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SUBJECT: COMMENTS ON THE PRE-REGULATORY DRAFT REGULATION FOR HAZARD TRAITS AND ENVIRONMENTAL AND TOXICOLOGICAL ENDPOINTS

Dear Ms. Kammerer:

The Dow Chemical Company has reviewed and is providing comments to the Office of Environmental Health Hazard Assessment (OEHHA) on its Pre-regulatory Draft Regulation for the Hazard Traits, Environmental and Toxicological End-points, and Other Relevant Data that are to be included in the state's Toxics Information Clearinghouse. The Department of Toxic Substances Control (DTSC) will use information from the clearinghouse to help identify chemicals of concern in consumer products, pursuant to Health & Safety Code section 25252.

Overall, the current draft is seriously lacking the appropriate structure, technical detail and specific guidance needed to deliver on the objective of the Health & Safety Code section 25252. It is unclear how the comprehensive list of non-conventional hazard traits, each with its own exhaustive list of endpoints and other relevant data are intended to be used to help inform the assessment and identification of chemicals of concern in consumer products. The pre-regulatory document needs to provide greater clarity around how the reliability and weighting of the source documents, studies, endpoints and other relevant data will be accomplished and more specifically what information will be used to populate the Toxics Information Clearinghouse, how this information is intended to be used and by whom. Without these modifications the Toxics Information Clearinghouse is likely to contain data that will be largely misleading as to the true hazards of substances with little or no utility in reliably identifying chemicals of concern in consumer products.

Specific comments to the pre-regulatory draft follow.

General comments:
There are already numerous sources of information on chemicals readily available to the public, e.g. OECD eChemPortal, NIH and ATSDR. These existing resources provide access to a great

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deal of toxicity information that have been evaluated by regulatory authorities around the world and organized into resources that are readily accessible. We believe these sources are sufficient to satisfy OEHHA's statutory obligation to "evaluate and specify the hazard traits and toxicological endpoints and any other relevant data."

If California is determined to establish its own database, it should be noted that, while OEHHA has outlined a comprehensive listing of hazard traits and other endpoints, the categories of "toxicological hazard traits" described on pages 5-14 of the OEHHA document are inconsistent with other widely recognized international categories. The OECD countries have developed the Screening Information Data Set (SIDS) and OECD Guidelines for Testing of Chemicals to understand chemical hazard, which is used broadly by OECD member states and others as a basis for developing information on and making regulatory decisions about chemicals. It is not clear why OEHHA failed to incorporate any aspects of these systems into this discussion document. In contrast, the OEHHA hazard traits classification system is overly specific. There is no need to break out systemic toxicity or target organ toxicity by specific systems (*e.g.*, cardiovascular, gastrointestinal, liver, renal, *etc.*) when the goal is hazard identification. The critical issue for chemical hazard classification should be identifying the most sensitive system(s) affected by chemical exposure.

In fact the whole concept of labeling hazardous traits of product components based on the parameters listed in the proposal is seriously flawed. In the proposed regulatory text, many terms are so poorly or loosely defined that a literal interpretation would allow almost anything to be classified. OEHHA needs to define more specific and clear criteria for declaring a change in an endpoint as evidence for classification (e.g. dose-response relationship, magnitude of the effect, biological relevance/relevance to humans, or the reliability/validity of an endpoint for estimating an adverse outcome to human health or the environment).

OEHHA states that a weight of evidence (WOE) approach will be used in assessing for Class One and Class Two Hazard Traits but it is unclear how OEHHA will apply WOE. This pattern is repeated throughout the document and needs to be revised to avoid populating the Toxics Information Clearinghouse with irrelevant and misleading information that may inappropriately implicate a substance for a specific hazard to human health or the environment where none exists.

We suggest developing specific criteria for determining when a change in an endpoint constitutes credible evidence of an adverse effect. We also recommend OEHHA develop a hierarchy for weighting sources of information/endpoints within a Hazard Trait to give appropriate emphasis to more reliable data in the weight of evidence assessment (e.g. evidence in humans > evidence in GLP/guideline animal study > validated in vitro assays > QSARs > non-validated methods).

<u>Specific comments:</u>

2. Definitions:

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In Definitions, page 4, “Adverse environmental effect” is incorrectly defined to include a “significant change that negatively affects an ecosystem or ecosystem component at the system . . . or individual level”. Environmental effects are not studied at the individual level but always at the population level. The definition for “Adverse environmental effect” needs to be corrected.

Class One and Class Two substances are defined on the subjective basis of "strong" or "lesser" bodies of evidence. The criteria for what constitutes a "strong" or "lesser" body of evidence are not clearly defined. Similarly, the term “Not Classifiable” is defined as meaning there is "insufficient evidence" to classify as Class One or Two hazard trait. As noted for the terms "strong" and "lesser", the term "insufficient" would need to be defined on the basis of specific criteria to ensure unambiguous and uniform classifications. However, throughout the document, there are references to "strong indications" of certain effects or properties attributed to Class One or Two substances. A key example of this occurs on Page 26. "At the request of DTSC, OEHHA may determine whether or not the chemical, In accordance with the methods in subsection 4(a)(ii), the Developmental Toxicity (Class Two) Hazard Trait because: 1. It has strong indications of the developmental toxicity hazard trait from validated Quantitative Structure Activity Relationship programs such as those used by U.S. Environmental Protection Agency to evaluate the potential toxicity of new or existing chemicals". To our knowledge, such a validated QSAR for developmental toxicity do not exist. Page 27 includes similar verbiage relating to reproductive toxicity; again, validated QSAR for predicting reproductive effects are not known to exist or to be validated and used by EPA.

It should be noted that evidence from QSAR is not mentioned for identifying potential hazard from other physical or chemical properties or structures, many of which are used by EPA and are validated for such purposes. For example, QSAR for predicting biodegradability, aquatic toxicity, bioaccumulation potential could be cited here for use as part of weight of evidence for either including or excluding substances in the proposed hazard classes.

The proposal defines the term "authoritative organization" to include OEHHA, DTSC and other State of California Boards, Departments, Offices or Agencies. Also defined is the term "document", as a report, memo, list or other written material released in paper or electronic form. Such "documents" are stated as being sufficient evidence to identify substances as Class One or Class Two substances, without any standards for establishing reliability, peer-review, or authenticity of the document. If these definitions and context are taken literally, OEHHA, DTSC, or any other Authoritative Organization has the ability to identify a substance as exhibiting Class One or Class Two hazard traits "because we say so".

The proposal defines the term "exposure potential characteristic" as an inherent property of a chemical substance that contributes to likelihood of significant human or environmental exposure. It could be assumed that this is referring to a finite set of physical/chemical properties; however, such inherent properties are not specifically identified, and relevance to potential exposure scenarios are not defined. It should be clearly defined how a specific chemical

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property relates to potential for exposure under the conditions of use for a substance. For example, vapor pressure alone cannot be used to infer high potential for respiratory exposure, if the substance is also highly water soluble and used only in aqueous formulations. Furthermore, the degree of exposure which is regarded as "significant" is also not defined. The lack of definition here could be viewed as leaving these matters open to interpretation by OEHHA, DTSC, or others on a case-by-case or otherwise inconsistent basis.

"Mechanistic Similarity" is defined, but again, no criteria are specified (e.g., structure similarity indices, defined parametric domains) to determine what degree of similarity will be regarded as sufficient for associating potential hazard/effects of one substance with another.

The definition for “Environmental endpoints” is confusing in that it is defined as an adverse environmental effect. Environmental endpoints are measured dependent variables that may or may not indicate an adverse effect. Again, certain predetermined criteria must be met before a change in an endpoint can be used as sufficient evidence for classifying a substance as a Class 1 or 2 Hazard.

It is unclear how the definition of 'Exposure potential characteristic' can be justified. A chemical substance can have a physical or environmental property, which may or may not have the potential to impact humans or the environment. However, merely having that characteristic does not mean that it is likely to contribute to significant human or environmental exposure or to an adverse outcome. One needs to consider the actual exposure not potential, as well as toxicity, in the evaluation of risk.

In Definitions, page 5, and throughout section 4, 'well conducted' should be replaced by guideline compliant (i.e. conducted in accordance with OECD or OPPTS test guidelines), using validated test methods and according to GLP. GLP stands for OECD Principles of Good Laboratory Practice.

Additionally, “Well conducted scientific studies” are defined to mean studies published in the open literature or submitted to a local, state, national or international government agency, using methods and analyses which are scientifically valid according to generally accepted principles. This definition does not include the requirement for, or criteria to judge, the valid performance of these methods/analyses and valid interpretation of results. Such requirements and criteria have been defined by Klimisch et al. (1996) for evaluating reliability of toxicological studies for regulatory/assessement purposes. These could be adopted to better and more uniformly define a "well conducted scientific study" in context of this proposed regulatory document.

In Specific Hazard Traits, and Endpoints and Other Relevant Data - 3(a) “Toxicological hazard traits – these hazard traits affect human health.” Suggest revising to read “traits *adversely* affect human health”.

Suggest adding the following definitions:

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"Endpoints – dependent variables, measured in a study, serve as indicators of an adverse effect but changes in an endpoint alone do not necessarily confirm an adverse effect or lead to classification for a Hazard Trait."
"Other relevant data – supplemental data to help inform the assessment of the Hazard Trait. These data can help to ascertain the relevance of a toxicity endpoint observed in animals for humans (i.e. mode of action) or lend support to a weight of evidence assessment. A positive finding in a parameter from other relevant data alone does not confirm an adverse effect or lead to classification of a Hazard Trait."

3.a. Toxicological Hazard Traits

On page 5 a.i.3. Carcinogenicity: It appears that data showing mechanisms of action identified in animals as not appropriate for humans will not be considered in assessment. Clarify that mechanistic data may be used to prove an adverse event in animals is not relevant to humans.

On page 6 a.ii.3. In vitro toxicity does not prove in vivo toxicity; normal homeostatic protective mechanisms (e.g. ADME, repair) may prevent in vivo effects. Suggest stating that in vitro findings could warrant further in vivo testing. Clarify that mechanistic data may be used to prove an adverse event in animals is not relevant to humans

On page 7 a.iii.1. Standard guideline studies (OECD, EPA, FDA) do not evaluate heat and fluid maintenance, or electrolyte homeostasis. This would require extensive use of additional animal testing or rely on data from non-validated, non-standard test methods.

On page 7 a.iv.3. Epigenetic changes do not equate to developmental toxicity or teratogenicity. Clarify that mechanistic data may be used to prove an adverse event in animals is not relevant to humans.

On page 8 a.v. Endocrine Toxicity - Suggest revising to "Endocrine Disruption", the more conventional, widely accepted term for this category of Hazard Trait. Endocrine disruption is considered a mode of action and not an adverse effect *per se*. Thus a cause-effect relationship must be established between a quantified chemical exposure and the observed adverse effect. These concepts should be addressed in the context of the overall weight of evidence.

Also, the hazard attribute is proposed to be identified from evidence relating to in-silico predictions of binding of a chemical substance or its metabolites to hormones or hormonal receptors or inhibition of hormone synthesis. It should be noted that such models are not sufficiently validated for a meaningful breadth of substances, such that this in-silico evidence alone could be used as basis for identifying or screening substances as exhibiting Class One or Class Two hazard traits.

No consideration is given Receptor Binding Theory, e.g. kinetics, binding affinity, firing threshold, etc. For example, binding affinity in vivo may be so low with a prospective toxicant

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that not enough of the toxicant will bind the receptor to elicit a response. These well-known, well-establish rules of receptor binding must be considered.

On page 8 a.v.3. Binding to a receptor in vitro or in silico does not indicate endocrine disruption. In vivo effects are required to demonstrate actual adverse effects.

On page 8 a.vi.1 Epigenetic changes do not necessarily result in adverse outcomes. These changes may be adaptive in response to exposures and occur with exposure to "natural chemicals". Would a "naturally occurring chemical" that induced epigenetic change be labeled as a hazard under this program?

On page 8 a.vi.3. Again, in vitro data does not prove the same in vivo response.

On page 9. a.vii. In vitro data must be supported by in vivo findings. Protective mechanisms (ADME, DNA repair, etc) may prevent in vitro genotoxicant from having the same in vivo effects.

On page 9 a.ix.3 In vitro data must be supported by in vivo findings. Protective mechanisms may prevent in vitro hematotoxicant from having same in vivo effects.

On page 11 a.xi.3 In vitro data must be supported by in vivo findings. Protective mechanisms may prevent in vitro musculoskeletal toxicant from having same in vivo effects.

On page 11 a.xii.2. Formation of calculi in animals (rats) is often rat specific, i.e. without human correlate, which means the effect does not occur in humans. Regulating human exposure on laboratory animal specific (non-human) events is inappropriate. In vitro data must be supported by in vivo findings. Protective mechanisms may prevent in vitro nephrotoxicant from having same in vivo effects.

On page 12 a.xiii.3 In vitro data must be supported by in vivo findings. Protective mechanisms may prevent in vitro neurotoxicant from having same in vivo effects.

On page 12 a.xv.3 In vitro data must be supported by in vivo findings. Protective mechanisms may prevent in vitro ototoxicant from having same in vivo effects.

On page 13 a.xvi. Does this include binding to albumin or other carrier protein, which generally has no adverse effect? If so, many known "safe" chemicals, including "natural" chemicals would be considered toxicants per this section. This section basically describes metabolism of toxicants and natural chemicals; metabolism is generally a protective not adverse event. The body produces hydroxyl radicals as a part of its normal functioning.

On page 13 a.xvii.3 In vitro data must be supported by in vivo findings. Protective mechanisms may prevent in vitro reprotoxicant from having same in vivo effects.

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On page 14 a.xviii.3 Dust and dirt would be labeled as hazardous under this section. In vitro data must be supported by in vivo findings. Protective mechanisms may prevent an in vitro respiratory toxicant from having same in vivo effects.

Environmental Hazard Traits:
Page 14 b.i. - Wildlife survival impairment
1. The wildlife survival impairment hazard trait is defined as the occurrence of increased incidence of death, disease or other biological impairment, following exposure to a chemical substance that significantly decreases the potential for wildlife survival in the environment. It should be noted that a cause-effect relationship must be established between a quantified chemical exposure and the observed adverse effect; such as demonstrated in a valid and reliable (per Klimisch?) study conducted under controlled experimental conditions. For example, detection of a substance in the environment (or in tissues, serum, etc.) which is coincidental with an observed adverse effect does not by itself establish a cause-effect relationship. The statement on Page 15 is contradictory to this first principle of scientific investigation "Correlative data from field studies linking exposure to a chemical substance with reductions in animal reproduction are also considered relevant." This comment can be applied to most/all of the hazard traits defined here. Any adverse effect or change which is observed following a known or suspected exposure to a substance cannot be regarded as sufficient evidence for a cause-effect relationship, unless the exposure occurs under conditions where other potential causative events are experimentally controlled.

Page 16 b.v. - Non-target phytotoxicity:
1. The non-target phytotoxicity hazard trait is defined as unwanted detrimental deviations from the normal pattern of appearance, growth, or function of plants following exposure to a chemical substance. The phytotoxic response may occur during germination, growth, differentiation, or maturation of plants, and may be of a temporary or long-term nature.
In this paragraph, the terms "unwanted" and "detrimental deviations" are not defined. Is not an "unwanted" trait a matter of opinion or perspective, and not of scientific or objective fact? One man's "weed" is another man's "flower".

On page 17 (c) the title of the section, Exposure potential hazard traits, is confusing as in the Definitions, the defined term is 'Exposure potential characteristic' yet here the term exposure and hazard is combined. It is unclear what OEHHA is trying to articulate. As this is a non-standard term, we would propose that the traits in this section should be organized in more universally acceptable categories: chemical, physical, and environmental. Also, within section c, there are numerous non-standard definitions that are utilized, OEHHA is encouraged to utilize terms that have already been evaluated and agreed upon by other regulatory bodies. (See specific comments below on a few of the traits.)

Page 17 c.i. - Ambient ozone formation

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1. The ambient ozone formation hazard trait is defined as the capacity for chemicals such as volatile organic compounds and oxides of nitrogen to generate photochemical smog and ozone and other oxidants indoors.
2. A chemical's propensity to form ozone can be indicated by photochemical and other reactivity to form ozone and other oxidants. A chemical substance has this hazard trait if it or its breakdown products meets the definition of photoreactivity as determined by the Air Resources Board protocol. This needs a negligible reactivity definition, needs to use MIR reactivity scale to measure reactivity, needs to explicitly define and distinguish category I and category II for this trait. Furthermore, it needs to recognize that the way a chemical is used, for example a down-the-drain use, will determine whether a chemical is available for photochemical reaction. In addition chemical with low vapor pressures have degradation or elimination pathways other than the participation in the formation of photochemical smog ozone.

Page 17 c.ii. - Bioaccumulation:
A substance has this hazard trait if it, its metabolite or environmental degradation product has a bioaccumulation factor greater than 2000, a log octanol water coefficient greater than or equal to 4, has been shown to bioaccumulate in animal or human tissues, or when it inhibits an efflux transporter. It should be clearly stated whether any of one these parameters are sufficient (that is, "or" between each parameter) or if all traits are required (that is, "and" between each parameter). The activity of a substance as inhibitor of efflux transporter cannot by itself be used to identify bioaccumalative substances. The species or cells and associated exposure conditions in which such inhibition is observed, and the molecules whose efflux is inhibited, are not identified. Large Log P are not associated with large bioaccumulation potential because such chemicals are not available for absorption by an organism.

Page 18 c.iii. - Environmental persistence
1. The environmental persistence hazard trait is defined as the propensity for a substance to exist in the environment for a long time period subsequent to its release.
2. A chemical substance has this hazard trait if it, or its environmental degradation product has the following half-lives in the environment: marine water – greater than 60 days; fresh or estuary water – greater than 40 days; marine sediment – greater than 180 days; ambient air – greater than 2 days; soil – greater than 6 months.

Page18 c.iv. - Global warming potential:
1. The global warming potential hazard trait is defined as the propensity to be a greenhouse gas, that is, to absorb infra-red radiation in the atmosphere, and thereby contribute to the general warming of the planet.
It is not clear whether the criteria and methods of CARB will be the exclusive basis for identifying global warming potential. Nearly all organic substances will absorb infra-red radiation (most will exhibit an IR spectrum), but does not implicate the substance as greenhouse gas. Also, this needs to include atmospheric lifetime because global warming potential is conventionally defined for a 100 yr time period, and must in any case refer to some time period. Short lived compounds have less GWP than longer lived compounds.

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Page 19 c.vi. - Mobility in environmental media:
1. The mobility in environmental media hazard trait is defined as the capacity of a chemical substance for rapid movement in the environment. Here, the methods or criteria for defining "rapid" are not identified, and thus could be subject to interpretation on a case-by-case basis or otherwise inconsistent manner.
2. A chemical substance has this trait if rapid or broad environmental mobility has been reported in the scientific literature, if it is volatile, water soluble, or possesses other physico-chemical characteristics predisposing to ease of movement through environmental compartments such as air, water, and soil. Here again, the terms "rapid" and "broad" are not defined or qualified. This is too vague to be useful.

The mobility of a substance alone should not be considered as an undesired or adverse hazard trait. Water itself is highly mobile in the environment, in its solid, liquid, and vapor forms. Does this mean water will be determined to exhibit a Class One hazard trait? Mobility of a substance must be considered along with other relevant properties such as toxicity, rate and modes of degradation, etc.

Page 19 c.viii. - Persistence in biota:
1. The biopersistence hazard trait is defined as the propensity for a substance to exist in the biota (including humans) for a long time period subsequent to its release.
2. Chemicals that have the following half-lives are considered biopersistent: humans – greater than one month; other species – greater than 0.1% of their lifespan.
In this context, persistence must be linked with causing with some other proven adverse effect. One could name many substances in the body which "persist" for more than one month, and most of these are essential to survival. "Other species" should be perhaps defined. Could even a bacterial cell, with lifespan on the order of hours to days, be considered to contain a persistent substance a substance were to reside in the cell for minutes?

Page 20 c.ix. - Stratospheric ozone depletion potential
1. This hazard trait is defined as the capacity for a chemical substance to deplete stratospheric ozone, and thereby contribute to higher levels of ultraviolet B radiation reaching the earth's surface. This trait definition needs to include atmospheric lifetime since short lifetime compounds are not around long enough to be transported in significant quantities to the stratosphere where ozone depletion reactions occur.

Page 20 c.x. - Toxic environmental transformation:
1. The toxic environmental transformation hazard trait is defined as the potential for a chemical substance to be transformed environmentally to a form that is more toxic or more persistent. This hazard trait is insufficiently defined, and could unnecessarily include many safe/beneficial substances. If the transformation product is more persistent than the parent substance, but still not exceeding criteria for persistence in any given medium, is this hazard trait relevant?

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Likewise, if a transformation product is known to be more toxic than the parent substance, but has very short lifetime in the organism or environment, is this trait relevant or applicable?
2. A chemical substance has this hazard trait if such transformations are observed in the field or laboratory or reliably predicted through structure activity analyses. Structure-activity predictions of metabolic transformations and associated products are not sufficiently validated for a sufficient breadth of substances to be used as a stand-alone indicator of this hazard trait. The metabolic pathway(s) and metabolite(s) of a substance are very much controlled by the specific environment/conditions under which the chemical and organism(s) responsible for the transformation are coinciding.

Page 21 d.vi. - Radioactivity:
1. The radioactivity hazard trait is defined as hazards due to radioactive decay.
2. Chemical substances have this hazard trait if they are radioactive elements or isotopes or if they contain radioactive elements or isotopes. It is not specified which type or types of radioactive decay are relevant (alpha, beta, gamma, or all three?). Nor is it specified at what dose or energy the decay must occur to pose this hazard. There are many naturally-occurring substances/minerals which contain radioactive components- would these all be considered to be exhibiting Class One hazard for radioactivity? Bear in mind that all organic substances contain some (measurable) levels of carbon-14, such as employed in radio-carbon dating techniques.

Pg. 19 Mobility in environmental media - a chemical substance will be labeled with this negative trait if "it is volatile, water soluble, or possesses other physical-chemical characteristics predisposing to ease of movement through environmental compartments such as air, water and soil." This is a completely arbitrary endpoint and does not consider the fact that aqueous-based products (as opposed to solvent based) are widely considered in the marketplace to be more environmentally desirable (i.e., paints and coatings based on aqueous emulsions vs. solvent systems). In order to make water-based product formulations, the product ingredients must out of necessity be water-soluble.

Pg. 19 Particle size or fiber dimension. Identifying a chemical substance as having a hazardous trait because it is, for example, supplied as a respirable particle 10 microns or less is likely to be meaningless in the context of how the substance is incorporated into a product. Some powder products (e.g., TiO2) will be supplied as fine powders which are then incorporated/dissolved into aqueous or polymeric systems in which all exposure potential to the particular particle is eliminated.

The same type of argument applies to the other physical characteristics such as explosivity or flammability. For example, labeling a product with a Class 1 flammable trait is meaningless if it is based on a single component which ignites at a concentration of 100% when the same component is incorporated into an aqueous formulation at a much lower concentration.

On page 20, in (c) (x), while it is understood that there is increasing interest in linking degradation products to the original substance when evaluating the risk of use of a given

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substance, it should be recognized that 'Toxic environmental transformation' is a non-standard trait in international hazard classification schemes. If this trait is included, to be scientifically credible and not create further confusion amongst consumers, there needs to be further definition around what is 'more toxic' or 'more persistent' and additional criteria on the types of studies that would be valid to demonstrate this trait.

In section 4, page 22 and beyond, where methodology is outlined for identifying and most importantly, classifying toxicological and environmental hazard traits, a key element that is missing is an assessment or consideration of exposure. When a system attempts to categorize a hazard without some concept of exposure in the assessment, it has the potential to create confusion and misuse of information in the Toxic Information Clearinghouse. OEHHA needs to incorporate some aspect of chemical use or exposure into the process for categorizing hazard traits.

Given the broad range of hazardous traits listed and the lack of consideration for actual exposure under typical use conditions, it seems very unlikely that many product ingredients would escape being labeled with at least one of the hazardous traits. In fact, the whole process as proposed leaves open the possibility that product ingredients with no or very little toxicity data have a greater chance of being considered "green" (i.e., no Class 1 or 2 hazardous traits) than those which have been extensively tested in a broad range of assays, and shown to be safe under actual use conditions using a more scientifically defensible risk/exposure-based process.

In section 4 (i), the requirement that DTSC or OEHHA is required to make a determination that a chemical substance does not have a particular hazard trait, otherwise it is assumed that they have the hazard trait, does not seem to be practical. With the tens of thousands of chemicals in the marketplace and the hazard traits identified in this document, it would not appear to be a valuable use of DTSC or OEHHA's time. Rather than requiring DTSC or OEHHA review, OEHHA should outline criteria, which identifies that the chemical lacks a hazard trait and thus should have a finding of 'Not a Hazard'. This information is just as valuable to a consumer as the identification of chemicals that do have a hazard trait.

There is no consideration given to dose-response, NOAEL/LOAELs, or component concentrations tested vs. those in the actual product in toxicology test results used as the basis for the Class 1 labels. For example, on pg. 7 for dermatotoxicity, it is quite possible that a material could be tested in animals as a pure material or at a high concentration and cause skin irritation or sensitization under those conditions, but at lower concentrations such as actually used in products would not cause such effects. This same argument may be used for many of the hazardous traits listed in the proposal - mainly that test conditions in animals etc. resulting in the toxic endpoint will likely not at all be relevant to product use concentrations and/or exposure conditions.

In closing, Dow has serious concerns with the pre-regulatory draft as it currently is written. We urge OEHHA to consider the comments provided herein and to develop a more technically

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robust document that contains specific and clear details for the process that will be used to identify chemicals of concern in consumer products and to ensure Toxics Information Clearinghouse contains relevant and robust data to contribute in the overall hazard assessment of substances.

Sincerely,

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