<u>GreenScreenTM Assessment for Dow's EcolibriumTM Bio-Based</u> <u>Plasticizers</u>

Also Called: [REDACTED]

Chemical Structure: [REDACTED]

ECOLIBRIUM[™] Bio-Based Plasticizers:

- LPLAS-1101 EXP4 (with minor antioxidant)
- LPLAS-1102 EXP2
- LPLAS-PURE EXP1
- LPLAS-PURE EXP2

For Polymers: Identify Monomers and Corresponding Properties:

Below is the Proprietary/Confidential Business Information of Dow LPLAS-1101 EXP4 [REDACTED], LPLAS-1102 EXP2 [REDACTED], LPLAS-PURE EXP1 [REDACTED] and LPLAS-PURE EXP2 [REDACTED]:

- 1. % of Each Proprietary Monomer [REDACTED]
- 2. Are the monomers blocked: [REDACTED]
- 3. Molecular Weight (MW) of Polymer: [REDACTED]
- 4. % of Polymer with:
 - a. MW <500: [REDACTED]
 - b. MW <1,000: [REDACTED]
- 5. % Weight Residual Monomers: [REDACTED]
- 6. Solubility/Dispersability/Swellability: [REDACTED]
- 7. Particle Size: n/a
- 8. Overall Polymer Charge: n/a

A Hazard Summary for Dow's Proprietary Bio-Based Plasticizers is tabulated in Table 1 with each of the proprietary polymers represented by the lowest scoring proprietary monomer [REDACTED].

									F	ormi	ilatio	ns											
			0	broup I	Hum	an Hea	lth		-	Gro	up II a	nd II*]	Human H	ealth			Ecoto	xicity	Fa	te	Phy	sical	
Chemical ¹	CAS RN	% In Ingredient	Carcinogenicity	Mutagenicity	Reproductive	Developmental	Endocrine Activity	Acute Toxicity	E	Systemic Loxicity		Neuroloxicity	Skin Sensitization*	Respiratory Sensitization*	Skin Irritation	Eye Irritation	Acute Aquatic	Chronic Aquatic	Persistence	Bioaccumulation	Reactivity	Flammability	GS Benchmark Score (Chemical) ²
									s	r*	S	r*											
LPLAS-1101 EXP4	[REDACTED]		L	L	L	М	dg	L	dg	М	dg	dg	L	dg	L	L	L	L	Н	vL	L	L	2
LPLAS-1102 EXP2	[REDACTED]		L	L	L	L	dg	L	dg	L	dg	L	М	dg	L	L	L	L	vL	vL	L	L	3
LPLAS-PURE EXP1	[REDACTED]		L	L	L	L	dg	L	dg	L	dg	L	М	dg	L	L	L	L	vL	vL	L	L	3
LPLAS-PURE EXP2	[REDACTED]		L	L	L	L	dg	L	dg	L	dg	L	М	dg	L	L	L	L	vL	vL	L	L	3
s=single dose r=repe dg=not determined/u	at dose nknown																						

Table 1: Hazard Summary Table for Dow's Green ScreenTM Assessment for Dow EcolibriumTM Bio-Based Plasticizer

L=Low Hazard M=Moderate Hazard H=High Hazard vH=very High Hazard-Endpoints in colored text (L, M, H, and vH) were assigned based on experimental data.

Endpoints in black italics (*L*, *M*, and *H*) were assigned using estimated values and professional judgment (Structure Activity Relationships)

¹ Redacted chemicals will be identified by their general chemical class and will indicate the presence and identity of metals and halogens.

 $^{^{2}}$ For inorganic chemicals with low human and ecotoxicity values across all hazard endpoints and low bioaccumulation, persistence alone will not be deemed problematic. Inorganic chemicals that are only persistent will be evaluated under the criteria for Benchmark 4.

References

Clean Production Action (CPA). 2011a. The GreenScreen[™] for Safer Chemical Version 1.2. Available: <u>http://www.cleanproduction.org/Greenscreen.v1-2.php</u>

Clean Production Action (CPA). 2011b. Red List of Chemicals. Available: http://www.cleanproduction.org/library/greenScreenv1-2/GS_v_1_2_Benchmark_1_Lists.pdf

Clean Production Action (CPA). 2011c. The GreenScreen[™] for Safer Chemicals v 1.2 Guidance for Hazard Assessment and Benchmarking Chemicals. 10/18/2011. http://www.cleanproduction.org/library/greenScreenv1-2/DRAFT GreenScreen v1-2 Guidance 2011 1018 v2.pdf

GreenScreenTM Assessment for Antioxidant (CAS #[REDACTED])

GreenScreen[™] Version 1.2 Draft Assessment Note: Validation Has Not Been Performed on this GreenScreen[™] Assessment

Chemical Name: Antioxidant (CAS #[REDACTED])

GreenScreenTM Assessment Prepared By:

Name: Chris Schlosser, M.F.S. Title: Associate Toxicologist Organization: ToxServices LLC Date: January 19, 2012 Revised: February 23, 2012

Quality Control Performed By:

Name: Margaret H. Whittaker, Ph.D., M.P.H., CBiol., F.S.B., E.R.T., D.A.B.T. Title: Managing Director and Chief Toxicologist Organization: ToxServices LLC Date: March 8, 2012

Confirm application of the *de minimus* rule³: yes

Chemical Name (CAS #): Antioxidant (CAS #[REDACTED])

Also Called: [REDACTED]

Chemical Structure(s): [REDACTED]

Identify Applications/Functional Uses: (e.g. Cleaning product, TV casing) 1. Antioxidant

GreenScreen[™] Rating⁴: Antioxidant was assigned a GreenScreen[™] Benchmark Score of 2 based on Moderate Developmental Toxicity (D), High Persistence (P) with Moderate Systemic Toxicity (ST). This corresponds to GreenScreen[™] benchmark classification 2c or 2e in CPA 2011a. Data gaps (dg) exist for Endocrine Activity (E), Neurotoxicity (N), and Respiratory Sensitization (SnR). As outlined in CPA (2011c) Section III(1)(Benchmarking Chemicals With Data Gaps), Antioxidant meets requirements for a GreenScreen[™] Benchmark Score of 2, despite the hazard data gaps. In a worst-case scenario, if Antioxidant were assigned a High score for E, it would become a GreenScreen[™] Benchmark 1 chemical.

NOTE: Full toxicological studies or extended abstracts were not available for review by ToxServices. Only limited quantitative details (i.e., statistical significance, organ weight values, and percent changes in measured endpoints) were disclosed/reported in study abstracts/summaries. Therefore, ToxServices has assigned a low confidence score for each hazard endpoint, as reflected by the italicized hazard ratings.

³ Every chemical in a material or formulation should be assessed if it is:

^{1.} intentionally added and/or

^{2.} present at greater than or equal to 100 ppm.

⁴ For inorganic chemicals with low human and ecotoxicity across all hazard endpoints and low bioaccumulation potential, persistence alone will not be deemed problematic. Inorganic chemicals that are only persistent will be evaluated under the criteria for Benchmark 4.

	Green Screen Hazard Ratings: Antioxidant																		
	Group I Human Group II and II* Human										Eco	tox	Fate		Physical				
С	м	R	D	Е	AT	S	ST		N	SnS*	SnR*	IrS	IrE	AA	CA	Р	в	Rx	F
						single	repeat	single	repeat										
L	L	L	М	dg	L	dg	М	dg	dg	L	dg	L	L	L	L	Н	vL	L	L

Note: Hazard levels (Very High (vH), High (H), Moderate (M), Low (L), Very Low (vL)) in *italics* reflect estimated values and lower confidence. Hazard levels in **BOLD** font reflect values based on test data (See Guidance). Note: Please see Appendix A for a glossary of hazard acronyms.

Transformation Products and Ratings:

Identify relevant fate and transformation products (i.e., dissociation products, transformation products, valence states) **and/or moieties of concern**⁵

Functional Use	Life Cycle Stage	Transformation Pathway	Transformation Products	CAS #	On CPA Red List ⁶ ?	GreenScreen [™] Rating ⁷
n/a	End	Combustion	Carbon Monoxide	630-08-0	Y	n/a
n/a	End	Combustion	Carbon Dioxide	124-38-9	Ν	n/a

Introduction

Antioxidant is a phenolic antioxidant and is used as a non-discoloring stabilizer for organic substrates like plastics, synthetic fibers, elastomers, adhesives, waxes, oils and fats. It protects against thermo-oxidative degradation (UNEP 2006).

⁵ A moiety is a discrete chemical entity that is a constituent part or component of a substance. A moiety of concern is often the parent substance itself for organic compounds. For inorganic compounds, the moiety of concern is typically a dissociated component of the substance or a transformation product.

⁶ The CPA "Red List" refers to chemicals 1. flagged as Benchmark 1 using the GreenScreen[™] List Translator or 2. flagged as Benchmark 1 or 2 using the GreenScreen[™] List Translator and further assessed and assigned as Benchmark 1. The most recent version of the GreenScreen[™] List Translator should be used (CPA 2011b).

⁷ GreenScreenTM reviews of transformation products depend on the GreenScreen Benchmark Score of the parent chemical (See Guidance in CPA 2011c).

Hazard Classification Summary Section:

NOTE: Complete versions of toxicological studies or extended abstracts were not available for review by ToxServices. Limited quantitative details (i.e. statistical significance, organ weight values, and percent changes in measured endpoints) were disclosed/reported in study abstracts/summaries reviewed by ToxServices. Therefore, ToxServices has assigned a low confidence score for each hazard endpoint, as reflected by italicized hazard ratings.

Group I Human Health Effects (Group I Human)

Carcinogenicity (C) Score (H, M or L): L

Antioxidant was assigned a score of Low for carcinogenicity based on no increases in tumors or signs of carcinogenicity following two-year chronic toxicity/carcinogenicity assays in rats and mice utilizing the dietary route of exposure.

- Not listed as a known carcinogen by IARC, NTP, U.S. EPA, or CA Prop 65.
- Ciba-Geigy 1974 -
 - A (GLP status not reported) 2 year chronic toxicity/carcinogenicity assay (method not reported) was conducted using (strain not reported) male and female rats (50/sex/dose). Rats were administered doses ranging from 0 to approximately 200 mg/kg (purity not reported) of Antioxidant in males, and from 0 to approximately 300 mg/kg of Antioxidant in females, in the diet over a 2-year period. No statistically significant increases in tumors were reported under the tested conditions.
- Ciba-Geigy 1982a -
 - A (GLP status not reported) 2 year chronic toxicity/carcinogenicity assay (method not reported) was conducted using (strain not reported) male and female mice (50/sex/dose). Mice were administered doses ranging from 0 to approximately 50 mg/kg (purity not reported) of Antioxidant in the diet, over a 2-year period. No statistically significant increases in tumors were reported under the tested conditions.

Mutagenicity/Genotoxicity (M) Score (H, M or L): L

Antioxidant was assigned a score of Low for mutagenicity based on no signs of mutagenicity or clastogenicity following *in vitro* or *in vivo* genotoxicity assays.

- Ciba-Geigy 1977 -
 - A (GLP status not reported) bacterial reverse mutation assay (method not reported) was conducted utilizing *Salmonella typhimurium* tester stains TA98, TA100, TA1535 and TA1537 at concentrations of up to 100 µg/plate (purity not reported) with activation, and 250 µg/plate without activation (note: explanation of different dosing paradigm not provided). Antioxidant was reported as negative for mutagenicity under all tested conditions.
- Ciba-Geigy 1976a
 - A (GLP status not reported) micronucleus assay (method not reported) was conducted using male and female Chinese hamsters (3/sex/group). Hamsters were administered doses ranging from 0 to approximately 2,000 mg/kg (purity not reported) of Antioxidant via oral gavage for 2 days. Animals were sacrificed 24 hours after dosing and no increased incidence of micronucleated cells were found in any dose groups. Antioxidant was reported as negative for mutagenicity under all tested conditions.
- Ciba-Geigy 1981a
 - A (GLP status not reported) chromosomal aberration assay (method not reported) was conducted using male and female Chinese hamsters (4/sex/group). Mice were administered doses ranging from 0 to approximately 2,000 mg/kg (purity not reported) of Antioxidant for 2 days. Animals were sacrificed 30 hours after dosing and no increased incidence of micronucleated cells were found in any dose groups. Antioxidant was reported as negative for clastogenicity under all tested conditions.
- Ciba-Geigy 1975a -
 - A (GLP status not reported) dominant lethal assay (method not reported) was conducted using male (strain not reported) mice (20/dose). Mice were administered doses ranging from 0 to approximately 3,000 mg/kg (purity not reported) of the test substance via oral gavage. Males were mated with females for up to 6 weekly mating periods. No evidence of dominant lethal effects or differences in

mating ratio, number of implantation, or embryonic deaths was reported. Antioxidant was reported as negative for mutagenicity under all tested conditions.

Reproductive Toxicity (R) Score (H, M, or L): L

Antioxidant was assigned a score of Low for reproductive toxicity based on the absence of treatment-related effects on reproductive endpoints following an OECD 416 two generation reproductive toxicity study.

- Ciba-Geigy 1986
 - A GLP-compliant two generation reproductive toxicity study (OECD 416) was conducted using male 0 and female CD rats (number not reported). Rats were administered dietary doses ranging from 0 to approximately 5,000 ppm (0 to approximately 300 mg/kg in males and 0 to approximately 400 mg/kg in females) in the diet for 10-12 weeks pre-mating, during mating, during gestation and until weaning of offspring. In the F0 generation, relative liver weights were significantly increased in males and females of the top dose group. In addition, males in the top dose had enlarged livers. Relative spleen weights were decreased in all treated male groups. In the F0 and F1 generations, mating performance, pregnancy rate, and duration of gestation were not affected by treatment. Total litter loss was increased at the top dose (0/26, 1/24, 2/24, 4/27) in the F1 generation. Additionally, litter size was significantly reduced in all dose groups of the F1 generation. In the F2 generation reductions of litter size did not reach statistical significant and were not dose-related. The percentage of live pups per litter was significantly lower in the top dose group of the F1 generation. At the top dose post-natal survival was lower in both generations. Based on available data, the reproductive NOAEL is set at approximately300 mg/kg. Based on significantly decreased litter sizes in all F1 dose groups, and organ weight changes in pups, ToxServices established a developmental NOAEL and LOAEL of approximately 100 and 25 mg/kg, respectively. Limited data were provided on the reproductive toxicity endpoints analyzed. ToxServices confidence in the study is low due to the absence of a complete study summary with detailed endpoint evaluation, so the endpoint is reflected in italics.

Developmental Toxicity incl. Developmental Neurotoxicity (D) Score (H, M or L): M

Antioxidant was assigned a score of Moderate for developmental toxicity based on a NOAEL of 32 mg/kg identified for significantly decreased litter sizes and organ weight changes following an OECD two generation study, and decreased body weights with reduced ossification of phalangeal nuclei following a developmental toxicity study.

- Ciba-Geigy 1986 -
 - A GLP-compliant two generation reproductive toxicity study (OECD 416) was conducted using male 0 and female CD rats (number not reported). Rats were administered doses ranging from 0 to approximately 5,000 ppm (0 to approximately 300 mg/kg in males and 0 to approximately 400 mg/kg in females) in the food for 10-12 weeks pre-mating, during mating, during gestation and until weaning of offspring. In the F0 generation, relative liver weights were significantly increased in males and females of the top dose group. In addition, males in the top dose had enlarged livers. Relative spleen weights were decreased in all treated male groups. In the F0 and F1 generations, mating performance, pregnancy rate, and duration of gestation were not affected by treatment. Total litter loss was increased at the top dose (0/26, 1/24, 2/24, 4/27) in the F1 generation. Additionally, litter size was significantly reduced in all dose groups of the F1 generation. In the F2 generation, reductions of litter size did not reach statistical significance and were not dose-related. The percentage of live pups per litter was significantly lower in the top dose group of the F1 generation. At the top dose, post-natal survival was lower in both generations. Based on available data, the reproductive NOAEL is set at approximately 300 mg/kg. Based on significantly decreased litter sizes in all F1 dose groups, and organ weight changes in pups, ToxServices established a developmental NOAEL and LOAEL of approximately 100 and 25 mg/kg, respectively. Limited data were provided on the reproductive toxicity endpoints analyzed. ToxServices confidence in the study is low due to the absence of a complete study summary with detailed endpoint evaluation, so the endpoint is reflected in italics.
- Ciba-Geigy 1975b-
 - A (GLP status not reported) developmental toxicity study (similar to OECD 414) was conducted using female Sprague-Dawley rats. (25/group). Rats were administered doses ranging from 0 to approximately 1,000 mg/kg from day 6 to day 15 of gestation via oral gavage. A dose-related decrease in food consumption was noted in parental animals. No effects on pregnancy rate, number of implantations, early and late resorptions and number of live fetuses were reported. Fetal body weight was significantly reduced in the top two dose groups. In the top dose group an increased incidence of

delayed ossification of the phalangeal nuclei of the hind limbs was observed. Based on available data, ToxServices assigns a NOAEL and LOAEL of approximately150 and 500 mg/kg based on reduced pup body weights in the mid-dose group.

- Ciba-Geigy 1975c -
 - A (GLP status not reported) developmental toxicity study (similar to OECD 414) was conducted using female NMRI mice. (30/group). Mice were administered doses ranging from 0 to approximately 1,000 mg/kg from day 6 to day 15 of gestation via oral gavage. No mortality or maternal toxicity was noted. No effects on pregnancy rate, number of implantations, early and late resorptions and number of live fetuses were reported. A NOAEL of approximately1000 mg/kg was established for maternal and developmental toxicity by the study authors.

Endocrine Activity (E) Score (H, M or L): dg

Antioxidant has been assigned a data gap for endocrine activity. Although it is not a known endocrine disruptor, endocrine disruption testing has not performed on the chemical.

- Not listed as a potential endocrine disruptor on the EU Priority List of Suspected Endocrine Disruptors.
- Not listed as a potential endocrine disruptor on the OSPAR List of Chemicals of Possible Concern.
- Not listed as a potential endocrine disruptor on the Red List of Chemicals (CPA 2011b).
- No relevant data were identified for Antioxidant

Group II and II* Human Health Effects (Group II and II* Human)

Note: Group II and Group II* endpoints are distinguished in the v 1.2 Benchmark system. For Systemic Toxicity and Neurotoxicity, Group II and II* are considered sub-endpoints and test data for single or repeated exposures may be used. If data exist for single OR repeated exposures, then the endpoint is not considered a data gap. If data are available for both single and repeated exposures, then the more conservative value is used.

Acute Mammalian Toxicity (AT) Group II Score (vH, H, M or L): L

Antioxidant was assigned a score of Low for acute mammalian toxicity based on oral, dermal and inhalation LD/C_{50} values above the criteria for low acute toxicity (CPA 2011a).

- Ceiba-Geigy 1981b -
 - An oral LD_{50} value of > 5,000 mg/kg was established in (strain not reported) rats.
- Ceiba-Geigy 1992 -
 - A dermal LD₅₀ value (OECD 402) of > 2,000 mg/kg was established in (strain not reported) rats.
- Ceiba-Geigy 1978
 - An inhalation LC_{50} value of > 1.811 mg/L was established in (strain not reported) rats.

Systemic Toxicity/Organ Effects incl. Immunotoxicity (ST)

Group II Score (single dose: vH, H, M or L): dg

Antioxidant was assigned a data for systemic toxicity/organ effects based on single exposure.

• No relevant data were identified.

Group II* Score (repeated dose: H, M, L): M

Antioxidant was assigned a score of Moderate for systemic toxicity/organ effects based on repeated exposure based on consistent liver effects throughout multiple repeated dose studies. Antioxidant is classified as a GHS Category 2 Repeat Dose toxicant due to significant treatment-related effects between the 10 and 100 mg/kg GHS guidance values (UN 2011).

- Ciba-Geigy 1974
 - A (GLP status not reported) 2 year chronic toxicity/carcinogenicity assay (method not reported) was conducted using (strain not reported) male and female rats (50/sex/dose). Rats were administered doses ranging from 0 to approximately 200 mg/kg (purity not reported) of Antioxidant in males, and ranging from 0 to approximately 300 mg/kg of Antioxidant in females, in the diet over a 2-year period. Liver and thyroid weights were significantly increased in the high dose groups, while the weight of the adrenals and spleen was significantly decreased in the mid and high dose groups. In animals necropsied at study termination an enlarged thyroid and subpleural foci in the lung were reported. Histopathology (10 rats/sex of the control high dose group) showed prostatitis in males and

endometritis in females and no treatment related effects in the liver. Based on findings on body weight in females and organ weights a NOAEL of approximately 50 mg/kg was set by the study authors.

- Ciba-Geigy 1982a -
 - A (GLP status not reported) 2 year chronic toxicity/carcinogenicity assay (method not reported) was conducted using (strain not reported) male and female mice (50/sex/dose). Mice were administered doses ranging from 0 to approximately 60 mg/kg (purity not reported) of Antioxidant in males, and ranging from 0 to approximately 50 mg/kg of Antioxidant in females, in the diet, over a 2-year period. Liver weights were increased in all female dose groups and the low and mid dose groups in males. Microscopic evaluation showed fatty changes and lymphocytic infiltration in the liver, extramedullary hematopoiesis and hemosiderosis in the spleen, subscapular proliferation in the adrenal gland, lymphocytic infiltration in the kidney and urinary bladder, dilatation, and chronic inflammation in the seminal vesicles, cysts in the ovaries, and hyperplasia of the uterus in all dose groups, and controls. No NOAEL or LOAEL were reported by the authors. ToxServices established a LOAEL of approximately 0.5 mg/kg based on liver effects.
- Ciba-Geigy 1981c
 - A (GLP status not reported) 90-day toxicity study (method not reported) was conducted using male and female (breed not reported) dogs. Dogs were administered doses ranging from 0 to approximately 400 mg/kg in males and ranging from 0 to approximately 300 mg/kg in females. Significantly decreased hemoglobin and hematocrit were reported in the high dose group. Increased bilirubin was observed in the mid and high dose groups. No histopathological findings were reported. A NOAEL of approximately 30 mg/kg for males and 35 mg/kg for females was established by the study authors.
- Ciba-Geigy 1991
 - A GLP compliant 28-day oral gavage study (method not reported) was conducted using male and female Sprague-Dawley rats (5/sex/dose). Rats were administered ranging from 0 to approximately 300 mg/kg (purity not reported). Increases in liver weights were observed in the mid and high dose groups, with hypertrophy in the high dose group. Microsomal enzymes (cytochrome P450, ethoxyresorufin Ode-ethylase, pentoxyresorufin O-depentylase, epoxide hydrolase, morphine-UDP glucuronosyltransferase and bilirubin-UDP-glucuronosyltransferase) were investigated. Significant increases were seen in males at approximately100 and 300 mg/kg and in females at approximately 300 mg/kg. Based on the liver effects a NOAEL of approximately 30 mg/kg was established by the study authors.
- Ciba-Geigy 1979 -
 - A GLP status not reported) 21-day inhalation toxicity study (method not reported) was conducted using (strain not reported) male and female rats (10/sex/group). Rats were exposed to doses ranging from 0 to approximately 550 mg/m³ of Antioxidant (purity not reported) for 21 days. Liver weights were increased at all concentrations tested (no dose-response relationship). No histopathological findings were reported. Study authors reported a NOAEL of approximately 500 mg/m³ based on no histopathological finding corresponding with liver weights.
- UNEP 2006 -
 - All studies show effects on liver weight, possibly related to the induction of liver enzymes as indicated by the 28-day study. Furthermore, corresponding histopathology were observed in the 28-day rat study (liver hypertrophy and increased hepatocytic vacuolization) and 2-year mouse study (fatty changes and lymphocytic infiltration in the liver). SIDS authors reported a NOAEL of approximately 30 mg/kg for oral toxicity based on liver effects.
- Antioxidant is classified as a GHS Category 2 toxicant due to significant effects found in animal studies between the 10 and 100 mg/kg GHS guidance values (UN 2011).

Neurotoxicity (N)

Group II Neurotoxicity Score (single dose: vH, H, M or L): dg

Antioxidant has been assigned a data gap for neurotoxicity. Although it is not a known neurotoxicant, neurotoxicity testing has not performed on the chemical.

- Not classified as a developmental neurotoxicant (Grandjean and Landrigan 2006).
- Not listed as a potential neurotoxicant on the Red List of Chemicals (CPA 2011b).
- No relevant data were identified for Antioxidant.

Group II* Neurotoxicity Score (repeated dose: H, M, L): dg

Antioxidant has been assigned a data gap for neurotoxicity. Although it is not a known neurotoxicant, neurotoxicity testing has not performed on the chemical.

- Not classified as a developmental neurotoxicant (Grandjean and Landrigan 2006).
- Not listed as a potential neurotoxicant on the Red List of Chemicals (CPA 2011b).
- No relevant data were identified for Antioxidant.

Skin Sensitization (SnS) Group II* Score (H, M or L): L

Antioxidant was assigned a score of Low for skin sensitization based on being identified as non-sensitizing following a guinea pig optimization study.

- Ceiba-Geigy 1976b -
 - A (GLP-status not reported) optimization study (method not reported) was conducted using guinea pigs (strain/sex not reported, n=20). Guinea pigs were induced intradermally 3 times weekly for 2 weeks with a 0.1% solution of the test substance. Fourteen days after the last injection a 0.1% challenge dose was injected. One out of 20 animals had a reaction in the control group and 4 out of 20 in the tested group. Antioxidant is classified as not-sensitizing following GHS, as ≥ 30% of animals are required to show a reaction for a positive response (UN 2011).

Respiratory Sensitization (SnR) Group II* Score (H, M or L): dg

• No relevant data were identified for Antioxidant.

Skin Irritation/Corrosivity (IrS) Group II Score (vH, H, M or L): L

Antioxidant was assigned a score of Low for skin irritation/corrosivity based on minimal irritation effects that persisted less than 7 days under worst-case exposure conditions.

- Ceiba-Geigy 1982b
 - A (GLP status not reported) skin irritation study (method not reported) was conducted using (strain not reported) rabbits (n=6). Rabbits were exposed to Antioxidant (0.5 g) under an occlusive dressing during 24 hours. Slight to well defined erythema and very slight edema were reversible within 7 days. Compared to the exposure regimen given by the OECD 404 this study used a longer exposure period 24 hours instead of 4 hours and the test substance was applied under occlusion

Eye Irritation/Corrosivity (IrE) Group II Score (vH, H, M or L): L

Antioxidant was assigned a score of Low for eye irritation/corrosivity as average scores for conjunctival redness and chemosis did not reach 2.0 at any point in the study.

- Ceiba-Geigy 1982c
 - A (GLP status not reported) eye irritation study (method not reported) was conducted using New Zealand rabbits (sex not reported, n=6). Antioxidant was considered to cause minimal irritation to the eyes of rabbits (n=6) after 0.1 ml were instilled into the conjunctival sac of the eye. Redness of conjunctivae was not reported after 48 hours in rinsed animals, and only slight redness reported in non-rinsed animals after 7 days. Antioxidant was reported as minimally irritating to the eyes by SIDS authors. However, conjunctival redness and chemosis did not reach an average score of above 1.0 (0.3 to 0.7) at any point in the study. Following GHS guidelines chemicals with average scores below 2.0 at 24, 48 and 72 hours are not classifiable as eye irritants.

Ecotoxicity (Ecotox)

NOTE: Complete versions of studies or extended abstracts were not available for review by ToxServices. Limited quantitative details (i.e. statistical significance, organ weight values, and percent changes in measured endpoints) were disclosed/reported in study abstracts/summaries reviewed by ToxServices. Therefore, ToxServices has assigned a low confidence score for each hazard endpoint, as reflected by italicized hazard ratings.

Acute Aquatic Toxicity (AA) Score (vH, H, M or L): L

Antioxidant was assigned a score of Low for acute aquatic toxicity based on reported values being greater than 100 mg/L or greater than the highest tested concentration.

- Ciba-Geigy 1984a,b
 - A LC_{50} value (96-hr) of > 100 mg/L was identified for Antioxidant in bluegill and rainbow trout.
- Ciba-Geigy 1984c
 - An EC₅₀ value (24-hr) of > 100 mg/L was identified for Antioxidant in *Daphnia manga*.
- Ciba-Geigy 1992 -
 - \circ An EC₅₀ (72-hr) value of > 11.3 mg/L (highest dose tested) following an algae growth inhibition study.

Chronic Aquatic Toxicity (CA) Score (vH, H, M or L): L

• No chronic aquatic toxicity data were identified for this chemical. The globally harmonized system (GHS) does not require a chronic aquatic toxicity hazard rating for substances which are both rapidly biodegradable or have a BCF < 500 and log Kow < 4.

Environmental Fate (Fate)

NOTE: Complete versions of studies or extended abstracts were not available for review by ToxServices. Limited quantitative were disclosed/reported in study abstracts/summaries reviewed by ToxServices. Therefore, ToxServices has assigned a low confidence score for each hazard endpoint, as reflected by italicized hazard ratings.

Persistence (P) Score (vH, H, M, L, or vL): H

Antioxidant was assigned a score of high for persistence based on predicted half-lives between 60 and 100 days in soil and 40 to 60 days in water (CPA 2011a)(please see Appendix B for output files).

- Ceiba-Geigy 1991
 - Antioxidant was found to be 32-35% biodegradable following OECD 301B and 21 to 39% biodegradable following OECD 301C.
- U.S. EPA 2011 -
 - Fugacity III modeling predicts 87.3% partitioning to soil with a half-life of 120 days, and 12.3% partitioning to water with a half-life of 60 days

Bioaccumulation (B) Score (vH, H, M, L, or vL): vL

Antioxidant was assigned a score of Very Low for bioaccumulation based on a reported BCF value of less than 100 (CPA 2011a).

- CERI 1996
 - \circ Exposure of carp to 50 µg/L Antioxidant for 42 days resulted in a bioaccumulation factor of less than 12 indicating that this chemical is not likely to bioaccumulate.

Physical Hazards (Physical)

NOTE: Complete versions of studies or extended abstracts were not available for review by ToxServices. Limited quantitative were disclosed/reported in study abstracts/summaries reviewed by ToxServices. Therefore, ToxServices has assigned a low confidence score for each hazard endpoint, as reflected by italicized hazard ratings.

Reactivity (Rx) Score (vH, H, M or L): L

Antioxidant was assigned a score of Low for reactivity based on this chemical being reported as not explosive.

- UNEP 2006 -
 - Antioxidant is not explosive.

Flammability (F) Score (vH, H, M or L): L

Antioxidant was assigned a score of Low for flammability based on not being considered a readily combustible solid.

• UNEP 2006 -

• Antioxidant has a flash point of 273°C. Antioxidant is not a flammable solid as it is not considered to be readily combustible.

References

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APPENDIX A: Hazard Benchmark Acronyms (in alphabetical order)

- (AA) Acute Aquatic Toxicity
- (AT) Acute Mammalian Toxicity
- (B) Bioaccumulation
- (C) Carcinogenicity
- (CA) Chronic Aquatic Toxicity
- (Cr) Corrosion/ Irritation (Skin/ Eye)
- (D) Developmental Toxicity
- (E) Endocrine Activity
- (F) Flammability
- (IrE) Eye Irritation/Corrosivity
- (IrS) Skin Irritation/Corrosivity
- (M) Mutagenicity and Genotoxicity
- (N) Neurotoxicity
- (P) Persistence
- (R) Reproductive Toxicity
- (Rx) Reactivity
- (SnS) Sensitization-Skin
- (SnR) Sensitization-Respiratory
- (ST) Systemic/Organ Toxicity

[REDACTED]

APPENDIX B: EPISuite Results

Antioxidant GreenScreenTM Evaluation Prepared By:

Christing E Schloson

Christopher E. Schlosser, M.F.S. Associate Toxicologist ToxServices LLC

Antioxidant GreenScreen[™] Evaluation QC'd By:

Margat H. White

Margaret H. Whittaker, Ph.D., M.P.H., CBiol., F.S.B., E.R.T., D.A.B.T. Managing Director and Chief Toxicologist ToxServices LLC

<u>GreenScreenTM Assessment for Dow Proprietary Monomer #1</u> (CAS #[REDACTED])

GreenScreen[™] Version 1.2 Draft Assessment Note: Validation Has Not Been Performed on this GreenScreen Assessment

Chemical Name: Dow Proprietary Monomer #1 (CAS #[REDACTED])

GreenScreen Assessment Prepared By:

Name: Chris Schlosser, M.F.S. Title: Associate Toxicologist Organization: ToxServices LLC Date: October 10, 2011 Revised: February 23, 2012

Quality Control Performed By:

Name: Margaret Whittaker, PhD., M.P.H., CBiol., F.S.B., E.R.T., D.A.B.T. Title: Managing Director and Chief Toxicologist Organization: ToxServices LLC Date: March 8, 2012

Confirm application of the *de minimus* rule⁸: yes

Chemical Name (CAS #): Dow Proprietary Monomer #1 (CAS #[REDACTED])

Also Called: [REDACTED]

Chemical Surrogates, analogs or moieties used in this assessment (CASs #): n/a

Chemical Structure(s): [REDACTED]

Identify Applications/Functional Uses: (e.g. Cleaning product, TV casing) 1. Plasticizer

GreenScreen Rating⁹: Dow Proprietary Monomer #1 was assigned a GreenScreenTM Benchmark Score of 3 as it does not meet the data gap requirements for a Benchmark score of 4. Data gaps (dg) exist for Endocrine Activity (E), Neurotoxicity (N) and Respiratory Sensitization (SnR). As outlined in CPA (2011c) Section III(1)(Benchmarking Chemicals With Data Gaps), Dow Proprietary Monomer #2meets requirements for a GreenScreenTM Benchmark Score of 3. In a worst-case scenario, if Dow Proprietary Monomer #1 was assigned a High score for E it would be assigned a Benchmark Score of 1.

⁸ Every chemical in a material or formulation should be assessed if it is:

^{1.} intentionally added and/or

^{2.} present at greater than or equal to 100 ppm.

⁹ For inorganic chemicals with low human and ecotoxicity across all hazard endpoints and low bioaccumulation potential, persistence alone will not be deemed problematic. Inorganic chemicals that are only persistent will be evaluated under the criteria for Benchmark 4.

	Green Screen Hazard Ratings: Dow Proprietary Monomer #1																		
Group I Human Group II and II* Human											Eco	tox	I	Fate	Phys	sical			
С	Μ	R	D	Е	AT	5	ST	I	N	SnS*	SnR*	IrS	IrE	AA	CA	Р	В	Rx	F
						single	repeat*	single	single repeat*										
L	L	L	L	dg	L	dg	L	dg	dg	L	dg	L	L	L	L	L	L	L	L

Note: Hazard levels (Very High (vH), High (H), Moderate (M), Low (L), Very Low (vL)) in *italics* reflect estimated values and lower confidence. Hazard levels in **BOLD** font reflect values based on test data (See Guidance). Note: Please see Appendix A for a glossary of hazard acronyms.

Transformation Products and Ratings:

Identify relevant fate and transformation products (i.e., dissociation products, transformation products, valence states) **and/or moieties of concern**¹⁰

Functional Use	Life Cycle Stage	Transformation Pathway	Transformation Products	CAS #	On CPA Red List ¹¹ ?	GreenScreen Rating ¹²
n/a	End	Combustion	Carbon Monoxide	630-08-0	Y	N/A
n/a	End	Combustion	Carbon Dioxide	124-38-9	Ν	N/A

Introduction

Dow Proprietary Monomer #1 is approved as an inert ingredient in pesticides, and functions as an acid scavenger to protect the application equipment from corrosion. They also function for use as PVC plasticizers for use in wide range of applications including food-contact materials (UNEP 2006).

¹⁰ A moiety is a discrete chemical entity that is a constituent part or component of a substance. A moiety of concern is often the parent substance itself for organic compounds. For inorganic compounds, the moiety of concern is typically a dissociated component of the substance or a transformation product.

¹¹ The CPA "Red List" refers to chemicals 1. flagged as Benchmark 1 using the GreenScreenTM List Translator or 2. flagged as Benchmark 1 or 2 using the GreenScreenTM List Translator and further assessed and assigned as Benchmark 1. The most recent version of the GreenScreenTM List Translator should be used (CPA 2011b).

¹² GreenScreenTM reviews of transformation products depend on the GreenScreen Benchmark Score of the parent chemical (See Guidance).

Hazard Classification Summary Section: Group I Human Health Effects (Group I Human)

Carcinogenicity (C) Score (H, M or L): L

Dow Proprietary Monomer #1 was assigned a score of Low for carcinogenicity based on no carcinogenic effects following a two-year chronic toxicity/carcinogenicity study.

- Not listed as a known carcinogen by IARC, NTP, U.S. EPA, or CA Prop 65.
- UNEP 2006
 - A (GLP status not reported) 2-year chronic toxicity study (guideline not reported) was conducted using male and female (strain not reported) rats. (15/sex/dose). Rats were administered doses ranging from 0 to approximately 1,000 mg/kg (purity not reported) in the diet daily for two years. No increases in tumors were reported under the tested conditions and no further details were provided.

Mutagenicity/Genotoxicity (M) Score (H, M or L): L

Dow Proprietary Monomer #1 was assigned a score of Low for mutagenicity based on testing negative for mutagenicity and clastogenicity in *in vitro* assays.

- UNEP 2006 -
 - Dow Proprietary Monomer #1 was found negative for mutagenicity following a bacterial reverse mutation assay utilizing *Salmonella typhimurium* tester strains TA98, TA100, TA102, TA1535 and TA1537 and *E. coli* tester strain uvrA in the presence and absence of metabolic activation at concentrations up to 5,000 µg/plate (purity not reported).
 - Dow Proprietary Monomer #1 was found negative for mutagenicity following a mouse lymphoma assays utilizing L5178Y cells in the presence and absence of metabolic activation at concentrations up to 5,000 μg/ml (purity not reported).
 - Dow Proprietary Monomer #1 was found negative for mutagenicity following a HGPRT assay utilizing Chinese Hamster Ovary (CHO) cells in presence and absence of metabolic activation.
 - Dow Proprietary Monomer #1 was found to be negative for chromosomal aberrations in human peripheral blood lymphocytes in the presence and absence of mutagenicity when tested to its solubility limit.
 - Limited details were available for these studies.

Reproductive Toxicity (R) Score (H, M, or L): L

Dow Proprietary Monomer #1 was assigned a score of Low for reproductive toxicity based on a NOAEL of approximately1,000 mg/kg and no significant effects observed in a reproductive toxicity study.

- UNEP 2006 -
 - A GLP-compliant reproductive toxicity study (method not reported) was conducted using male and female (strain not reported) rats (28/sex/dose). Rats were administered doses ranging from 0 to approximately 1,000 mg/kg of Dow Proprietary Monomer #1 (purity not reported) in via oral gavage for 71 days in males and 15 days in females. Dow Proprietary Monomer #1 did not induce any toxic effects in parental rats or offspring. No effects were observed on reproductive performance or mating parameters. A NOEL of approximately 1,000 mg/kg was established by the study authors for reproductive and parental toxicity.

Developmental Toxicity incl. Developmental Neurotoxicity (D) Score (H, M or L): L

Dow Proprietary Monomer #1 was assigned a score of Low for developmental toxicity based on a NOAEL of approximately1,000 mg/kg and no significant effects reported in a developmental toxicity study.

- UNEP 2006
 - A GLP-compliant developmental toxicity study (method not reported) was conducted using female rats (strain/number not reported). Rats were administered doses ranging from 0 to approximately 1,000 mg/kg (purity not reported) from day 6 to day 15 of pregnancy. Dow Proprietary Monomer #1 was well tolerated by dams at all dose levels. No clinical signs, deaths, or abortions were noted in any groups. The mean number of corpora lutea, implantation sites, live fetuses, were similar to control groups. No dose-related effects were reported on the incidence of skeletal variations, anomalies or malformations. The NOAEL for developmental and maternal toxicity was reported as approximately 1,000 mg/kg by the study authors.

Endocrine Activity (E) Score (H, M or L): dg

Dow Proprietary Monomer #1 has been assigned a data gap for endocrine activity. Although it is not a known endocrine disruptor, endocrine disruption testing has not performed on the chemical.

- Not listed as a potential endocrine disruptor on the EU Priority List of Suspected Endocrine Disruptors.
- Not listed as a potential endocrine disruptor on the OSPAR List of Chemicals of Possible Concern.
- Not listed as a potential endocrine disruptor on the Red List of Chemicals (CPA 2011b).
- No relevant data were identified for Dow Proprietary Monomer #1.

Group II and II* Human Health Effects (Group II and II* Human)

Note: Group II and Group II* endpoints are distinguished in the v 1.2 Benchmark system. For Systemic Toxicity and Neurotoxicity, Group II and II* are considered sub-endpoints and test data for single or repeated exposures may be used. If data exist for single OR repeated exposures, then the endpoint is not considered a data gap. If data are available for both single and repeated exposures, then the more conservative value is used.

Acute Mammalian Toxicity (AT) Group II Score (vH, H, M or L): L

Dow Proprietary Monomer #1 was assigned a score of Low for acute mammalian toxicity based on oral and dermal LD_{50} values of greater than 5,000 and 19,000 mg/kg, respectively.

- UNEP 2006 -
 - Oral LD_{50} (rat) = 5,000 to 41,500 mg/kg
 - $\circ \quad \text{Dermal LD}_{50} \text{ (rabbit)} > 19,000 \text{ mg/kg}$

Systemic Toxicity/Organ Effects incl. Immunotoxicity (ST) Group II Score (single dose: vH, H, M or L): dg

• No relevant data identified for Dow Proprietary Monomer #1.

Group II* Score (repeated dose: H, M, L): L

Dow Proprietary Monomer #1 was assigned a score of low for systemic toxicity/organ effects based on a LOAEL of greater than 100 mg/kg for systemic effects from 90-day repeated dose studies.

- UNEP 2006 -
 - A (GLP status not reported) 2-year chronic toxicity study (guideline not reported) was conducted using male and female (strain not reported) rats. (15/sex/dose). Rats were administered doses ranging from 0 to approximately 1,000 mg/kg in the diet daily for two years. Liver weight was increased in mid dose group and above. However, no cellular changes were observed. No other effects were reported and a NOAEL and LOAEL of approximately 100 and 200 mg/kg were reported based on liver weight changes.
 - In rats (strain/number/sex not reported) receiving up to approximately 2.5 mg/kg for 15 weeks liver changes were observed at approximately1.5 mg/kg and greater doses. No further details were provided.
 - In a 90-day sub-chronic study (strain/number not reported) male and female rats received doses of ranging from 0 to approximately1,000 mg/kg of Dow Proprietary Monomer #1 daily for 90 days. Gross effects were noted on the liver (male and female) and kidney (male only) of rats in the 1 and 5% groups. In addition, liver weights were increased in rats in the 5% group. A NOAEL and LOAEL of approximately 50 and 250 mg/kg were reported for this study based on liver changes. No further details were provided.

Neurotoxicity (N)

Group II Score (single dose: vH, H, M or L): dg

Dow Proprietary Monomer #1 has been assigned a data gap for neurotoxicity. Although it is not a known neurotoxicant, neurotoxicity testing has not performed on the chemical.

- Not classified as a developmental neurotoxicant (Grandjean and Landrigan 2006).
- Not listed as a potential neurotoxicant on the Red List of Chemicals (CPA 2011b).
- No relevant data were identified for Dow Proprietary Monomer #1.

Group II* Score (repeated dose: H, M, L): dg

Dow Proprietary Monomer #1 has been assigned a data gap for neurotoxicity. Although it is not a known neurotoxicant, neurotoxicity testing has not performed on the chemical.

- Not classified as a developmental neurotoxicant (Grandjean and Landrigan 2006).
- Not listed as a potential neurotoxicant on the Red List of Chemicals (CPA 2011b).
- No relevant data were identified for Dow Proprietary Monomer #1.

Skin Sensitization (SnS) Group II* Score (H, M or L): L

Dow Proprietary Monomer #1 was assigned a score of Low for skin sensitization based on negative results from a skin sensitization study in guinea pigs.

- UNEP 2006 -
 - A (GLP status not reported) skin sensitization study (method not reported) was conducted using male (stain not reported) albino guinea pigs (n=20). Guinea pigs were administered 8 intracutaneous injections, and topical applications of a 0.1% Dow Proprietary Monomer #1 solution (purity not reported) during 2.5 weeks. Following a 3 week incubation period a challenge dose was administered. No signs of sensitization were observed, and Dow Proprietary Monomer #1 was reported as negative for skin sensitization.

Respiratory Sensitization (SnR) Group II* Score (H, M or L): dg

• No relevant data identified for Dow Proprietary Monomer #1

Skin Irritation/Corrosivity (IrS) Group II Score (vH, H, M or L): L

Dow Proprietary Monomer #1 was assigned a score of Low for skin irritation/corrosivity based on transient erythema not persisting for up to 3 days (CPA 2011).

- UNEP 2006 -
 - Dow Proprietary Monomer #1 caused transient erythema in 4 animals exposed to approximately 20 mL/kg for a 24-hour contact period.

Eye Irritation/Corrosivity (IrE) Group II Score (vH, H, M or L): L

Dow Proprietary Monomer #1 was assigned a score of Low for eye irritation/corrosivity based on no signs of irritation following animals testing.

- UNEP 2006 -
 - Dow Proprietary Monomer #1 did not cause any irritation following instillation of .5 mL into the eyes of 5 animals.

Ecotoxicity (Ecotox)

Acute Aquatic Toxicity (AA) Score (vH, H, M or L): L

Dow Proprietary Monomer #1 was assigned a score of Low for acute aquatic toxicity based on limited water solubility and no effects predicted at saturation (CPA 2011a).

- ESIS 2000 -
 - Dow Proprietary Monomer #1 has reported L/EC₅₀ values of >500 mg/kg (fish, 48-hr), >100 mg/L (daphnid, 24-hr), and < 10 mg/L (algae, 72-hr).
- The Dow Proprietary Monomer #1 has a reported water solubility of < 0.02 mg/l. Therefore, the reported L/EC₅₀ values are not relevant as they cannot be reached under normal conditions. Furthermore, following OECD guidance for poorly soluble substance, the maximum concentrated tested should not exceed a saturated solution of the test substance (OECD 2002).

Chronic Aquatic Toxicity (CA) Score (vH, H, M or L): L

• No chronic aquatic toxicity data were identified for this chemical. The globally harmonized system (GHS) does not require a chronic aquatic toxicity hazard rating for substances which are both rapidly biodegradable or have a BCF < 500 and log Kow < 4.

Environmental Fate (Fate)

Persistence (P) Score (vH, H, M, L, or vL): L

Dow Proprietary Monomer #1 was assigned a score of Low for persistence based on being reported as readily biodegradable following an OECD 301B assay.

- UNEP 2006
 - Dow Proprietary Monomer #1 was found to be readily biodegradable following OECD 301B with 79% biodegradation occurring in 28-days. UNEP SIDS authors reported that based on available data in the epoxidized oils category that Dow Proprietary Monomer #1 is expected to be readily biodegradable.

Bioaccumulation (B) Score (vH, H, M, L, or vL): vL

Dow Proprietary Monomer #1 was assigned a score of Very Low for bioaccumulation based on a modeled BAF of less than 100, the cutoff for very low bioaccumulation potential (CPA 2011a).

- U.S. EPA 2011 -
 - \circ BCFBAF predicts a bioaccumulation factor (BAF) of 0.893 and a log K_{ow} of 14.84 indicating that this chemical is not likely to bioaccumulate.

Physical Hazards (Physical)

Reactivity (Rx) Score (vH, H, M or L): L

Dow Proprietary Monomer #1 was assigned a score of Low for reactivity based on not having any chemicals or functional groups expected to contain high energy bonds or oxidizing species which may cause reactivity.

• Dow Proprietary Monomer #1 would not be classified as an oxidizing chemical as its structure does not contain a halogen and oxygen atoms present are only bonded to carbon or hydrogen (UN 2011). In addition, Dow Proprietary Monomer #1 is not expected to be explosive as it does not contain structural groups or high-energy bonds that would cause concern for explosion. Furthermore, the high flashpoint (> 300°C) further supports that Dow Proprietary Monomer #1 is not a reactive chemical.

Flammability (F) Score (vH, H, M or L): L

Dow Proprietary Monomer #1 was assigned a score of Low for flammability based on not being classified as flammable.

- ESIS 2000 -
 - \circ Not flammable as it has a flashpoint > 300 °C (open cup).

References

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European Chemical Substances Information System (ESIS). 2000. IUCLID Dataset for Dow Proprietary Monomer #1. European Commission Joint Research Centre. Available: <u>http://ecb.jrc.ec.europa.eu/esis/</u>

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United Nations. 2009. Globally Harmonized System of Classification and Labeling of Chemicals, Third Revised Edition. Available: <u>http://live.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html</u>

United States Environmental Protection Agency (U.S. EPA). 2011. Estimation Programs Interface (EPI) Suite[™] Web, v4.10, Washington, DC, USA.

APPENDIX A: Hazard Benchmark Acronyms (in alphabetical order)

- (AA) Acute Aquatic Toxicity
- (AT) Acute Mammalian Toxicity
- (B) Bioaccumulation
- (C) Carcinogenicity
- (CA) Chronic Aquatic Toxicity
- (Cr) Corrosion/ Irritation (Skin/ Eye)
- (D) Developmental Toxicity
- (E) Endocrine Activity
- (F) Flammability
- (IrE) Eye Irritation/Corrosivity
- (IrS) Skin Irritation/Corrosivity
- (M) Mutagenicity and Genotoxicity
- (N) Neurotoxicity
- (P) Persistence
- (R) Reproductive Toxicity
- (Rx) Reactivity
- (SnS) Sensitization-Skin
- (SnR) Sensitization-Respiratory
- (ST) Systemic/Organ Toxicity

APPENDIX B: EPISuite Results

[REDACTED]

APPENDIX C: ECOSAR Results

[REDACTED]

Dow Proprietary Monomer #1 GreenScreen Evaluation Prepared By:

Christing E Schloson

Chris Schlosser, M.F.S. Associate Toxicologist ToxServices LLC

Dow Proprietary Monomer #1 GreenScreen Evaluation QC'd By:

Margat H. White

Margaret H. Whittaker, Ph.D., M.P.H., CBiol., F.S.B., E.R.T., D.A.B.T. Managing Director and Chief Toxicologist ToxServices LLC

<u>GreenScreenTM Assessment for Dow Proprietary Monomer #2</u> (CAS #[REDACTED])

GreenScreenTM Version 1.2 Draft Assessment Note: Validation Has Not Been Performed on this GreenScreenTM Assessment

Chemical Name: Dow Proprietary Monomer #2(CAS #[REDACTED])

GreenScreenTM Assessment Prepared By:

Name: Chris Schlosser, M.F.S. Title: Associate Toxicologist Organization: ToxServices LLC Date: January 16, 2012 Revised: February 13, 2012

Quality Control Performed By:

Name: Margaret H. Whittaker, Ph.D., M.P.H., CBiol., F.S.B., E.R.T., D.A.B.T. Title: Managing Director Organization: ToxServices LLC Date: March 8, 2012

Confirm application of the *de minimus* **rule**¹³**:** Yes

Chemical Name (CAS #): Dow Proprietary Monomer #2(CAS #[REDACTED])

Also Called: [REDACTED]

Chemical Surrogates, analogs or moieties used in this assessment (CASs #): Dow Proprietary Monomer #3(CAS #[REDACTED]) and Dow Proprietary Monomer #1 (CAS #[REDACTED])

Chemical Structure(s): [REDACTED]

Identify Applications/Functional Uses: (e.g., Cleaning product, TV casing) 1. Plasticizer

GreenScreenTM Rating¹⁴: Dow Proprietary Monomer #2was assigned a GreenScreenTM Benchmark Score 3based on Moderate Skin Sensitization (SnS). This corresponds to GreenScreenTM benchmark classification 3b in CPA 2011a. Data gaps (dg) exist for Endocrine Activity (E), and Respiratory Sensitization (SnR). As outlined in CPA (2011c) Section III(1)(Benchmarking Chemicals With Data Gaps), Dow Proprietary Monomer #2meets requirements for a GreenScreenTM Benchmark Score of 3. In a worst-case scenario, if Dow Proprietary Monomer #2were assigned a High score for E, it would become a GreenScreenTM Benchmark 1 chemical.

¹³ Every chemical in a material or formulation should be assessed if it is:

^{1.} intentionally added and/or

^{2.} present at greater than or equal to 100 ppm.

¹⁴ For inorganic chemicals with low human and ecotoxicity across all hazard endpoints and low bioaccumulation potential, persistence alone will not be deemed problematic. Inorganic chemicals that are only persistent will be evaluated under the criteria for GreenScreenTM Benchmark 4.

NOTE: Complete copies of toxicological studies or extended abstracts were not available for review by ToxServices. Only limited quantitative details (e.g., statistical significance, organ weight values, and percent changes in measured endpoints) were provided/disclosed for each endpoint. Therefore, a low confidence rating has been assigned for each endpoint, as reflected by italics for each hazard endpoint.

	Green Screen Hazard Ratings:Dow Proprietary Monomer #2																		
	Gro	up I H	luman		Group II and II* Human									Ecotox		Fate		Physical	
С	Μ	R	D	Е	AT	S	Т	Ν		SnS*	SnR*	IrS	IrE	AA	CA	Р	В	Rx	F
						single	repeat	single	repeat										
L	L	L	L	dg	L	dg	L	dg	L	<i>M</i> *	dg	L	L	L	L	vL	vL	L	L

Note: Hazard levels (Very High (vH), High (H), Moderate (M), Low (L), Very Low (vL)) in *italics* reflect estimated values and lower confidence. Hazard levels in **BOLD** font reflect values based on test data (See Guidance). Note: Please see Appendix A for a glossary of hazard acronyms.

* DOW is currently conducting sensitization studies on Dow Proprietary Monomer #2itself and this endpoint is subject to change based on review of those results.

Transformation Products and Ratings:

Identify relevant fate and transformation products (i.e., dissociation products, transformation products, valence states) **and/or moieties of concern**¹⁵

Functional Use	Life Cycle Stage	Transformation Pathway	Transformation Products	CAS #	On CPA Red List ¹⁶ ?	GreenScreen [™] Rating ¹⁷
n/a	End	Combustion	Carbon Monoxide	630-08-0	Y	n/a
n/a	End	Combustion	Carbon Dioxide	124-38-9	Ν	n/a

Introduction

Dow Proprietary Monomer #2is used as a plasticizer. No toxicological data were available for this chemical. The structurally similar chemicals Dow Proprietary Monomer #1 and Dow Proprietary Monomer #3were used to fill data gaps as noted above.

¹⁵ A moiety is a discrete chemical entity that is a constituent part or component of a substance. A moiety of concern is often the parent substance itself for organic compounds. For inorganic compounds, the moiety of concern is typically a dissociated component of the substance or a transformation product.

¹⁶ The CPA "Red List" refers to chemicals: 1) flagged as Benchmark 1 using the GreenScreenTM List Translator, or 2). flagged as Benchmark 1 or 2 using the GreenScreenTM List Translator and further assessed and assigned as Benchmark 1. The most recent version of the GreenScreenTM List Translator should be used (CPA 2011b).

¹⁷ GreenScreen[™] reviews of transformation products depend on the GreenScreen[™] Benchmark Score of the parent chemical (See Guidance in CPA 2011c).

Hazard Classification Summary Section:

NOTE: Complete copies of toxicological studies or extended abstracts were not available for review by ToxServices. Only limited quantitative details (i.e. statistical significance, organ weight values, and percent changes in measured endpoints) were provided/disclosed for each endpoint. Therefore, a low confidence rating has been assigned for each endpoint, as reflected by italics for each hazard endpoint.

Group I Human Health Effects (Group I Human)

Carcinogenicity (C) Score (H, M or L): L

Dow Proprietary Monomer #2was assigned a score of Low for carcinogenicity based on surrogate test data indicating no signs or increases in tumors in rats following 2-years of dietary exposure to Dow Proprietary Monomer #1.

- Dow Proprietary Monomer #1
- UNEP 2006
 - A (GLP status not reported) 2-year chronic toxicity study (guideline not reported) was conducted using male and female (strain not reported) rats. (15/sex/dose). Rats were administered doses of 0, 25, 125, 250, 625, and 1,250 mg/kg of Dow Proprietary Monomer #1 (purity not reported) in the diet daily for two years. No increases in tumors were reported under the tested conditions and no further details were provided.

Mutagenicity/Genotoxicity (M) Score (H, M or L): L

Dow Proprietary Monomer #2was assigned a score of Low for mutagenicity based on consistently negative *in vivo* and *in vitro* genotoxicity test results for the structurally similar surrogates Dow Proprietary Monomer #3 and Dow Proprietary Monomer #1.

Dow Proprietary Monomer #3

- DOW 2008
 - A GLP compliant bacterial reverse mutation assay (OECD 471) was conducted utilizing Salmonella typhimurium tester strains TA98, TA100, TA1537 and TA1537, and *E.coli* tester strain WP2 uvr A with and without metabolic activation at concentrations up to approximately 5,000 µg/plate (purity not reported). Dow Proprietary Monomer #3was found to be negative for mutagenicity under all tested conditions.
- DOW 2008 -
 - A GLP compliant mammalian cell gene mutation assay (OECD 476) was conducted utilizing Chinese Hamster Ovary (CHO) cells with and without metabolic activation at concentrations of up to approximately5,000 µg/ml with activation and 100 µg/ml without activation. Dow Proprietary Monomer #3was found to be negative for mutagenicity under all tested conditions.
- DOW 2008 -
 - A GLP compliant mammalian chromosome aberration test (OECD 473) was conducted utilizing (strain not identified) rat lymphocytes in the presence and absence of metabolic activation at concentrations up to approximately 5,000 µg/ml. Dow Proprietary Monomer #3was found to be negative for clastogenicity under all tested conditions.

Dow Proprietary Monomer #1

- UNEP 2006
 - Dow Proprietary Monomer #1 was found negative for mutagenicity following a bacterial reverse mutation assay utilizing *Salmonella typhimurium* tester strains TA98, TA100, TA102, TA1535 and TA1537 and *E.coli* tester strain uvrA in the presence and absence of metabolic activation at concentrations up to approximately 5,000 μg/plate (purity not reported).
 - Dow Proprietary Monomer #1 was found negative for mutagenicity following a mouse lymphoma assays utilizing L5178Y cells in the presence and absence of metabolic activation at concentrations up to approximately 5,000 µg/ml (purity not reported).
 - Dow Proprietary Monomer #1 was found negative for mutagenicity following a HGPRT assay utilizing Chinese Hamster Ovary (CHO) cells in presence and absence of metabolic activation.
 - Dow Proprietary Monomer #1 was found to be negative for chromosomal aberrations in human peripheral blood lymphocytes in the presence and absence of mutagenicity when tested to its solubility limit.

• Limited details were available for these studies.

Reproductive Toxicity (R) Score (H, M, or L): L

Dow Proprietary Monomer #2was assigned a score of Low for reproductive toxicity based on no evidence of reproductive toxicity in both structurally similar surrogates Dow Proprietary Monomer #3and Dow Proprietary Monomer #1.

Dow Proprietary Monomer #3

- DOW 2008
 - A GLP compliant combined repeated dose and reproductive/developmental screening study (OECD 422) was conducted using male and female Sprague-Dawley rats (number not reported). Rats were administered doses ranging from 0 to approximately 1,000 mg/kg via oral gavage from two weeks prior to breeding until necropsy (postpartum day 4 to 5 for females). No indications of neurological or reproductive toxicity were observed at any dose level. There were no adverse effects on prenatal/early neonatal growth and survival of the offspring. Based on available data, a NOAEL of approximately 1,000 mg/kg for reproductive/developmental toxicity was established by study authors.

Dow Proprietary Monomer #1

- UNEP 2006 -
 - A GLP-compliant reproductive toxicity study (method not reported) was conducted using male and female (strain not reported) rats (28/sex/dose). Rats were administered doses from 0 to approximately 1,000 mg/kg of Dow Proprietary Monomer #1 (purity not reported) in via oral gavage for 71 days in males and 15 days in females. Dow Proprietary Monomer #1 did not induce any toxic effects in parental rats or offspring. No effects were observed on reproductive performance or mating parameters. A NOEL of approximately 1,000 mg/kg was established by the study authors for reproductive and parental toxicity.

Developmental Toxicity incl. Developmental Neurotoxicity (D) Score (H, M or L): L

Dow Proprietary Monomer #2 was assigned a score of Low for developmental toxicity based on the absence of developmental toxicity for structurally similar surrogate Dow Proprietary Monomer #3. Dow Proprietary Monomer #3

- DOW 2008 -
 - A GLP compliant combined repeated dose and reproductive/developmental screening study (OECD 422) was conducted using male and female Sprague-Dawley rats (number not reported). Rats were administered doses of 0, 100, 500, and 1,000 mg/kg via oral gavage from two weeks prior to breeding until necropsy (postpartum day 4 to 5 for females). No indications of neurological or reproductive toxicity were observed at any dose level. There were no adverse effects on prenatal/early neonatal growth and survival of the offspring. Based on available data, a NOAEL of 1,000 mg/kg for reproductive/developmental toxicity was established by study authors.

Dow Proprietary Monomer #1

- UNEP 2006
 - A GLP-compliant developmental toxicity study (method not reported) was conducted using female rats (strain/number not reported). Rats were administered doses from 0 to approximately 1,000 mg/kg (purity not reported) from day 6 to day 15 of pregnancy. Dow Proprietary Monomer #1 was well tolerated by dams at all dose levels. No clinical signs, deaths, or abortions were noted in any groups. The mean number of corpora lutea, implantation sites, live fetuses, were similar to control groups. No dose-related effects were reported on the incidence of skeletal variations, anomalies or malformations. The NOAEL for developmental and maternal toxicity was reported as approximately1,000 mg/kg by the study authors.

Endocrine Activity (E) Score (H, M or L): dg

Dow Proprietary Monomer #2has been assigned a data gap for endocrine activity. Although it is not a known endocrine disruptor, endocrine disruption testing has not performed on the chemical.

- Not listed as a potential endocrine disruptor on the EU Priority List of Suspected Endocrine Disruptors.
- Not listed as a potential endocrine disruptor on the OSPAR List of Chemicals of Possible Concern.
- Not listed as a potential endocrine disruptor on the Red List of Chemicals (CPA 2011b).
- No relevant data were identified for Dow Proprietary Monomer #2.

Group II and II* Human Health Effects (Group II and II* Human)

Note: Group II and Group II* endpoints are distinguished in the v 1.2 Benchmark system. For Systemic Toxicity and Neurotoxicity, Group II and II* are considered sub-endpoints and test data for single or repeated exposures may be used. If data exist for single OR repeated exposures, then the endpoint is not considered a data gap. If data are available for both single and repeated exposures, then the more conservative value is used.

Acute Mammalian Toxicity (AT) Group II Score (vH, H, M or L): L

Dow Proprietary Monomer #2was assigned a score of Low for acute mammalian toxicity based on oral and dermal LD_{50} values above the 2,000 mg/kg cut off for the structurally similar surrogates Dow Proprietary Monomer #3 and Dow Proprietary Monomer #1 (CPA 2011a).

Dow Proprietary Monomer #3

- DOW 2008
 - An Oral LD_{50} value of > 2,000 mg/kg was identified in rats (OECD 425).
- DOW 2008 -

• A Dermal LD_{50} value of > 2,000 mg/kg was identified in rats (OECD 402).

Dow Proprietary Monomer #1

- UNEP 2006 -
 - An oral LD₅₀ of 5,000 to approximately 40,000 mg/kg was identified in rats.
 - A dermal LD₅₀ of approximately 20,000 mg/kg was identified in rabbits.

Systemic Toxicity/Organ Effects incl. Immunotoxicity (ST) Group II Score (single dose: vH, H, M or L): dg

• No relevant data were identified.

Group II* Score (repeated dose: H, M, L): L

Dow Proprietary Monomer #2was assigned a score of Low for systemic toxicity/organ effects based on repeated exposure, as both structurally similar surrogates Dow Proprietary Monomer #3and Dow Proprietary Monomer #1 have reported LOAEL values of greater than 100 mg/L. Following GHS criteria neither surrogate is classifiable as Category 1 or 2 Repeated Dose Toxicant (UN 2011).

Dow Proprietary Monomer #3

- DOW 2008 -
 - A GLP compliant combined repeated dose and reproductive/developmental screening study (OECD 422) was conducted using male and female Sprague-Dawley rats (number not reported). Rats were administered doses from 0 to approximately 1,000 mg/kg via oral gavage from two weeks prior to breeding until necropsy (postpartum day 4 to 5 for females). In the top dose group male and females had increases in absolute and relative liver weights. In males, increased liver weights corresponded to slight hypertrophy of centrilobular and midzonal hepatocytes. No histopathological changes were identified in female rats. No systemic effects were observed at the mid- to low-dose in either sex. No indications of neurological or reproductive toxicity were observed at any dose level. There were no adverse effects on prenatal/early neonatal growth and survival of the offspring. Based on available data, ToxServices assigned a NOAEL and LOAEL of approximately 500 and 1,000 mg/kg based on increased liver weights, with slight histopathological liver changes in male rats.

Dow Proprietary Monomer #1

- UNEP 2006
 - A (GLP status not reported) 2-year chronic toxicity study (guideline not reported) was conducted using male and female (strain not reported) rats. (15/sex/dose). Rats were administered doses from 0 to approximately 1,250 mg/kg in the diet daily for two years. Liver weights were increased in the low-dose group and above. However, no cellular changes were observed. No other effects were reported and a NOAEL and LOAEL of approximately 125 and 250 mg/kg were reported based on liver weight changes.
 - In rats (strain/number/sex not reported) receiving up to approximately 2.5 mg/kg for 15 weeks, liver changes were observed at approximately 1.5 mg/kg and greater doses. No further details were provided.
 - In a 90-day sub-chronic study (strain/number not reported) male and female rats received doses from 0 to approximately 1,250 mg/kg of Dow Proprietary Monomer #1 daily for 90 days. Gross effects were

noted on the liver (male and female) and kidney (male only) of rats in the 1 and 5% groups. In addition, liver weights were increased in rats in the 5% group. A NOAEL and LOAEL of approximately 50 and 250 mg/kg were reported for this study based on liver changes. No further details were provided.

Neurotoxicity (N)

Group II Score (single dose: vH, H, M or L): dg

Dow Proprietary Monomer #2has been assigned a data gap for neurotoxicity. Although it is not a known neurotoxicant, neurotoxicity testing has not performed on the chemical.

- Not classified as a developmental neurotoxicant (Grandjean and Landrigan 2006).
- Not listed as a potential neurotoxicant on the Red List of Chemicals (CPA 2011b).
- No relevant data were identified for Dow Proprietary Monomer #2.

Group II* Score (repeated dose: H, M, L): L

Dow Proprietary Monomer #2has been assigned a score of Low for neurotoxicity based on no negative effects from a functional observational battery during a 90-day OECD screening study.

- Not classified as a developmental neurotoxicant (Grandjean and Landrigan 2006).
- Not listed as a potential neurotoxicant on the Red List of Chemicals (CPA 2011b).
- DOW 2008 -
 - A GLP compliant combined repeated dose and reproductive/developmental screening study (OECD 422) was conducted using male and female Sprague-Dawley rats (number not reported). Rats were administered doses from 0 to approximately 1,000 mg/kg via oral gavage from two weeks prior to breeding until necropsy (postpartum day 4 to 5 for females). No effects were reported following a functional observation battery including: sensory evaluations, grip performance, and motor activity. Based on the available data, ToxServices assigns a NOAEL of approximately1,000 mg/kg for neurotoxicity.

Skin Sensitization (SnS) Group II* Score (H, M or L): M*

Dow Proprietary Monomer #2was assigned a score of Moderate for skin sensitization based on signs of a weakly sensitizing effects following a local lymph node assay and mouse ear swelling test for the structurally similar surrogate Dow Proprietary Monomer #3, and being classified as a GHS Category 1B sensitizer (CPA 2011a). *NOTE – DOW is currently conducting sensitization studies on Dow Proprietary Monomer #2itself and this endpoint is subject to change based on review of those results. Dow Proprietary Monomer #3

- DOW 2008
- DOW 2008
 - A GLP compliant local lymph node assay was performed using female CBA/J mice (number not reported). Mice were exposed to concentrations of 5, 20 and 80% of the test substance. The test substance displayed stimulation indices of 2.0, 3.2, and 7.4 (number ratio of sensitized animals, test:control) when compared to controls, and EC₃₀ value of 17.5%. Study authors report that Dow Proprietary Monomer #3is weakly sensitizing under the tested conditions. Following GHS criteria and EC₃₀ of greater than 2% is classified as a Category 1B sensitizer.
- DOW 2008
 - A GLP compliant mouse ear swelling test was conducted using female CBA mice (number not reported). Mice exposed to Dow Proprietary Monomer #3had a 21% increase in ear swelling at 24 hours. No differences were identified at 48 hours. Based on the slight ear swelling, the study authors reported Dow Proprietary Monomer #3as being weakly sensitizing.
- DOW 2008 -
 - A GLP compliant guinea pig maximization test was conducted using male Hartley guinea pigs. Guinea pigs were induced with an intra-dermal dose (concentration not reported). 0% of guinea pigs had positive reactions following a challenge dose 48 hours after induction, or 24 and 48 hours after the first challenge dose. Study authors reported Dow Proprietary Monomer #3non-sensitizing to guinea pigs.

Dow Proprietary Monomer #1

• UNEP 2006 -

A (GLP status not reported) skin sensitization study (method not reported) was conducted using male (stain not reported) albino guinea pigs (n=20). Guinea pigs were administered 8 intracutaneous injections, and topical applications of a 0.1% Dow Proprietary Monomer #1 solution (purity not reported) during 2.5 weeks. Following a 3 week incubation period a challenge dose was administered. No signs of sensitization were observed, and Dow Proprietary Monomer #1 was reported as negative for skin sensitization.

Respiratory Sensitization (SnR) Group II* Score (H, M or L): dg

• No relevant data were identified.

Skin Irritation/Corrosivity (IrS) Group II Score (vH, H, M or L): L

Dow Proprietary Monomer #2was assigned a score of Low for skin irritation/corrosivity based on minimal transient erythema not achieving a score \geq to 1.5 and neither structurally similar surrogate being classifiable as a GHS irritant (CPA 2011a).

Dow Proprietary Monomer #3

- DOW 2008
 - o Two GLP compliant skin irritation/corrosion studies (OECD 404) were conducted using New Zealand white rabbits (number and sex not reported). Only minimal to slight signs of erythema were reported with all irritation being fully reversible within 7 days. As the erythema and edema scores did score ≥ to 1.5 at 24, 48, or 72 hours no GHS classification is required (UN 2011). Dow Proprietary Monomer #3was reported as non-irritating by the study authors under the test conditions.

Dow Proprietary Monomer #1

- UNEP 2006 -
 - Dow Proprietary Monomer #1 caused transient erythema in 4 animals exposed to 20 mL/kg for a 24hour contact period.

Eye Irritation/Corrosivity (IrE) Group II Score (vH, H, M or L): L

Dow Proprietary Monomer #2was assigned a score of Low for eye irritation/corrosivity based on no irritation following studies with both structurally similar analogs Dow Proprietary Monomer #3and Dow Proprietary Monomer #1.

Dow Proprietary Monomer #3

- DOW 2008 -
 - Two GLP compliant eye irritation studies (OECD 405) was conducted on New Zealand white rabbits (n=3). No eye irritation was observed under the test conditions. Minimal study details were available. Study authors reported Dow Proprietary Monomer #3as non-irritating under the test conditions.

Dow Proprietary Monomer #1

- UNEP 2006
 - Dow Proprietary Monomer #1 did not cause any irritation following instillation of .5 mL into the eyes of 5 animals (specific animal species unknown).

Ecotoxicity (Ecotox)

NOTE: Complete copies of studies or extended abstracts were not available for review by ToxServices. Only limited quantitative details were provided/disclosed for each endpoint. Therefore, a low confidence rating has been assigned for each endpoint, as reflected by italics for each hazard endpoint.

Acute Aquatic Toxicity (AA) Score (vH, H, M or L): L

Dow Proprietary Monomer #2was assigned a score of Low for acute aquatic toxicity values above 100 mg/L, or acute toxicity values above the water solubility (CPA 2011a).

Dow Proprietary Monomer #3

• DOW 2008 -

 \circ A LC₅₀ value of > 8,000 mg/L was identified in *Oncorhynchus mykiss* (fish, 96-hr) (OECD Test Guideline 203).

- DOW 2008
 - An EC₅₀ value of > 8,000 mg/L was identified in *Daphnia magna* (daphnid, 48-hr) (OECD Test Guideline 202).
- DOW 2008 -
 - An EC₅₀ value of > 201 mg/L was identified for *Pseudokirchnerella subcapitata* (algae, 72-hr) (OECD Test Guideline 201).
- Dow Proprietary Monomer #1
- ESIS 2000 -
 - Dow Proprietary Monomer #1 has reported L/EC₅₀ values of 900 mg/kg (fish, 48-hr), > 100 mg/L (daphnid, 24-hr), and 8 mg/L (algae, 72-hr).
- The Dow Proprietary Monomer #1 has a reported water solubility of < 0.02 mg/l. Therefore, the reported L/EC₅₀ values are not relevant as they cannot be reached under normal conditions. Furthermore, following OECD guidance for poorly soluble substance, the maximum concentrated tested should not exceed a saturated solution of the test substance (OECD 2002).

Chronic Aquatic Toxicity (CA) Score (vH, H, M or L): L

• No chronic aquatic toxicity data were identified for this chemical. The globally harmonized system (GHS) does not require a chronic aquatic toxicity hazard rating for substances which are both rapidly biodegradable or have a BCF < 500 and log Kow < 4.

Environmental Fate (Fate)

NOTE: Complete copies of studies or extended abstracts were not available for review by ToxServices. Limited quantitative details were provided/disclosed for each endpoint. Therefore, a low confidence score has been assigned for each endpoint, as reflected by italics for each hazard endpoint.

Persistence (P) Score (vH, H, M, L, or vL): vL

Dow Proprietary Monomer #2was assigned a score of Low for persistence based on both structurally similar surrogates (Dow Proprietary Monomer #3and Dow Proprietary Monomer #1) being classified as readily biodegradable following OECD ready biodegradability studies.

Dow Proprietary Monomer #3

- DOW 2008
 - A GLP compliant biodegradation test (OECD 301F "Ready Biodegradability "Manometric Respirometry Test") was conducted using Dow Proprietary Monomer #3. The test substance was found to be readily biodegradable with greater than 100% biodegradation and greater than 80% biodegradation based on BOD and CO_2 evolution, respectively. The test substance reached greater than 50% within the 10-day window.

Dow Proprietary Monomer #1

- UNEP 2006 -
 - Dow Proprietary Monomer #1 was found to be readily biodegradable following OECD 301B with 79% biodegradation occurring in 28-days. UNEP SIDS authors reported that based on available data in the epoxidized oils category that Dow Proprietary Monomer #1 is expected to be readily biodegradable.

Bioaccumulation (B) Score (vH, H, M, L, or vL): vL

Dow Proprietary Monomer #2was assigned a score of Low for bioaccumulation based on predicted BCF values below less than 100 mg/L for both structurally similar surrogates (CPA 2011a)(please see Appendix B for detailed prediction output file for Dow Proprietary Monomer #1. Dow Proprietary Monomer #3

DOW 2009 –

• A predicted BCF of less than 50 was reported, indicating this chemical is not likely to bioaccumulate. <u>Dow Proprietary Monomer #1</u>

- U.S. EPA 2011
 - \circ BCFBAF predicts a bioaccumulation factor (BAF) of less than 1 and a log K_{ow} of 14.84 indicate that this chemical is not likely to bioaccumulate (as presented in Appendix B).

Physical Hazards (Physical)

NOTE: Complete copies of studies or extended abstracts were not available for review by ToxServices. Only limited quantitative details were provided/disclosed for each endpoint. Therefore, a low confidence rating has been assigned for each endpoint, as reflected by italics for each hazard endpoint.

Reactivity (Rx) Score (vH, H, M or L): L

Dow Proprietary Monomer #2was assigned a score of Low for reactivity based on structurally similar surrogates Dow Proprietary Monomer #1 and Dow Proprietary Monomer #3not having structural similarities or functional groups known to be unstable or cause oxidation.

Dow Proprietary Monomer #3

- DOW 2009
 - The molecular structure of the chemical does not contain any chemically-unstable or highly energetic groups, or functional groups known to cause oxidation.

Flammability (F) Score (vH, H, M or L): L

Dow Proprietary Monomer #2was assigned a score of Low for flammability based on structurally similar surrogates Dow Proprietary Monomer #1 and Dow Proprietary Monomer #3having flash points above 93°C, and not being classified as a reactive substance by GHS. Dow Proprietary Monomer #3

DOW 110prictary in
DOW 2009 -

- DOW 2009
 - Dow Proprietary Monomer #3has a flash point of 178°C. Liquids with a flashpoint above 93°C are not classified as flammable by GHS (UN 2011).

Dow Proprietary Monomer #1

- ESIS 2000
 - Dow Proprietary Monomer #1 has a flashpoint > 300 °C (open cup). Liquids with a flashpoint above 93° C are not classified as flammable by GHS (UN 2011).

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APPENDIX A: Hazard Benchmark Acronyms (in alphabetical order)

- (AA) Acute Aquatic Toxicity
- (AT) Acute Mammalian Toxicity
- (B) Bioaccumulation
- (C) Carcinogenicity
- (CA) Chronic Aquatic Toxicity
- (Cr) Corrosion/ Irritation (Skin/ Eye)
- (D) Developmental Toxicity
- (E) Endocrine Activity
- (F) Flammability
- (IrE) Eye Irritation/Corrosivity
- (IrS) Skin Irritation/Corrosivity
- (M) Mutagenicity and Genotoxicity
- (N) Neurotoxicity
- (P) Persistence
- (R) Reproductive Toxicity
- (Rx) Reactivity
- (SnS) Sensitization-Skin
- (SnR) Sensitization-Respiratory
- (ST) Systemic/Organ Toxicity

APPENDIX B: EPISuite Results

[REDACTED]

Dow Proprietary Monomer #2 GreenScreen[™] Evaluation Prepared By:

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