 5 LOAEL = 50 (RA)	No Data NOAEL = 5 LOAEL = 50 (RA)	No Data NOAEL = 5 LOAEL = 50 (RA)	No Data NOAEL = 5 LOAEL = 50 (RA)	No Data NOAEL = 5 LOAEL = 50 (RA)
Reproductive Toxicity Oral (mg/kg/day) NOAEL/LOAEL Reproductive Toxicity	No Data NOAEL = 50 LOAEL = 150 (RA)	No Data NOAEL = 50 LOAEL = 150 (RA)	No Data NOAEL = 50 LOAEL = 150 (RA)	No Data NOAEL = 50 LOAEL = 150 (RA)	No Data NOAEL = 50 LOAEL = 150 (RA)	No Data NOAEL = 50 LOAEL = 150 (RA)	No Data NOAEL = 50 LOAEL = 150 (RA)	No Data NOAEL = 50 LOAEL = 150 (RA)

Table 14. Summary Table of the Screening Information Data Set as Submitted under the U.S. HPV Challenge Program – Human Health Data

<i>Subcategory 1: Non-Hydroxylated FND Amines</i>								
Endpoints	N-Methyl-N-octadecyl-1-octadecanamine (4088-22-6)	Dihydrogenated tallow methylamine (61788-63-4)	Di-C14 – 18-alkylmethyl amines (67700-99-6)	Di-C12 – 18-alkyl amines (68153-95-7)	Ditallow alkyl amines (68783-24-4)	N-Decyl-N-methyl-1-decanamine (7396-58-9)	Tri-C8 – 10-alkyl amines (68814-95-9)	Tris(hydrogenated tallow alkyl) amines (61790-42-9)
Developmental Toxicity Oral (mg/kg/day) NOAEL/LOAEL	(rabbit) NOAEL = 50 LOAEL = 250	No Data (rat) NOAEL = 6 LOAEL = 30	No Data (rat) NOAEL = 6 LOAEL = 30	No Data (rat) NOAEL = 6 LOAEL = 30	No Data (rat) NOAEL = 6 LOAEL = 30	No Data (rat) NOAEL = 6 LOAEL = 30	No Data (rat) NOAEL = 6 LOAEL = 30	No Data (rat) NOAEL = 6 LOAEL = 30
Developmental Toxicity	NOAEL = 250 LOAEL = 1000	NOAEL = 6 LOAEL = 30 (RA)	NOAEL = 6 LOAEL = 30 (RA)	NOAEL = 6 LOAEL = 30 (RA)	NOAEL = 6 LOAEL = 30 (RA)	NOAEL = 6 LOAEL = 30 (RA)	NOAEL = 6 LOAEL = 30 (RA)	NOAEL = 6 LOAEL = 30 (RA)
Genetic Toxicity – Gene Mutation <i>In vitro</i>	Negative	Negative	No Data Negative (RA)	No Data Negative (RA)	No Data Negative (RA)	No Data Negative (RA)	No Data Negative (RA)	No Data Negative (RA)
Genetic Toxicity – Chromosomal Aberrations <i>In vitro</i>	–	–	–	–	–	–	–	–
Genetic Toxicity – Chromosomal Aberrations <i>In vivo</i>	No Data Negative (RA)	Negative	No Data Negative (RA)	No Data Negative (RA)	No Data Negative (RA)	No Data Negative (RA)	No Data Negative (RA)	No Data Negative (RA)
Genetic Toxicity – Other Unscheduled DNA synthesis <i>In vitro</i>	No Data Negative (RA)	Negative	No Data Negative (RA)	No Data Negative (RA)	No Data Negative (RA)	No Data Negative (RA)	No Data Negative (RA)	No Data Negative (RA)

Measured data in bold text; (RA) = Read Across; — indicates that endpoint was not addressed for this substance

¹ A range is presented due to different responses depending on the formulation used. Please see appropriate text for individual values.

Table 15. Summary Table of the Screening Information Data Set as Submitted under the U.S. HPV Challenge Program – Human Health Data								
	<i>Subcategory I: Non-Hydroxylated FND Amines</i>						<i>Subcategory II: Hydroxylated FND Amines</i>	
Endpoints	SUPPORTING CHEMICAL Cis-9-octadecylamine (112-90-3)	SUPPORTING CHEMICAL Octadecylamine (124-30-1)	SUPPORTING CHEMICAL Hexadecylamine hydrofluoride (3151-59-5) and 9-Octadecen-1-amine hydrofluoride (36505-83-6), 1:1 mixture	SUPPORTING CHEMICAL Coco alkyl amines (61788-46-3)	SUPPORTING CHEMICAL Tallow alkyl amines (61790-33-8)	SUPPORTING CHEMICAL N,N-Dimethyl-1-dodecanamine (112-18-5)	SPONSORED CHEMICAL N-Coco alkyl derivatives of 2,2'-iminobisethanol (61791-31-9)	SPONSORED CHEMICAL N-Tallow alkyl derivatives of 2,2'-iminobisethanol (61791-44-4)
Acute Oral Toxicity LD₅₀ (mg/kg)	1689	> 2000	–	1300 - >6000 ¹	1944	790 - 1220 ¹	> 5000	630 - >15,000 ¹
Acute Dermal Toxicity LD₅₀ (mg/kg)	–	–	–	> 2000	–	5000	No Data ~ 1600 (RA)	~ 1600
Repeated-Dose Toxicity Oral (mg/kg/day) NOAEL/LOAEL (systemic)	–	(dog) NOAEL = 3 LOAEL = 15	(rat) NOAEL = 6 LOAEL = 30 (dog) NOAEL = 12 (highest dose tested)	–	NOAEL = Not Established LOAEL = 12.5	–	No Data (rat) NOAEL = 50 LOAEL = 150 (dog) NOAEL = 13 LOAEL = 40 (RA)	(rat) NOAEL = 50 LOAEL = 150 (dog) NOAEL = 13 LOAEL = 40
Repeated-Dose Toxicity Dermal (mg/kg/day) NOAEL/LOAEL (systemic)	–	–	–	–	–	–	No Data NOAEL = 40 (RA)	(rabbit) NOAEL = 40 (only dose tested)

Table 15. Summary Table of the Screening Information Data Set as Submitted under the U.S. HPV Challenge Program – Human Health Data								
	<i>Subcategory I: Non-Hydroxylated FND Amines</i>						<i>Subcategory II: Hydroxylated FND Amines</i>	
Endpoints	SUPPORTING CHEMICAL Cis-9-octadecylamine (112-90-3)	SUPPORTING CHEMICAL Octadecylamine (124-30-1)	SUPPORTING CHEMICAL Hexadecylamine hydrofluoride (3151-59-5) and 9-Octadecen-1-amine hydrofluoride (36505-83-6), 1:1 mixture (61788-46-3)	SUPPORTING CHEMICAL Coco alkyl amines (61788-46-3)	SUPPORTING CHEMICAL Tallow alkyl amines (61790-33-8)	SUPPORTING CHEMICAL N,N-Dimethyl-1-dodecanamine (112-18-5)	SPONSORED CHEMICAL N-Coco alkyl derivatives of 2,2'-iminobis ethanol (61791-31-9)	SPONSORED CHEMICAL N-Tallow alkyl derivatives of 2,2'-iminobis ethanol (61791-44-4)
Reproductive Toxicity Oral (mg/kg/day) NOAEL/LOAEL	–	–	(rat) NOAEL = 30 (highest dose tested)	–	(rat) NOAEL = 50 LOAEL = 150	–	No data	No data
Reproductive Toxicity								
Developmental Toxicity Oral (mg/kg/day) NOAEL/LOAEL	(rat) NOAEL = 10 LOAEL = 40	–	(rat) NOAEL = 6 LOAEL = 30	–	(rat) NOAEL = Not Established LOAEL = 12.5	–	No Data	No Data
Maternal Toxicity								
Developmental Toxicity	NOAEL = 80 (highest dose tested)		NOAEL = 6 LOAEL = 30		NOAEL = 12.5 LOAEL = 50			
Maternal Toxicity	(rabbit) NOAEL = 3 LOAEL = 10							
Developmental Toxicity	NOAEL = 30 (highest dose tested)							

Table 15. Summary Table of the Screening Information Data Set as Submitted under the U.S. HPV Challenge Program – Human Health Data								
	<i>Subcategory I: Non-Hydroxylated FND Amines</i>						<i>Subcategory II: Hydroxylated FND Amines</i>	
Endpoints	SUPPORTING CHEMICAL Cis-9-octadecylamine (112-90-3)	SUPPORTING CHEMICAL Octadecylamine (124-30-1)	SUPPORTING CHEMICAL Hexadecylamine hydrofluoride (3151-59-5) and 9-Octadecen-1-amine hydrofluoride (36505-83-6), 1:1 mixture (61788-46-3)	SUPPORTING CHEMICAL Coco alkyl amines (61790-33-8)	SUPPORTING CHEMICAL Tallow alkyl amines (61790-33-8)	SUPPORTING CHEMICAL N,N-Dimethyl-1-dodecanamine (112-18-5)	SPONSORED CHEMICAL N-Coco alkyl derivatives of 2,2'-iminobis-ethanol (61791-31-9)	SPONSORED CHEMICAL N-Tallow alkyl derivatives of 2,2'-iminobis-ethanol (61791-44-4)
Genetic Toxicity – Gene Mutation <i>In vitro</i>	Negative	Negative	–	Negative	Negative	–	No Data Negative (RA)	Negative
Genetic Toxicity – Chromosomal Aberrations <i>In vitro</i>	Negative	–	–	–	–	–	No Data Positive (RA)	Positive (w/) Negative (w/o)
Genetic Toxicity – Chromosomal Aberrations <i>In vivo</i>	Negative	–	–	–	Negative	Negative	No Data Inconclusive (RA)	Inconclusive
Genetic Toxicity – Other UDS <i>In vitro</i>	–	–	–	–	–	–	No Data Negative (RA)	Negative

Measured data in bold; (RA) = Read Across; – endpoint not evaluated for this substance; w= with activation; w/o = without activation

¹ A range is presented due to different responses depending on the formulation used. Please see appropriate text for individual values.

4. Hazard to the Environment

A summary of aquatic toxicity data submitted for SIDS endpoints is provided in Table 16. The tables also indicate where data for tested category members are read-across (RA) to untested members of the category.

Acute Toxicity to Fish

Dodecylamine (CASRN 124-22-1)

In four studies, Zebra fish (*Brachydanio rerio*) were exposed to the test substance (CASRN 124-22-1) at nominal concentrations of 0, 0.25, 0.35, 0.5, 0.71, 1.0, 1.8, 2.5 and 3.5 mg/L under static conditions for 96 hours. Measured concentrations were not determined. Mortality was 100% at concentrations ≥ 0.5 mg/L.

96-h LC₅₀ = 0.42 mg/L

N,N-Dimethyl-1-tetradecanamine (CASRN 112-75-4)

(1) Rainbow trout (*Oncorhynchus mykiss*) were exposed to the test substance (CASRN 112-75-4) at nominal concentrations of 0.1, 0.32, 1.0, 3.2, 10, 32 and 100 mg/L under static conditions for 96 hours. Measured concentrations were not determined. Mortality was 100% at concentrations ≥ 1.0 mg/L.

96-h LC₅₀ = 0.18 mg/L

(2) In two studies, Zebra fish (*Brachydanio rerio*) were exposed to the test substance (CASRN 112-75-4) at nominal concentrations of 0.01 (study 2 only), 0.1 and 1 mg/L under static conditions for 96 hours. Measured concentrations were not stated. Mortality was 100% at 1 mg/L (study 1) and 0.1 and 1 mg/L (study 2).

96-h LC₅₀ > 0.01 and < 0.1 mg/L

(3) Zebra fish (*Brachydanio rerio*) were exposed to the test substance (CASRN 112-75-4) at nominal concentrations of 0.032, 0.058, 0.10, 0.18, 0.32, 0.58 and 1 mg/L under static-renewal conditions for 96 hours. Measured concentrations were not determined. Mortalities were observed at concentrations ≥ 0.58 mg/L.

96-h LC₅₀ = 0.35 mg/L

N,N-Dimethyl-1-hexadecanamine (CASRN 112-69-6)

(1) Rainbow trout (*Oncorhynchus mykiss*) were exposed to the test substance (CASRN 112-69-6) at nominal concentrations of 0.1, 0.32, 1.0, 3.2, 10, 32 and 100 mg/L under static conditions for 96 hours. Measured concentrations were not determined. Mortality was 100% at ≥ 3.2 mg/L

96-h LC₅₀ = 0.18 mg/L

(2) Zebra fish (*Brachydanio rerio*) were exposed to the test substance (CASRN 112-69-6) at nominal concentrations of 0.1, 1.0 and 10 mg/L under static conditions for 96 hours. Measured concentrations were not provided. Mortalities were observed at ≥ 1.0 mg/L

96-h LC₅₀ > 0.1 and < 1 mg/L

N,N-Dimethyl-1-octadecanamine (CASRN 124-28-7)

(1) Rainbow trout (*Oncorhynchus mykiss*) were exposed to the test substance (CASRN 124-28-7) at nominal concentrations of 0.1, 0.32, 1.0, 3.2, 10, 32 and 100 mg/L under static conditions for 96 hours. Measured concentrations were not determined. Mortalities were observed at ≥ 1.0 mg/L.

96-h LC₅₀ = 0.18 mg/L

(2) Zebra fish (*Brachydanio rerio*) were exposed to the test substance (CASRN 124-28-7) at nominal concentrations of 0.1 and 1.0 mg/L under static conditions for 96 hours. Measured concentrations were not provided. Mortalities were observed at both dose levels.

96-h LC₅₀ > 0.1 and < 1.0 mg/L

Dimethyl soya alkyl amines (CASRN 61788-91-8)

The study submitted was inadequate.

N-Methyl-N-octadecyl-1-octadecanamine (CASRN 4088-22-6)

The study submitted was inadequate.

Dihydrogenated tallow methylamine (CASRN 61788-63-4)

Two submitted studies were inadequate.

Cis-9-Octadecenylamine (CASRN 112-90-3, supporting chemical)

Fathead minnow (*Pimephales promelas*) were exposed to the test substance (CASRN 112-90-3) at nominal concentrations of 0.05, 0.09, 0.15, 0.27 and 0.49 mg/L under static conditions for 96 hours. Measured concentrations were 0.032, 0.12 (0.27 mg/L nominal concentration not provided) and 0.40 mg/L. Mortality was 100% at ≥ 0.15 mg/L.

96-h LC₅₀ = 0.11 mg/L

Chronic Toxicity to Fish

N-Coco alkyl derivatives of 2,2'-iminobis ethanol (CASRN 61791-31-9)

Zebra fish (*Brachydanio rerio*) were exposed to the test substance (CASRN 61791-31-9) at measured concentrations of 0.027, 0.049, 0.050, 0.11 and 0.15 mg/L under flow-through conditions for 28 days. Larvae survival was the only indicator of an effect. Survival of larvae at 0.11 and 0.15 mg/L was less than controls.

30-d LC₅₀ = 0.0179 mg/L

Acute Toxicity to Aquatic Invertebrates

N,N-Dimethyl-1-octadecanamine (CASRN 124-28-7)

Mysid shrimp (*Mysidopsis bahia*) were exposed to the test substance (CASRN 124-28-7) at nominal concentrations of 0.052, 0.088, 0.140, 0.240 and 0.400 mg/L under static conditions for 96 hours. Measured concentrations were not determined. Mortalities occurred at ≥ 0.052 mg/L.

96-h LC₅₀ = 0.074 mg/L

Dihydrogenated tallow methylamine (CASRN 61788-63-4)

The eight studies submitted were inadequate.

Cis-9-Octadecenylamine (CASRN 112-90-3, supporting chemical)

Waterfleas (*Daphnia magna*) were exposed to the test substance (CASRN 112-90-3) at nominal concentrations of 0.006, 0.011, 0.023, 0.045 and 0.090 mg/L under static conditions for 48 hours. Measured concentrations for the nominal solutions of 0.011, 0.023 and 0.090 mg/L were 0.007, 0.010, 0.011 and 0.048 mg/L.

48-h EC₅₀ = 0.011 mg/L

N-Coco alkyl derivatives of 2,2'-iminobis ethanol (CASRN 61791-31-9)

Waterfleas (*Daphnia magna*) were exposed to the test substance (CASRN 61791-31-9) at nominal concentrations of 0.29, 0.37, 0.48, 0.62, 0.28, 1.0, 1.3 and 1.7 mg/L under static conditions for 48 hours. Measured concentrations were not determined.

48-h LC₅₀ = 0.38 mg/L

Chronic Toxicity to Aquatic Invertebrates

N-Coco alkyl derivatives of 2,2'-iminobis ethanol (CASRN 61791-31-9)

(1) Waterfleas (*Daphnia magna*) were exposed to the test substance (CASRN 61791-31-9) at nominal concentrations of 0.0018, 0.0032, 0.0056, 0.010, 0.018, 0.032, 0.056, 0.10, 0.18 or 0.32 mg/L under static conditions for 21 days. Survival and reproduction of *Daphnia magna* was measured over the exposure period. Measured concentrations were determined, but not reported. The growth and condition of the test organism was poor compared to controls in the 0.18 and 0.32 mg/L groups. Reproduction was lower in the 0.18 and 0.32 mg/L groups.

21-d LC₅₀ = 0.15 mg/L

(2) Waterfleas (*Daphnia magna*) were exposed to the test substance (CASRN 61791-31-9) at nominal concentrations of 0.036, 0.058, 0.101, 0.195 or 0.477 mg/L under static conditions for 21 days. Survival and reproduction of *Daphnia magna* was measured over the exposure period. Measured concentrations were not determined. The growth and condition of the test organism was poor compared to controls in the 0.195 and 0.477 mg/L groups. Reproduction appeared impaired in the 0.477 mg/L group. Daily production and mean length of F₀ survivors in the 0.101 and 0.195 mg/L groups were lower than controls.

21-d LC₅₀ = 0.14 mg/L

Toxicity to Aquatic Plants

Dihydrogenated tallow methylamine (CASRN 61788-63-4)

Green algae (*Pseudokirchneriella subcapitata*) were exposed to the test substance (CASRN 61788-63-4) at nominal concentrations of 0.010, 0.030, 0.090, 0.270 or 0.810 mg/L under static conditions for 72 hours. Measured concentrations were not determined. Test result details not provided.

72-h EC₅₀ = 0.05 mg/L (biomass)

72-h EC₅₀ = 0.12 mg/L (growth rate)

N,N-Dimethyl-1-octadecanamine (CASRN 124-28-7)

The study submitted was inadequate.

Cis-9-Octadecenylamine (CASRN 112-90-3, supporting chemical)

Green algae (*Pseudokirchneriella subcapitata*) were exposed to the test substance (CASRN 112-90-3) at nominal concentrations of 0.01, 0.02, 0.04, 0.08 or 0.15 mg/L under static conditions for 96 hours. Measured concentrations in control, 0.01, 0.04 and 0.15 mg/L were 0, ND, 0.016, 0.011 and ND mg/L.

96-h EC₅₀ = 0.03 mg/L (biomass)

96-h EC₅₀ = 0.04 mg/L (growth rate)

Conclusion: The typical 96-h LC₅₀ for fish with the supporting chemical, CASRN 112-90-3, is 0.11 mg/L and the typical 48-h EC₅₀ for aquatic invertebrates is 0.011 mg/L. The 96/72-h EC₅₀ values for aquatic plants are 0.03 mg/L and 0.04 mg/L for biomass and growth rate, respectively. For CASRN 61791-31-9, the 30-d fish chronic value is 0.0179 mg/L and the 21-d aquatic invertebrates value is 0.14 mg/L.

Table 16. Summary Table of the Screening Information Data Set as Submitted under the U.S. HPV Challenge Program – Aquatic Toxicity Data

Endpoints	Dodecyl-amine (124-22-1)	Hexadecyl-amine (143-27-1)	N-(9Z)-octa-decenyl-1,3-propanedia mine (7173-62-8)	C14 – 18-alkyl amines (68037-91-2)	C16 – 18 and C18-unsaturated alkyl amines (68037-95-6)	C14 – 18 and C16 – 18-unsaturated alkyl amines (68155-38-4)	Soya alkyl amines (61790-18-9)	N,N-Dimethyl-1-hexa-decan-amine (112-69-6)	N,N-Di-methyl-1-tetradecan-amine (112-75-4)	N,N-Di-methyl-1-octa-decanamine (124-28-7)	N-Tallow alkyltri-methylene-diamines (61791-55-7)	Dimethyl soya alkyl amines (61788-91-8)	(Hydrogen-ated tallow alkyl)-dimethyl amines (61788-95-2)
SPONSORED CHEMICALS													
Fish 96-h LC₅₀ (mg/L)	0.42 (m)	No Data 0.11 (RA)	No Data 0.11 (RA)	No Data 0.11 (RA)	No Data 0.11 (RA)	No Data 0.11 (RA)	No Data 0.11 (RA)	0.18	0.18 (m)	0.18	No Data 0.11 (RA)	No adequate data 0.11 (RA)	No Data 0.11 (RA)
Aquatic Invertebrates 48-h EC₅₀ (mg/L)	No Data 0.011 (RA)	No Data 0.011 (RA)	No Data 0.011 (RA)	No Data 0.011 (RA)	No Data 0.011 (RA)	No Data 0.011 (RA)	No Data 0.011 (RA)	No Data 0.011 (RA)	No Data 0.011 (RA)	0.074	No Data 0.011 (RA)	No Data 0.011 (RA)	No Data 0.011 (RA)
Aquatic Plants 72/96-h EC₅₀ (mg/L)	No Data 0.03	No Data 0.03	No Data 0.03	No Data 0.03	No Data 0.03	No Data 0.03	No Data 0.03	No Data 0.03	No Data 0.03	No Data 0.03	No adequate data 0.03	No Data 0.03	No Data 0.03
Biomass Growth rate	0.04 (RA)	0.04 (RA)	0.04 (RA)	0.04 (RA)	0.04 (RA)	0.04 (RA)	0.04 (RA)	0.04 (RA)	0.04 (RA)	0.04 (RA)	0.04 (RA)	0.04 (RA)	0.04 (RA)
Chronic Toxicity to Fish 21-d EC₅₀ (mg/L)	No Data 0.0179 (RA)	No Data 0.0179 (RA)	No Data 0.0179 (RA)	No Data 0.0179 (RA)	No Data 0.0179 (RA)	No Data 0.0179 (RA)	No Data 0.0179 (RA)	No Data 0.0179 (RA)	No Data 0.0179 (RA)	No Data 0.0179 (RA)	No Data 0.0179 (RA)	No Data 0.0179 (RA)	No Data 0.0179 (RA)
Chronic Toxicity to Invertebrates 21-d EC₅₀ (mg/L)	No Data 0.14 (RA)	No Data 0.14 (RA)	No Data 0.14 (RA)	No Data 0.14 (RA)	No Data 0.14 (RA)	No Data 0.14 (RA)	No Data 0.14 (RA)	No Data 0.14 (RA)	No Data 0.14 (RA)	No Data 0.14 (RA)	No Data 0.14 (RA)	No Data 0.14 (RA)	No Data 0.14 (RA)

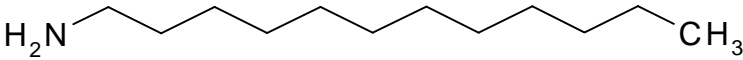
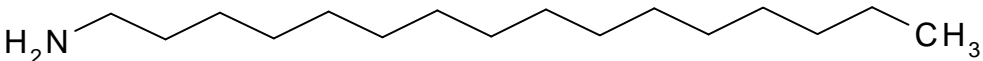
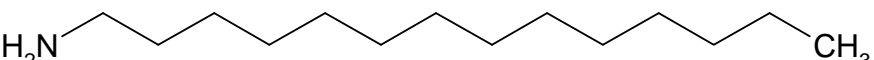
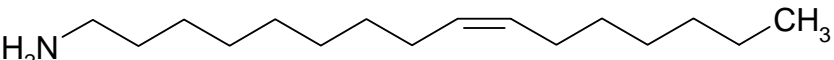
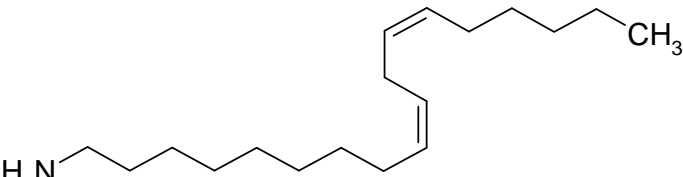
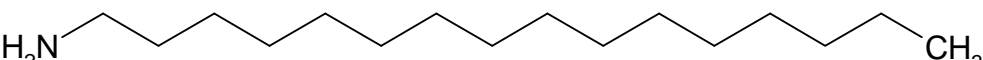
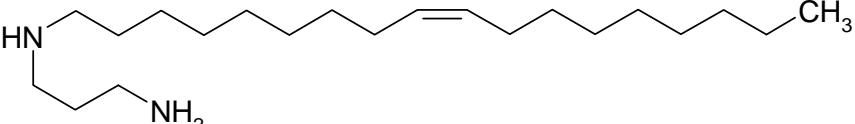
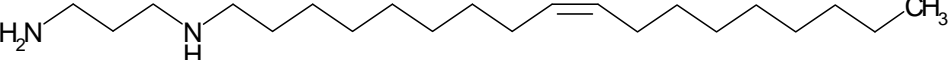
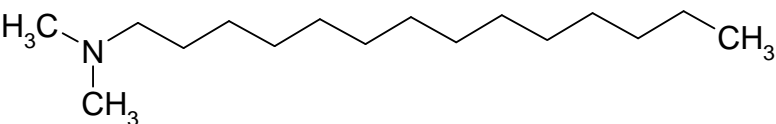
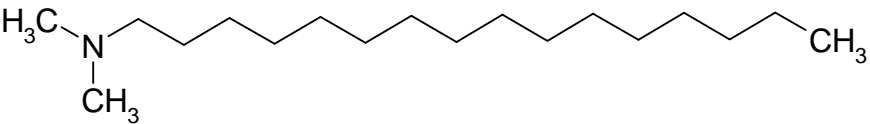
bold = measured data (i.e., derived from testing); (RA) = Read Across; – indicates that endpoint was not evaluated for this substance

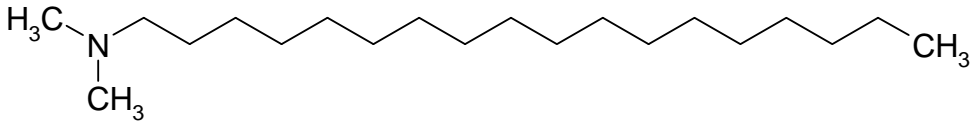
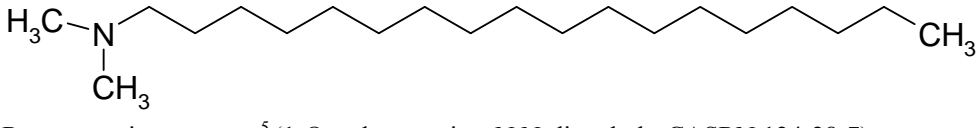
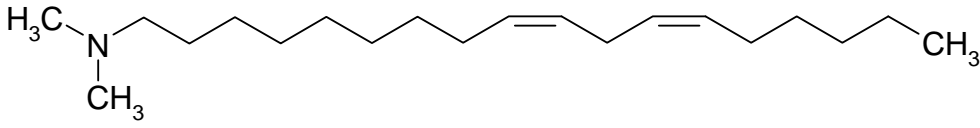
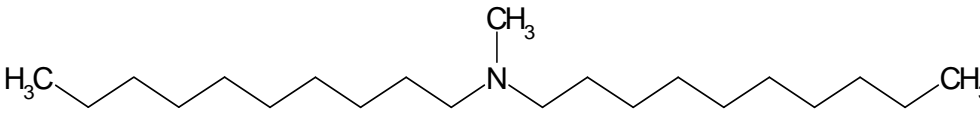
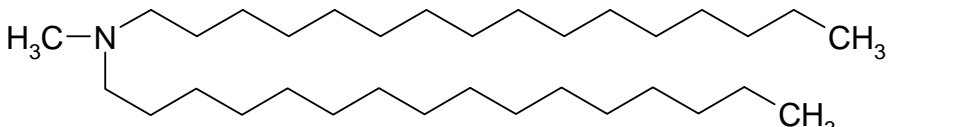
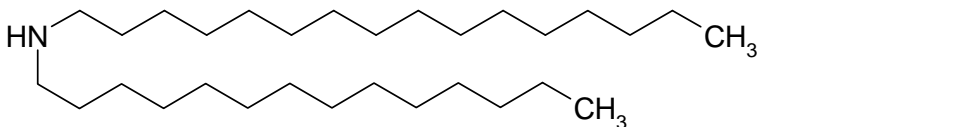
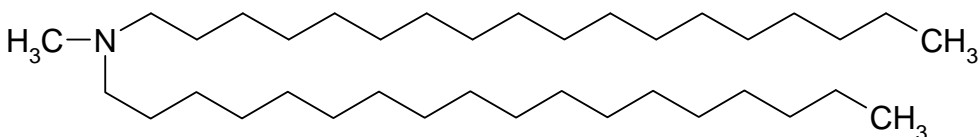
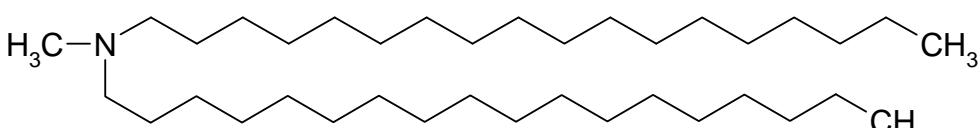
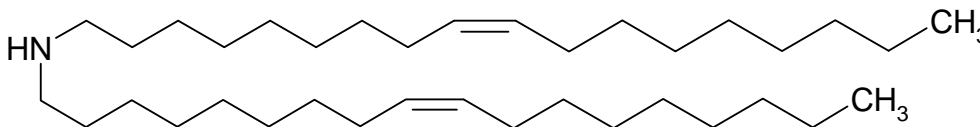
Table 16. Summary Table of the Screening Information Data Set as Submitted under the U.S. HPV Challenge Program – Aquatic Toxicity Data

Endpoints	N-Methyl-N-octadecyl-1-octadecanamine (4088-22-6)	Dihydrogenated tallow methylamine (61788-63-4)	Di-C14 – 18-alkylmethyl amines (67700-99-6)	Di-C12 – 18-alkyl amines (68153-95-7)	Ditallow alkyl amines (68783-24-4)	N-decyl-N-methyl-1-decanamine (7396-58-9)	Tri-C8 – 10-alkyl amines (68814-95-9)	Tris-(hydrogenated tallow alkyl) amines (61790-42-9)	Cis-9-octadecylamine (112-90-3, supporting chemical)	N-Coco alkyl derivatives of 2,2'-iminobis ethanol (61791-31-9)	N-Tallow alkyl derivatives of 2,2'-iminobis-ethanol (61791-44-4)
SPONSORED CHEMICALS									SUPPORTING CHEMICAL	SPONSORED CHEMICALS	
Fish 96-h LC₅₀ (mg/L)	No adequate data 0.11 (RA)	No adequate data 0.11 (RA)	No Data 0.11 (RA)	No Data 0.11 (RA)	No Data 0.11 (RA)	No Data 0.11 (RA)	No Data 0.11 (RA)	No Data 0.11 (RA)	0.11	No Data 0.11 (RA)	No Data 0.11 (RA)
Aquatic Invertebrates 48-h EC₅₀ (mg/L)	No Data 0.011 (RA)	No adequate data 0.011 (RA)	No Data 0.011 (RA)	No Data 0.11 (RA)	No Data 0.11 (RA)	No Data 0.11 (RA)	No Data 0.11 (RA)	No Data 0.11 (RA)	0.011	0.38	No Data 0.011 (RA)
Aquatic Plants 72/96-h EC₅₀ (mg/L)	No Data 0.03 0.04 (RA)	0.05 0.12 (72-h)	No Data 0.03 0.04 (RA)	No Data 0.03 0.04 (RA)	No Data 0.03 0.04 (RA)	No Data 0.03 0.04 (RA)	No Data 0.03 0.04 (RA)	No Data 0.03 0.04 (RA)	0.03 0.04 (96-h)	No Data 0.03 0.04 (RA)	No Data 0.03 0.04 (RA)
Chronic Toxicity to Fish 21-d EC₅₀ (mg/L)	No Data 0.0179 (RA)	No Data 0.0179 (RA)	No Data 0.0179 (RA)	No Data 0.0179 (RA)	No Data 0.0179 (RA)	No Data 0.0179 (RA)	No Data 0.0179 (RA)	No Data 0.0179 (RA)	–	0.0179	No Data 0.0179 (RA)
Chronic Toxicity to Invertebrates 21-d EC₅₀ (mg/L)	No Data 0.14 (RA)	No Data 0.14 (RA)	No Data 0.14 (RA)	No Data 0.14 (RA)	No Data 0.14 (RA)	No Data 0.14 (RA)	No Data 0.14 (RA)	No Data 0.14 (RA)	–	0.14	No Data 0.14 (RA)

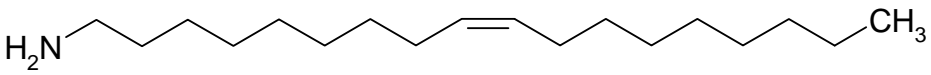
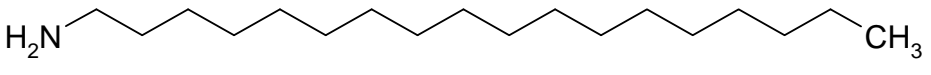
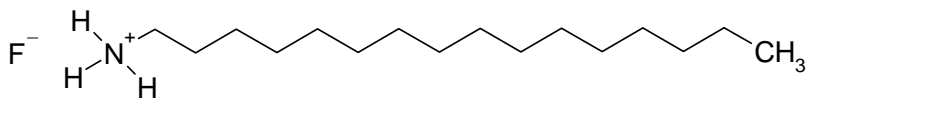
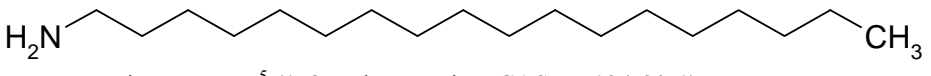
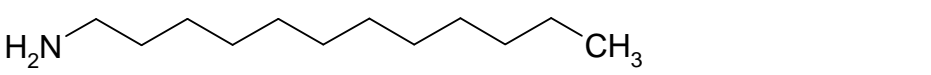
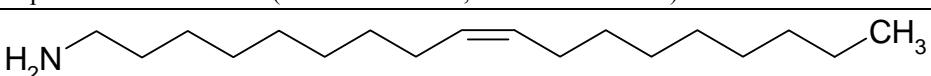
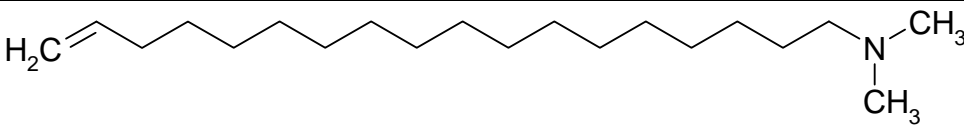
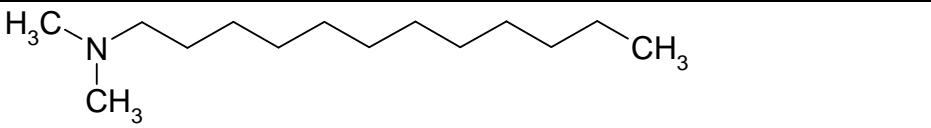
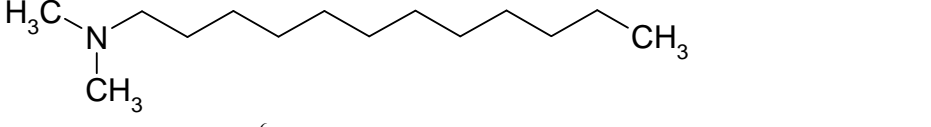
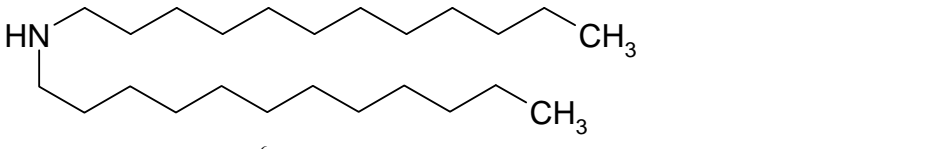
bold = measured data (i.e., derived from testing); (RA) = Read Across; – indicates that endpoint was not evaluated for this substance

APPENDIX 1: Structures for FND Amines Category

SPONSORED CHEMICALS		
Name	CASRN	Structure
<i>Subcategory I: Hydroxylated FND Amines (21)</i>		
1-Dodecanamine	124-22-1	
1-Hexadecan-amine	143-27-1	
Amines, C14-18-alkyl	68037-91-2	 Representative structure ¹ (1-tetradecanamine, CASRN 2016-42-4)
Amines, C14-18 and C16-18-unsatd. alkyl	68155-38-4	 Representative structure ¹
Amines, soya alkyl	61790-18-9	 Representative structure ²
Amines, C16-18 and C18-unsatd. Alkyl	68037-95-6	 Representative structure ³ (1-hexadecanamine, CASRN 143-27-1)
Amines, N-tallow alkyltrimethylene di-	61791-55-7	 Representative structure ⁴
1,3-Propanedi-amine, N1-(9Z)-9-octadecen-1-yl-	7173-62-8	
1-Tetradecan-amine, N,N-dimethyl-	112-75-4	
1-Hexadecan-amine, N,N-dimethyl-	112-69-6	

SPONSORED CHEMICALS		
Name	CASRN	Structure
1-Octadecanamine, N,N-dimethyl-	124-28-7	
Amines, (hydrogenated tallow alkyl)dimethyl	61788-95-2	 Representative structure ⁵ (1-Octadecanamine, N,N-dimethyl-, CASRN 124-28-7)
Amines, dimethylsoya alkyl	61788-91-8	 Representative structure ²
1-Decanamine, N-decyl-N-methyl-	7396-58-9	
Amines, di-C14-18-alkylmethyl	67700-99-6	 Representative structure ¹
Amines, di-C12-18-alkyl	68153-95-7	 Representative structure ¹
1-Octadecanamine, N-methyl-N-octadecyl-	4088-22-6	
Amines, bis(hydrogenated tallow alkyl)methyl	61788-63-4	 Representative structure ⁵ (1-octadecanamine, N-methyl-N-octadecyl-, CASRN 4088-22-6)
Amines, ditallow alkyl	68783-24-4	 Representative structure ⁴

SPONSORED CHEMICALS		
Name	CASRN	Structure
Amines, tri-C8-10-alkyl	68814-95-9	<p>Representative structure¹</p>
Amines, tris(hydrogenated tallow alkyl)	61790-42-9	<p>Representative structure⁵</p>
<i>Subcategory II: Hydroxylated FND Amines (2)</i>		
Ethanol, 2,2'-iminobis-, N-coco alkyl derivs.	61791-31-9	<p>Representative structure⁶</p>
Ethanol, 2,2'-iminobis-, N-tallow alkyl derivs.	61791-44-4	<p>Representative structure⁴</p>

Supporting Chemicals (All for Subcategory I – Nonhydroxylated FND Amines)		
Name	CASRN	Structure
9-Octadecen-1-amine, (9Z)-	112-90-3	
1-Octadecanamine	124-30-1	
1-Hexadecanamine, hydrofluoride	3151-59-5	
Amines, hydrogenated tallow alkyl	61788-45-2	 Representative structure ⁵ (1-Octadecanamine, CASRN 124-30-1)
Amines, coco alkyl	61788-46-3	 Representative structure ⁶ (1-Dodecanamine, CASRN 124-22-1)
Amines, tallow alkyl	61790-33-8	 Representative structure ⁴ (9-Octadecen-1-amine, (9Z)-, CASRN 112-90-3)
Octadecen-1-amine, N,N-dimethyl-	28061-69-0	 Representative structure, position of double bond unspecified
1-Dodecanamine, N,N-dimethyl-	112-18-5	
Amines, coco alkyl dimethyl	61788-93-0	 Representative structure ⁶ (1-Dodecanamine, N,N-dimethyl-, CASRN 112-18-5)
Amines, dicoco alkyl	61789-76-2	 Representative structure ⁶

Supporting Chemicals (All for Subcategory I – Nonhydroxylated FND Amines)		
Name	CASRN	Structure
Amines, dicocoalkylmethyl	61788-62-3	<p>Representative structure⁶</p>
Amines, bis(hydrogenated tallow alkyl)	61789-79-5	<p>Representative structure⁵</p>

¹Average chain length is used for the representative structure.

²For soya fatty amine mixtures, the sponsor provides the following distribution: 43–56% linoleic amine; 20–30% oleic amine; 8–14% linolenic amine; 7–11% palmitic amine; 2–7% stearic amine. The representative structures shown for soy fatty amines contain a diunsaturated 18 carbon chain length, as it is the highest concentration in the mixture according to the sponsor.

³The chain length and degree of unsaturation are not specified by the sponsor for CASRN 68037-95-6 (Amines, C16-18 and C18-unsatd. alkyl). The representative structure shown is for the 16 carbon chain unsaturated alkyl amine.

⁴For tallow fatty amine mixtures, the sponsor provides the following distribution: 35–46% oleic amine; 20–37% palmitic amine; 14–21% stearic amine; 4–10% linoleic amine. The representative structures shown for tallow fatty amines contain a monounsaturated 18 carbon chain length, as it is the highest concentration in the mixture according to the sponsor.

⁵For hydrogenated tallow fatty amine mixtures, the sponsor provides the following distribution: 49–67% stearic amine; 23–46% palmitic amine; 1–6% myristic amine. The representative structures shown for hydrogenated tallow fatty amines contain a saturated 18 carbon chain length, as it is the highest concentration in the mixture according to the sponsor.

⁶For coco (coconut) fatty amine mixtures, the sponsor provides the following distribution: 44–53% lauric amine; 13–19% myristic amine; 8–11% palmitic amine; 5–10% decanoic amine; 5–9% octanoic amine; 5–8% linoleic amine. The representative structures shown for coco fatty amines contain a saturated 12 carbon chain length, as it is the highest concentration in the mixture according to the sponsor.