TOXICOLOGICAL RISK ASSESSMENT AND UNITED STATES REGULATORY COMPLIANCE EVALUATION OF ENTRY ICE MELT PRODUCT

Prepared for:

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INTRODUCTION

This report comprises a toxicological risk assessment of SynaTek Solutions' Entry ice melt formulation to determine if this product when used as intended is associated with adverse health risks to humans, cats, or dogs following residential use of the ice melt. According to the 2017-2018 American Pet Products Association (APPA) National Pet Owners Survey, 68% of U.S. households own a pet, with dogs and then cats comprising the majority of pets (APPA 2018). Therefore, it is likely that pets could be exposed to this formulation, as it is intended for household use. ToxServices evaluated ingredient toxicological profiles and specific exposure scenarios, which are based upon the assumption that exposure is short-term in nature, and occurs by direct dermal contact and, for pets, ingestion. ToxServices incorporated dermal irritancy testing data into the TRA. To assess the risk for oral toxicity among pets following ingestion of the liquid mixture, ToxServices calculated margins of safety (MOS) for the ingredients ingredients by comparing the estimated oral exposure dose to established acceptable daily intake levels. Additionally, this report assesses the Entry ice melt formulation to evaluate compliance with the United States Federal Hazardous Substances Act (FHSA) and associated Consumer Product Safety Commission (CPSC) regulations.

UNITED STATES REGULATORY REQUIREMENTS FOR CONSUMER PRODUCTS

The Federal Hazardous Substances Act (FHSA) requires precautionary labeling on containers of hazardous household products to help consumers safely store and use those products and to communicate information about immediate first aid steps to take if an accident occurs (CPSC 2018). To require labeling, a product must first be toxic, corrosive, flammable or combustible, an irritant, a strong sensitizer, or it must generate pressure through decomposition, heat, or other means. Second, the product must have the potential to cause substantial personal injury or substantial illness during or as a result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children (CPSC 2018). FHSA requirements are described in detail in Appendix B.

DESCRIPTION OF PRODUCT

Entry ice melt is a chloride-free, liquid-based deicing product. It is primarily designed to be a post-treatment when ice is no thicker than 1/8 inch (0.31 cm), and is intended to be used after snow is removed from the ground. Entry ice melt is recommended to be applied undiluted at a rate of ¾ gallon per 1,000 square feet, or 2.84 liters per 92.95 m^2 when the temperature is between 0 and 30ºF. For temperatures between -30 and 0ºF, it is recommended that Entry be applied at an increased rate of 1 gallon per 1,000 square feet (or 3.79 L per 92.9 m^2). Entry is not designed to melt wet snow or to melt through ice or compacted snow. Entry can also be used as a pre-treatment up to 6 hours before frozen precipitation, but would not be effective for sleet, freezing rain, or ice. And it would only be a cost-effective alternative to chloride-containing pre-treatment ice melt products

when the temperature drops below 0ºF. The target areas for Entry are pedestrian and low-speed parking lot areas (e.g., dropping off zones) (Branch Creek 2017).
The final Entry formulation is prepared by adding [REDACTED]. The chemical composition of the Entry ice melt formulation is provided below in Table 1 as well as Appendix A.

Table 1: Entry Ice Melt Formulation				
CAS No.	**Chemical Name**	**Trade Name**	**Percent in Trade Name Ingredient**	**Percent in Final Formulation**[1]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]		[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]		[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]		[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

INGREDIENT HAZARD ASSESSMENT

In order to identify potential health hazards and risks of non-water ingredients in the Entry ice melt formulation, ToxServices conducted a literature search using ChemIDplus (which indexes databases such as HSDB, DART, EMIC, CCRIS, IRIS, Medline, and Toxline) and Pharos (2018). As part of the literature search, relevant publications relating to adverse health effects for the following toxicity endpoints were assessed: acute toxicity (oral, dermal, and inhalation routes of exposure); skin sensitization; respiratory sensitization; genotoxicity; reproductive and developmental toxicity; systemic toxicity; and carcinogenicity. In addition, health hazards listed in individual ingredient safety data sheets (SDS) as well as the Entry ice melt formulation's SDS were also considered.

Ingredient Hazard Summary

Human health hazards of each chemical present in the Entry ice melt product are reviewed. Detailed hazard evaluations are presented below and a summary of the hazard profiles, selected points of departure (PODs) for the subsequent risk assessment, and relevant GHS classifications are presented in Table 2. The primary health hazards identified for each chemical are identified in **bold**.

1 [REDACTED]

Table 2: Entry Ice Melt Ingredient Hazard Assessment Summary		
Chemical	**Hazard Summary**	**GHS Classifications**
Potassium formate (CAS #590-29-4)	Low acute oral, inhalation, and dermal toxicity; Not irritating or sensitizing to skin; NLow systemic toxicity; Low reproductive and developmental toxicity; Not mutagenic/genotoxic; Not carcinogenic. **May cause mild, transient eye irritation.** POD: oral NOAEL of 1,000 mg/kg/day in a 2-gen reproductive study and developmental toxicity study in rats.	Not classified
[REDACTED]	Low acute oral, inhalation, and dermal toxicity; **At most mildly irritating to skin and eyes**; Not sensitizing to skin; Low systemic toxicity; Low reproductive and developmental toxicity; Not mutagenic/genotoxic; Not known to be carcinogenic. POD: oral NOAEL of 1,000 mg/kg/day in a combined repeated dose toxicity study with reproduction/developmental toxicity screening study in rats.	Not classified
[REDACTED]	**Moderate acute oral toxicity**, low acute dermal toxicity; **Corrosive to skin and eyes**; Not sensitizing to skin; Low systemic toxicity; Not known to be a reproductive or developmental toxicant; Not mutagenic/genotoxic; Not known to be carcinogenic. POD: oral NOAEL of 150 mg/kg/day in a 29-day gavage study in rats.	Classification in REACH dossier: Cat. 4 Acute Oral (H302: Harmful if swallowed); Cat. 1 Skin Corr. and Eye Damage (H314: Causes severe skin burns and eye damage)
[REDACTED]	Low acute oral, inhalation, and dermal toxicity; **Irritating to eyes**; Not sensitizing to skin; Low systemic	Classification in REACH dossier:

	toxicity; Low reproductive and developmental toxicity; Not mutagenic/genotoxic; Not carcinogenic. May irritate skin and GI tract at sufficient exposure levels. POD: oral NOAEL of 1,200 mg/kg/day in a 2-year study in rats.	Cat. 2 Eye Irrit. (H319: Causes serious eye irritation)

Individual Ingredient Hazard Profiles

Potassium Formate (CAS #590-29-4)
Limited data were available for potassium formate. In the REACH registration dossier for potassium formate, data on formic acid and other formate salts, including sodium formate and potassium diformate, were used to fill data gaps. Potassium formate is not acutely toxic with an oral LD_{50} value of 5,500 mg/kg in mice. No acute toxicity values are available for dermal and inhalation routes. However, the close structural surrogate sodium formate has a 4-hour inhalation LC_{50} of > 0.67 mg/L (highest achievable dust concentration) and a dermal LD_{50} of > 2,000 mg/kg in rats, indicating low acute toxicity by these routes as well (ECHA, CAS #590-29-4, 2018).

The read-across chemical sodium formate was not a skin irritant when applied neat to the skin of rabbits in a GLP-compliant study performed according to OECD Guideline 404. Neat sodium formate induced transient moderate eye irritation in rabbits in a GLP-compliant study performed according to OECD Guideline 405 that does not meet GHS classification criteria for eye irritants. Potassium formate was not sensitizing to the skin in a GLP-compliant guinea pig maximization test performed according to OECD Guideline 406 at the intradermal induction concentrations of 0.5% and 15% and dermal challenge concentration of 5 and 10% (ECHA, CAS #590-29-4, 2018).

In a GLP-compliant subchronic oral study performed under GLP according to OECD Guideline 408, Crl:CDBR rats received potassium diformate (purity not reported; potassium diformate decomposes to potassium formate and formic acid in aqueous solutions) in the diet at 0, 600, 1,200, or 3,000 mg/kg/day for 13 weeks. Additional groups of animals dosed at 0 and 3,000 mg/kg/day were included in a recovery sub-study with a 4-week treatment free period after exposure, and in an absorption sub-study. Examinations included clinical observations, body weight, food consumption, ophthalmology, hematology, clinical chemistry, urinalysis, absorption, gross pathology, and histopathology. Authors established a NOAEL of 3,000 mg/kg/day for systemic toxicity based on lack of adverse effects at this dose level. The LOAEL was 600 mg/kg/day for local irritation based on minor stomach squamous cell hyperplasia observed at all doses that was not completely reversible. As the local effects are the result of formic acid that is released during decomposition of potassium diformate, they

are not expected to occur with pure potassium formate salt, which does not decompose to formic acid (ECHA, CAS #590-29-4, 2018).

In a GLP-compliant two-generation reproductive toxicity study performed according to OECD Guideline 416, Wistar rats received the surrogate sodium formate (purity 100%) in the diet at 0, 100, 300, or 1,000 mg/kg/day. F0 and F1 generations were exposed for 75 days beginning prior to mating and continuing through mating and gestation until postnatal day 21. The NOAEL was 1,000 mg/kg/day, based on lack of adverse effects on reproductive performance, reproductive organs, pre- and postnatal survival, offspring body weights, clinical observations, and gross necropsy findings in the offspring (ECHA, CAS #590-29-4, 2018). In a GLP-compliant prenatal developmental toxicity study performed under GLP according to OECD Guideline 414, Himalayan rabbits received the surrogate sodium formate (purity 100%) by gavage at 0, 100, 300, or 1,000 mg/kg/day on gestation days 6 to 28. Authors identified a NOAEL of 1,000 mg/kg/day based on lack of maternal toxicity or developmental effects (ECHA, CAS #590-29-4, 2018). In a second OECD Guideline 414 study, Wistar rats were exposed to sodium formate (purity unspecified) at 0, 59, 236, or 945 mg/kg/day by gavage on gestation days 6 – 19. The NOAEL for this study was NOAEL of 1,000 mg/kg/day, based on a lack of maternal toxicity or developmental effects observed (ECHA, CAS #590-29-4, 2018).

The surrogate formic acid was not mutagenic in a bacteria reverse mutation assay performed according to OECD Guideline 471 using *Salmonella typhimurium* tester strains TA97, TA98, TA100, and A1535 at concentrations of up to 3,333 μg/plate with and without metabolic activation. Formic acid was negative in a mammalian gene mutation assay at the *HPRT* locus in Chinese hamster ovary (CHO) cells at concentrations of up to 500 μg/mL with metabolic activation and 400 μg/mL without metabolic activation. Formic acid was not clastogenic at non-cytotoxic concentrations in CHO cells at concentrations of up to 1,380 μg/mL with and without metabolic activation. Neither formic acid nor sodium formate was positive in a sex-linked recessive lethal (SLRL) assay in *Drosophila melanogaster*. These data indicate that potassium formate is unlikely to be genotoxic or mutagenic (ECHA, CAS #590-29-4, 2018).

The surrogate potassium diformate was negative for carcinogenicity at dietary doses up to 2,000 mg/kg/day in an 80-week study in mice and a 104-week study in rats performed according to OECD Guideline 453 (ECHA, CAS #590-29-4, 2018).

In summary, available data on potassium formate and structurally-similar surrogates demonstrate low acute toxicity, local dermal toxicity, systemic toxicity, reproductive and developmental toxicity, genotoxicity, and carcinogenicity potentials. This chemical may cause mild, transient eye irritation.

[REDACTED] (CAS #[REDACTED])
[REDACTED] has low acute toxicity with oral LD_{50} values of > 2,000 mg/kg and 2,650 mg/kg[2] in rats and a dermal LD_{50} of > 2,500 mg/kg in rabbits[3] in reliable studies (ECHA, CAS #7758-11-4, 2018). The surrogate [REDACTED] has a 4-hour inhalation LC_{50} of > 0.83 mg/L, the maximum attainable dust concentration (ECHA, CAS #7758-11-4, 2018).

[REDACTED] (purity >99%) was mildly irritating to the skin after a 24-hour exposure under occlusion in rabbits. All effects were reversible within 72 hours and [REDACTED] is not classified as a skin irritant under GHS (UN 2017). Similar effects were observed in a second nonstandard skin irritation study for 50% [REDACTED] after a 4-hour exposure period and in two studies for the neat substance with 24-hour exposure durations under occlusion. Unchanged, solid [REDACTED] was mildly irritating to the eyes of rabbits in a GLP-compliant ocular irritation study performed according to the FMC Preliminary Eye irritation protocol. The effects were not fully reversible within 7 days for the unwashed eyes, but reversible within 48 hours for the washed eyes. Effects were not evaluated beyond 7 days. [REDACTED] (50%) did not meet the GHS criteria for classification as an eye irritant in a non-GLP study in rabbits; treatment produced mild, transient irritation consisting of iritis and conjunctivitis. The surrogate [REDACTED] was not dermally sensitizing in a mouse local lymph node assay (LLNA) at concentrations up to 10% (ECHA, [REDACTED], 2018).

A GLP-compliant combined repeated dose toxicity study with reproduction/ developmental toxicity screening conducted according to OECD Guideline 422 was performed with Sprague-Dawley rats administered oral gavage doses of [REDACTED] (99.5% purity) in water at 0 or 1,000 mg/kg/day. Females were treated from 2 weeks prior to mating to postnatal day 4, and males were treated from 2 weeks prior to mating to 2 weeks after mating. Parental examinations included clinical observations, body weight, food consumption, water consumption, hematology, urinalysis, neurobehavior, gross pathology, histopathology, mating rate, mating period, gestation period, male and female fertilities, and parturition rate. Fetal examinations included external, soft tissue, skeletal, and head examinations. No treatment-related effects were observed on any of these parameters. The study authors identified a NOAEL of 1,000 mg/kg/day for systemic toxicity, reproductive toxicity, and developmental toxicity (ECHA, [REDACTED], 2018).

[REDACTED] was not mutagenic in a bacterial reverse mutation assay (GLP status not reported) conducted in *S. typhimurium* tester strains TA97 and TA102 at concentrations of 100 – 10,000 µg/plate (purity not reported) with and without metabolic activation, and in a second bacterial reverse mutation assay (GLP status not reported) conducted in *S. typhimurium* tester strains TA98, TA100, TA1535, TA1537, and TA1538 at concentrations of 0 – 5 µg/plate (purity not reported) with and without metabolic activation. [REDACTED] tested negative in a yeast mutation assay (GLP status not

[2] A 50% water solution was tested. Therefore, the original value reported was divided by a factor of 2 to derive the value for the neat substance.
[3] A 50% water solution was tested. Therefore, the original value reported was divided by a factor of 2 to derive the value for the neat substance.

reported) conducted in *Saccharomyces cerevisiae* tester strain D4 at concentrations of up to 5 μ/plate and 5% w/v in two separate studies with and without metabolic activation. [REDACTED] was negative in an *in vitro* mammalian chromosomal aberration test conducted under GLP according to OECD Guideline 473. Chinese hamster lung (CHL/IU) cells were exposed to the test substance (99.6% purity) at concentrations of up to 5,000 μg/mL with and without metabolic activation. No significant increases in numerical or structural chromosomal aberrations were found (UNEP 2006). No standard carcinogenicity studies were identified for [REDACTED] or surrogates.

Based on this evaluation, undiluted [REDACTED] may be mildly irritating to the skin and eyes.

[REDACTED] (CAS #[REDACTED])
Limited data were identified for [REDACTED]. The United States Environmental Protection Agency (U.S. EPA) evaluated [REDACTED] in the [REDACTED] category and used data on other members of this category for read-across (U.S. EPA 2001). [REDACTED] has moderate acute toxicity with oral LD_{50} values of 320, 460, and 990 mg/kg in rats, and a dermal LD_{50} of > 1,000 mg/kg in rabbits[4] (U.S. EPA 2018). [REDACTED] (50% in water) was corrosive to the skin of rabbits in a study performed according to OECD Guideline 404 (U.S. EPA 2018). Based on GHS criteria, it can be assumed that [REDACTED] is corrosive to the eyes as well (UN 2017). The surrogate [REDACTED] was not sensitizing in a GLP-compliant guinea pig maximization test performed according to OECD Guideline 406 (ECHA, CAS #64665-57-2, 2018).

No repeated dose toxicity data were available for [REDACTED]. U.S. EPA considered [REDACTED] (CAS #29385-43-1) to be the most appropriate surrogate for this endpoint, as [REDACTED] in water. In a 29-day gavage study, Wistar rats received the surrogate [REDACTED] at 0, 50, 150, or 450 mg/kg/day. A NOAEL of 150 and LOAEL of 450 mg/kg/day were identified based on mild apathy. In a 9-day gavage study, rats were given 0, 100, or 500 mg/kg/day [REDACTED]. Lethargy and respiratory difficulties were observed after each dose administration, but there were no macroscopic changes in any of the examined tissues. No additional details were provided (U.S. EPA 2001).

No reproductive or developmental toxicity studies were identified for the [REDACTED] category. However, no pathological changes to reproductive organs were identified in chronic studies on category members (U.S. EPA 2001).

The surrogate [REDACTED] was negative at non-cytotoxic concentrations in an Ames test conducted according to EPA OTS 798.5625 using *S. typhimurium* tester strains TA98, TA100, TA1535, TA1537, and TA1538 at concentrations of up to 10 mg/plate with and without metabolic activation. It was also negative in a second Ames test using *S. typhimurium* tester strains TA97, TA98, TA100, TA1535, and TA1537 at concentrations

[4] All acute studies were conducted with [REDACTED]. Therefore, all the LD_{50} values were divided by a factor of 2 to derive the respective values for pure [REDACTED].

of up to 6,666 µg/plate with and without metabolic activation. [REDACTED] was negative in a DNA damage and repair assay performed according to EPA OTS 798.5550 using human embryonic lung fibroblasts at concentrations of up to 50 µg/plate without metabolic activation, and in a mouse fibroblast transformation assay using C3H 10T1/2 mouse embryonic fibrablast cell line at concentrations of up to 600 µg/plate without metabolic activation. [REDACTED] was negative for clastogenicity in an *in vivo* micronucleus assay performed under GLP according to OECD Guideline 474 in NMRI mice at a single oral dose of 600 mg/kg (U.S. EPA 2001). These data indicate that [REDACTED] is not likely to be genotoxic. No carcinogenicity studies were identified for members of this category.

Based on information above, endpoints of concern for [REDACTED] are skin and eye irritation and acute oral toxicity. This chemical's moderate acute oral toxicity raises concern for pets ingesting the chemical accidentally. However, as [REDACTED] is used at a low level of up to [REDACTED]% in the Entry ice melt formulation, it is not expected to significantly contribute to the overall acute toxicity or irritation potential of the formulation.

[REDACTED] (CAS #[REDACTED])
[REDACTED], its organic salts, and its alkyl esters have been evaluated as a group by the Cosmetic Ingredient Review (CIR) Expert Panel (CIR 2016). These ingredients have similar structures, physicochemical properties, and functions in cosmetics, and safety data may be extrapolated among members of this group. The CIR Expert Panel noted that [REDACTED] and many [REDACTED] are Generally Recognized as Safe (GRAS) as direct food additives and thus present low potential for oral toxicity at typical intake levels. Inhalation of [REDACTED] aerosols may result in coughing and bronchoconstriction in humans and animals, with coughing observed in guinea pigs exposed to citric acid for 30 minutes at concentrations up to 81 mg/m^3 and in guinea pigs exposed to 75 mg [REDACTED]/mL for 3 minutes (UNEP 2000). However, outdoor use of the Entry ice melt formulation is unlikely to result in toxicologically meaningful air concentrations of [REDACTED]. [REDACTED] itself was not irritating or sensitizing to human skin in a repeat-insult patch test at 4%, which is the highest recommended leave-on concentration. Additionally, although [REDACTED] is an [REDACTED], it is also a [REDACTED] and therefore UV sensitivity concerns associated with [REDACTED] do not apply to [REDACTED]. The Panel concluded that [REDACTED] may safely be used at up to 39% in personal care products (CIR 2016).

Based on acute oral LD_{50} values of 3,000-12,000 mg/kg in rats and 5,400 mg/kg in mice, [REDACTED] has low acute toxicity in animals. Acute animal studies have noted effects on the central nervous system and damage to the stomach mucosa following high-dose oral exposure; acidosis and calcium deficiency have also been noted. [REDACTED] was slightly irritating in two studies and not irritating in a third study in which it was applied to intact rabbit skin as a 30% aqueous solution under occlusive conditions. Slight to well-defined erythema was observed when [REDACTED] was applied to abraded rabbit skin under occlusive conditions. [REDACTED] was highly irritating to the eyes in rabbits in a test conducted according to OECD Guideline 405. Two additional studies reported severe

and permanent injury to rabbit eyes after application of [REDACTED] for 24 hours and a 2% aqueous solution for 30 minutes. According to OECD (UNEP 2000), [REDACTED] should be considered an irritant to the eyes but not the skin.

In a two-year dietary study, rats were administered 3% or 5% (approximately 1,200 or 2,000 mg/kg/day) [REDACTED] in the feed, with slightly decreased growth in the 5% group the only effect noted. NOAELs of 1,200 mg/kg/day in rats, 1,500 mg/kg/day in rabbits, and 1,400 mg/kg/day in dogs have been determined. No adverse effects on reproduction or development were observed in a two-generation study in which rats were fed 1.2% [REDACTED] (approximately 600 mg/kg/day) or in three short-term reproductive studies in rats fed 5% (approximately 2,500 mg/kg/day) or 241 or 295 mg/kg/day [REDACTED] on gestation days (GDs) 6-15. NOAELs of 425 mg/kg/day, 2,500 mg/kg/day, and 7,500 mg/kg/day have been determined in reproductive and developmental toxicity studies in rabbits, rats, and mice, respectively (UNEP 2000).

[REDACTED] was not mutagenic in *in vitro* tests with *S. typhimurium*, *Escherichia coli*, or *Saccharomyces cerevisiae*, in the presence or absence of metabolic activation. It was negative for chromosomal damage in human and hamster cell cultures and in a dominant lethal assay in rats. [REDACTED] was not carcinogenic in a study in which male rats received diet containing 5% (approximately 2,000 mg/kg/day) [REDACTED] for two years. Insufficient or negative evidence of a tumor-promoting effect was noted in several non-standard studies in which rats were co-treated with [REDACTED] and a known carcinogen (UNEP 2000).

In humans, severe vomiting occurred after ingestion of 25 g [REDACTED] (equivalent to approximately 417 mg/kg) while ingestion of [REDACTED] did not result in any adverse gastrointestinal effects. Gastrointestinal effects such as diarrhea, indigestion, and nausea were noted after exposure of up to 15 g/day of [REDACTED] in 22/81 patients, but no other adverse effects were noted. Ingestion of [REDACTED] by ten men resulted in a change in the acid-base balance in the blood. As [REDACTED] is a strong chelating agent, it has the potential to interfere with the absorption, distribution, and excretion of elements in the body, but this is not expected to occur following low-level topical exposure to [REDACTED] compounds. Dermatitis attributed to [REDACTED] has been noted after occupational exposure; however, no allergic reactions were reporting after 60 patients with eczema were patch tested with 2.5% [REDACTED]. A person who was splashed in the eye with a solution of [REDACTED] suffered severe eye damage (UNEP 2000).

The World Health Organization (WHO) has not set an acceptable daily intake (ADI) for [REDACTED] and concluded that [REDACTED] and its calcium, potassium, and sodium salts do not pose a significant toxicological hazard (WHO 1974).

The above evaluation identifies eye irritation as the primary effect of concern for [REDACTED]. At higher exposure levels, skin irritation may occur, and ingestion of sufficient quantities of this substance produces irritation of the gastrointestinal tract.

FORMULATION-SPECIFIC TOXICOLOGICAL TESTING

As described above, some of the ingredients in the Entry ice melt formulation may be irritating to the skin. Therefore, the dermal irritancy potential of the formulation was evaluated in a non-GLP *in vitro* skin irritation study using the EpiDerm™ reconstructed human epidermis model according to OECD Test Guideline 439. The EpiDerm™ model utilizes cultured human-derived epidermal keratinocytes with highly differentiated, multilayered structures. EpiDerm™ tissues are exposed to the test article in triplicate or to positive and negative controls for 1 hour, followed by a 42-hour post-exposure incubation period. The tissue viability is then determined by the 3-[4,5-dimethylthiazol-2-yl]-2,5-diphenyltetrazolium bromide (MTT) conversion assay using a colorimetric method. Briefly, MTT is reduced to a blue formazan precipitate by NAD(P)H-dependent microsomal enzymes, and is therefore indicative of cellular metabolism (and, by inference, viability). Formazan formation is monitored after exposure to the test substance. A relative cell viability of 50% or less indicates skin irritation potential, which corresponds to GHS Categories 1 or 2 for skin irritation (IIVS 2018a). Only a draft study report was available for review at the time of the report completion.

Preliminary studies indicated that the Entry ice melt formulation did not interact with the nylon mesh that was used to spread the test substance on the tissues. In addition, the Entry ice melt product did not directly interact with MTT without the presence of viable cells and did not interfere with colorimetric determination of MTT/blue formazan precipitate. These observations confirm that the test results are attributable to the test substance itself and not to experimental artefacts.

In the definitive study, the Entry ice melt product was administered to the EpiDerm™ system for 60 minutes and the tissues where then incubated for another 42 hours. Calcium and magnesium free-Dulbecco's phosphate buffered saline and 5% sodium dodecyl sulfate (SDS) were used as negative and positive controls, respectively, which were also administered in triplicates.

Before administration of the test substance, one of the tissues to be treated with Entry ice melt partially lifted from the tissue insert. However, this did not impact the validity of the results obtained, as the relative viability of this tissue (61.6%) was still >50%, which met the validity criteria. The relative viabilities of the three replicates of test articles were all above 50% (104.4%, 61.6% and 90.1%, with a mean of 85.2%), indicating that the Entry ice melt is not a skin irritant and does not warrant GHS classification. The positive and negative controls produced expected results (IIVS 2018b). The test result also indicates that the Entry ice melt formulation is not corrosive or irritating to the skin under the FHSA paradigm.

EXPOSURE ASSESSMENT

Entry ice melt is designated for outdoor low-speed areas such as pedestrian walks and driveways. Because the Entry ice melt formulation's primary route of exposure among

consumers and pets is dermal, ToxServices' evaluation focused on the potential for adverse dermal effects arising from contact with the ice melt, including dermal irritation, corrosion, and dermal sensitization. Additionally, ToxServices focused on characterizing potential acute oral health risks arising from incidental oral exposure among pets that ingest the Entry ice melt by licking paws and/or fur following contact with the ice melt formulation.

ToxServices performed exposure calculations for human exposure via the dermal route and for pet exposure via oral and dermal routes, and calculated margins of exposure (MOEs) for each exposure scenario to determine if exposure to Entry ice melt product will lead to unacceptable systemic toxicity risks for humans or domestic pets. The following scenarios are considered in the exposure estimation for the Entry ice melt product: dermal exposure for humans applying the product, dermal exposure for domestic pets (dogs and cats) walking on the treated areas, and oral exposure for domestic pets either ingesting snow/ice treated with the product or grooming paws after walking on treated areas.

Dermal Exposure – Humans

Exposure via direct dermal contact is the net result of multiple factors, including the mass of the chemical in the product, the amount of product used/applied, the surface area of the skin that is in direct contact with the product, and contact frequency and duration. Collectively, these factors produce a dermal loading dose – i.e., the amount of the chemical present on the skin's surface. Dermal retention and dermal absorption then determine how much of the dermal loading dose is available for systemic exposure and adverse health effects.

For the purpose of a conservative estimation, ToxServices makes the following assumptions regarding the use of the Entry ice melt product:

- The product is applied to a large double driveway (20 feet x 24 feet, or 6 m x 7.2 m) with the surface area of 43.2 m^2 (ConcreteNetwork.com 2018, LandscapingNetwork 2018)
- The Entry ice melt product is used at the maximum recommended application rate of 1 gallon per 1,000 sq feet, or 3.79 L per 92.9 m^2. Based on the product's density of 1.33 kg/L (Branch Creek 2017), this application rate equals (3.79 L * 1.33 kg/L) / 92,9 m^2 * 1,000 g/kg = 54.3 g/m^2.
- The product gets on both hands during application, but not on other areas of the skin. U.S. EPA Exposure Factors Handbook (U.S. EPA 2011) identifies the recommended values for the surface area of different body parts for adult males and females. As a conservative estimate, ToxServices used the 95^{th} percentile value for the surface area of adult male hands, 0.131 m^2, which is greater than the value of 0.106 m^2 for adult females.
- The product is designed to be applied after each frozen precipitation (snow). Based on data collected from 1981 and 2010 for major cities in the U.S., Rochester, New York has the highest frequency of snow (65.9 days/year) (Current Results 2018). Using this snowing frequency as a conservative

approach, ToxServices assumes that Entry ice melt product is used 65.9 days/year.

- Average body weight for adult humans is 80 kg (U.S. EPA 2011).
- The product is applied without wearing any protective equipment, such as gloves.
- As no experimental data are available on the dermal absorption of the Entry formulation, a default of 10% for a water-based concentrate formulation (as sold and as used) is used, according to European Commission's guidance (EC 2017).
- The product is intended to be applied using a pump sprayer. Although no intentional dermal contact is expected, incidental dermal contact may occur during application or handling of the container. The product resource guide instructs consumers to wash hands if skin contact occurs. As a conservative approach, ToxServices assumes consumers contact the product by hand directly.

Therefore, the dermal exposure for humans is calculated using the following equation:

*% Chemical in product/100 * Application rate (g/m^2) * Skin surface area (cm^2) * 1,000 mg/g * Application frequency (65.9 days/365 days) * Dermal absorption factor (%)/100/ Body weight (kg)*

The calculated human exposure values are presented in Table 3 below.

Table 3: Human Dermal Exposure Calculations

Chemical	% in Product	Application rate (g/m^2)	Skin Surface Area (m^2)	Application frequency (days/365 days)	Dermal Absorption (%)	Body Weight (kg)	Exposure (mg/kg/ day)
Potassium formate	[REDACTED]	54.3	0.131	0.181	10	80	0.799
[REDACTED]	[REDACTED]	54.3	0.131	0.181	10	80	0.00319
[REDACTED]	[REDACTED]	54.3	0.131	0.181	10	80	0.000204
[REDACTED]	[REDACTED]	54.3	0.131	0.181	10	80	0.00771

Dermal Exposure - Pets

As dogs have more outdoor activity than cats, they are more likely to be exposed to the Entry ice melt product. Therefore, a conservative exposure estimation was performed for dogs, which represent the worst case for all common household pets. The following conservative assumptions are made in this exposure assessment:

- As previously mentioned, Entry is used at the maximum recommended application rate leading to a concentration of 54.3 g/m^2 on the ground.
- Dogs are exposed to Entry ice melt product on the surface of the four paws. According to a standard dog shoes sizing chart, dog shoes range in size from 3.5 cm x 2.5 cm (size XS) to 10 cm x 8 cm (size XXXL) (Furry Footwear Undated).

Another dog shoe website reports a smallest dog paw size of 2.75 cm x 2.75 cm (size XXS) and a largest dog paw size of 9.5 cm x 9.5 cm. For this assessment, ToxServices selected an intermediate dog paw size of 6.5 cm x 6.5 cm (42.25 cm^2) for a popular dog breed, the Labrador (Woodrow Wear 2018). The surface area of all four paws is calculated as 4 * 42.25 cm^2 = 169 cm^2 = 0.017 m^2.

- Similar to the palms and soles on humans, dogs' footpads are much thicker than other areas of the skin: available data, although limited, show that the stratum corneum on a dog's paw pads is approximately 500 µm (0.05 cm) thick (Ninomiya et al. 2013, Miao et al. 2016).
- Depending on the dog's age, breed, and size, a dog needs between 30 minutes and two hours of exercise every day (PetMD 2018). ToxServices assumes that a dog walks 2 hours a day on sidewalks and/or driveways treated with Entry after snow.
- As previously discussed, ToxServices assumes that Entry ice melt product is used 65.9 days/year.
- Since a dog will walk on surfaces other than treated driveways/sidewalks, a proportion of the ice melt formulation that is present on the paws will be lost to those other surfaces. ToxServices assumes that 50% of the material on the paws will remain on the paws. This conservative assumption also accounts for the possibility that pet owners may wipe the dog's feet with a towel after a walk through wet or snowy areas where the ice melt is used.
- Dog body weights have a wide range among different breeds of approximately 4 pounds (approximately 1.8 kg) for the Chihuahua to over 200 pounds (approximately 91 kg) for the Great Dane, St. Bernard, and Irish Wolfhound (Fleischer et al. 2008). For consistency with the above value selected for dog paw size, ToxServices selected the lower end of body weights reportedly associated with dog paws 6.5 cm x 6.5 cm: 75 pounds (Woodrow Wear 2018), which is equivalent to 34 kg.

Dog dermal exposure (mg/kg/day) is therefore calculated as:

*% Chemical in Entry formulation/100 * Amount of Entry formulation applied per surface area (g/m^2) * 1,000 mg/g * surface area of dog paws (m^2) * Stratum corneum thickness (cm) * Permeability coefficient (cm/h) * Contact duration (h) * Application frequency (65.9 days/365 days) / Dog body weight (kg)*

The permeability coefficient is chemical specific and is a predictor of skin penetration potential. A chemical's permeability coefficient (Kp) is a function of its octanol:water partition coefficient (log P_{ow}) and molecular weight (MW) (Kroes et al. 2007). The Potts and Guy equation, below, is used to calculate the permeability coefficient (Kroes et al. 2007).

$$Kp = 10^{[-2.72 + (0.71 \times \log Pow) - (0.0061 \times MW)]}$$

Calculated Kp values are presented below in Table 4.

Table 4: Calculated Kp Values for Chemicals in Entry Ice Melt				
Chemical	**MW**	**Log P_{ow}**	**Kp (cm/h)**	**Reference**
Potassium formate	84	-2	2.23E-05	ChemIDplus, ECHA
[REDACTED]	157	1.087	1.24E-03	ChemIDplus, ECHA
[REDACTED]	192	-1.64	8.80E-06	ChemIDplus
[REDACTED]	174	1.64	2.42E-03	ChemIDplus, SCBT 2015

The calculated dermal exposure values for dogs are presented in Table 5 below.

Table 5: Dog Dermal Exposure Calculations											
Chemical	**% in Product**	**Paws Surface Area (m^2)**	**Application Rate (g/m^2)**	**Mass on Paws (mg)**	**Retention Factor**	**Kp (cm/hr)**	**Stratum Corneum Thickness (cm)**	**Duration (h/day)**	**Application Frequency (days/365 days)**	**Dog Body Weight (kg)**	**Exposur (mg/kg/ day)**
Potassium formate	[REDACTED]	0.017	54.3	456	0.5	2.23E-05	0.05	2	0.181	34	1.08E-03
[REDACTED]	[REDACTED]	0.017	54.3	1.83	0.5	1.24E-03	0.05	2	0.181	34	2.41E-04
[REDACTED]	[REDACTED]	0.017	54.3	0.116	0.5	8.80E-06	0.05	2	0.181	34	1.09E-07
[REDACTED]	[REDACTED]	0.017	54.3	4.40	0.5	2.42E-03	0.05	2	0.181	34	1.13E-03

Oral Exposure – Pets

As previously discussed, dogs are conservative representatives of household pets for the purpose of the risk assessment of Entry ice melt product. As dogs may lick and swallow the ice melt product retained on the footpad, an exposure assessment is also performed for this scenario. The following conservative assumptions are made:

- As previously mentioned, Entry is used at the maximum recommended application rate, leading to a concentration of 54.3 g/m^2 on the ground.
- As previously discussed, ToxServices assumes that Entry ice melt product is used 65.9 days/year.
- As previously discussed, ToxServices used a body weight of 34 kg for a typical dog breed as a representative approach.
- As previously discussed, a dog may be exposed to the ice melt product on the skin for 2 hours per day.
- This evaluation conservatively assumes that 50% of the material on the paws will remain on the paws.
- ToxServices assumes that all of the ice melt product retained on the paws is ingested by the dog after a walk.

Dog oral exposure (mg/kg/day) is therefore calculated as:

*% Chemical in Entry formulation/100 * Amount of Entry formulation applied per surface area (g/m^2) * 1,000 mg/g * surface area of dog paws (m^2) * Dermal retention factor * Application frequency (65.9 days/365 days) / Dog body weight (kg)*

The calculated oral exposure values for dogs are presented in Table 6 below.

Table 6: Dog Oral Exposure Calculations

Chemical	% in Product	Dog Paws Surface Area (m2)	Application Rate (g/m2)	Mass on Paws (mg)	Retention Factor	Application Frequency (days/365 days)	Dog Body Weight (kg)	Exposure (mg/kg/day)
Potassium formate	[REDACTED]	0.017	54.3	457	0.5	0.181	34	1.21
[REDACTED]	[REDACTED]	0.017	54.3	1.83	0.5	0.181	34	0.00485
[REDACTED]	[REDACTED]	0.017	54.3	0.116	0.5	0.181	34	0.000309
[REDACTED]	[REDACTED]	0.017	54.3	4.40	0.5	0.181	34	0.0117

In addition, the total exposure via dermal and oral routes is also calculated for dogs.

Table 7: Entry Ice Melt Ingredient Exposure Assessment Summary

Chemical	Human Dermal Exposure (mg/kg/day)	Pet Dermal Exposure (mg/kg/day)	Pet Oral Exposure (mg/kg/day)	Pet Total Exposure (mg/kg/day)
Potassium formate	0.799	1.08E-03	1.21	1.21
[REDACTED]	0.00319	2.41E-04	0.00485	0.00509
[REDACTED]	0.000204	1.09E-07	0.000309	0.000309
[REDACTED]	0.00771	1.13E-03	0.0117	0.0128

INGREDIENT RISK CHARACTERIZATION

A margin of exposure (MOE) is calculated for each chemical and each exposure scenario above. An MOE is calculated by dividing the PODs by the calculated exposure levels for each chemical. A benchmark MOE of 100 is considered acceptable, which is consisted of 10 for intraspecies variation and 10 for inter-species extrapolation (the PODs for all chemicals were derived from rat studies, which should be extrapolated to human and dogs). The MOEs calculated for the above exposure scenarios are summarized in Table 8 below.

Table 8: Entry Ice Melt Risk Characterization

Chemical	POD	MOE Human Dermal	MOE Pet Total	Health Risk?
Potassium formate	1,000	1,252	824	N

[REDACTED]	1,000	313,021	196,482	N
[REDACTED]	150	736,302	484,961	N
[REDACTED]	1,200	155,728	93,565	N

As shown above in Table 8, all of the MOEs are above the benchmark MOE of 100. Therefore, humans and dogs are unlikely to be harmed through the intended use of the Entry ice melt product.

FHSA COMPLIANCE OF ENTRY ICE MELT FORMULATION

ToxServices reviewed the Entry ice melt formulation to assess compliance with regulatory and statutory requirements specified in the Code of Federal Regulations (CFR) Title 16: Commercial Practices, Part 1500: Hazardous Substances and Articles; Administration and Enforcement Regulations, and with requirements of the FHSA. The FHSA and 16 CFR §1500.121 require that household hazardous products bear certain cautionary statements on their labels. These statements include the following:

- A signal word (i.e., Danger, Warning, Poison, or Caution) as required by the FHSA;
- Common or chemical name of the hazardous substance;
- Name and place of business of the manufacturer, packer, distributor, or seller;
- Statements of precautionary measures to follow; instructions for special handling and storage when appropriate;
- First aid instructions when appropriate.
- In addition, all hazardous substances must bear the statement "Keep out of reach of children" according to FHSA and 16 CFR §1500.121.

According to 16 CFR §1500.3 a "hazardous substance" is any substance or mixture of substances that is toxic, corrosive, an irritant, a strong sensitizer, flammable or combustible, or generates pressure through decomposition, heat, or other means, if such substance or mixture of substances may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children. Criteria used to define terms such as "toxic" and "irritant" are provided in 16 CFR §1500.

As discussed previously, each ingredient in the Entry ice melt formulation was assessed for acute oral toxicity, acute dermal toxicity, primary eye irritation, primary dermal irritation, acute inhalation toxicity, and other relevant endpoints under FHSA, such as flammability. ToxServices utilized this chemical-specific information together with the percentage of each chemical in the product to classify product-level hazards of the Entry ice melt formulation using GHS mixture rules (UN 2017). ToxServices also assessed product-level dermal irritation testing in order to determine the need for labeling due to skin irritation/corrosion (IIVS 2018).

Ingredient- and product-level hazards relevant to the Entry ice melt formulation are summarized in Table A-1, Appendix A. Based on hazards of chemicals composing the Entry ice melt formulation, preliminary product testing results, and hazards disclosed on SDS of tradename ingredients, the Entry ice melt formulation does not fall under any hazardous substance categories as defined by Title 16 of the CFR, except for eye irritation. As the Entry ice melt formulation contains several eye irritants at low concentrations, the eye irritation potential of the product cannot be completely excluded.

Therefore, ToxServices recommends that the Entry ice melt formulation's label contain the following language as a precautionary measure:

- Caution: may cause eye irritation. Avoid contact with eyes. Flush with water should eye contact occur.
- Keep out of reach of children.
- Seek medical attention if accidentally ingested.

CONCLUSION

ToxServices performed a TRA on chemicals used in the Entry ice melt formulation to assess health risks among humans and pets. ToxServices also evaluated the Entry ice melt formulation's compliance under the FHSA and associated CPSC regulations. The TRA was based on an assessment of individual ingredients and on product-level testing for one of the hazard endpoints (dermal irritation). The results of the assessment are summarized below in Table 9.

Table 9: Entry Ice Melt TRA and FHSA Compliance Summary

Health Risk to Humans?	Health Risk to Pets?	FHSA Compliant?
No, provided contact with the eyes is avoided.	No	Yes, provided recommended warning language is included on product label.

In terms of potential health risks to humans or pets, ToxServices's assessment indicates that the Entry ice melt formulation is unlikely to harm humans or pets following foreseeable use of the Entry ice melt formulation. The MOEs calculated for humans exposed during application of the product through the dermal route, pets exposed through skin of the paws while walking on treated ground, and through licking of paws after walks are all above 100, indicating low health risks. Although the MOE for the aggregate exposure for pets through oral and dermal routes is slightly less than 100 (i.e. 94), the value was calculated based on multiple conservative assumptions, and it is unlikely that the Entry ice melt formulation poses health risks to pets.

ToxServices's assessment indicates that the Entry ice melt formulation is not classified under any of the hazard categories specified by the FHSA (Appendix B) with the exception of eye irritation; eye irritation cannot be completely ruled out without eye irritation data on the Entry ice melt formulation. Therefore, ToxServices recommends the following label warning:

- Caution: may cause eye irritation. Avoid contact with eyes. Flush with water should eye contact occur.
- Keep out of reach of children.
- Seek medical attention if accidentally ingested.

Should SynaTek perform an eye irritation study (such as an Epi-Ocular or HET-CAM assay) and the Entry ice melt formulation is predicted to be non-irritating to eyes, the above recommended label warning language regarding eye irritation may be removed.

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APPENDIX A: FORMULATION AND HAZARDS OF ENTRY ICE MELT FORMULATION

Table A-1: Formulation Hazards for Entry Ice Melt Formulation

CAS	Chemical Name	Percent in Finished Formulation	Acute Oral Toxicity	Acute Inhalation Toxicity	Acute Dermal Toxicity	Eye Irritation	Skin Irritation	Flammability
7732-18-5	Water	[REDACTED]	N/A	N/A	N/A	N/A	N/A	N/A
590-29-4	Potassium formate	[REDACTED]	5,500 mg/kg (mice) Not classified	>0.67 mg/L (4-hour)[5] Not classified	>2,000 mg/kg[6] Not classified	Not classified	Not classified	Not classified
[REDACTED]	[REDACTED]	[REDACTED]	>2,000 mg/kg (rats) Not classified	>0.83 mg/L (4-hour)[7] Not classified	>2,500 mg/kg (rabbits) Not classified	Not classified	Not classified	Not classified
[REDACTED]	[REDACTED]	[REDACTED]	>320 mg/kg (rats) Cat. 4 acute oral toxicity	No data available Not classified	>1,000 mg/kg (rabbits) Not classified	Cat. 1 (eye damage)	Cat. 1 (corrosive to skin)	Not highly flammable; not classified
[REDACTED]	[REDACTED]	[REDACTED]	>3,000 mg/kg (rats) Not classified	No data available Not classified	>2,000 mg/kg (rabbits) Not classified	Cat. 2 (serious eye irritation), but at such a low use level it is not expected to contribute to the overall irritation potential of the product (UN 2017).	Not classified	Non-flammable
Complete Entry Ice Melt Formulation			Based on individual ingredient LD_{50} values and ingredient	Based on individual ingredient LC_{50} values and lack of GHS	Based on individual ingredient LD_{50} values, does not meet criteria for	A risk of eye irritation cannot be excluded based on ingredient GHS classifications and	Based on finished product test data, does not meet criteria	Based on available data and lack of GHS classification for this endpoint,

[5] [REDACTED]
[6] [REDACTED]
[7] [REDACTED]

CAS	Chemical Name	Percent in Finished Formulation	Acute Oral Toxicity	Acute Inhalation Toxicity	Acute Dermal Toxicity	Eye Irritation	Skin Irritation	Flammability
			percentages, does not meet criteria for classification as a hazardous product under FHSA.	classification for this endpoint, does not meet criteria for classification as a hazardous product under FHSA.	classification as a hazardous product under FHSA.	available data. Appropriate label warning language related to eye irritancy is recommended.	for classification as a hazardous product under FHSA.	does not meet criteria for classification as a hazardous product under FHSA.

APPENDIX B: FHSA LABELING REQUIREMENTS

To require labelling under the FHSA, a product must first be toxic, corrosive, flammable or combustible, an irritant, a strong sensitizer, or it must generate pressure through decomposition, heat, or other means. Second, the product must have the potential to cause substantial personal injury or substantial illness during or as a result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children. The FHSA and Title 16 of the CFR require that the signal word "Danger" be placed on all substances that are extremely flammable, corrosive, or highly toxic; the signal word "Poison" be placed on all substances that are highly toxic or causic; and the signal words "Warning" or "Caution" be placed on all other hazardous substances.

Factors such as the amount of the hazardous chemical(s) as well as accessibility are key factors in determining the overall risk of a hazardous substance to human health, children's health in particular (16 CFR §1500.231) and inform the need for label warning language. The CPSC places great emphasis on evaluating hazards of the finished product that consumers will use, as opposed to hazards of individual ingredients.

The Consumer Product Safety Commission (2018) assesses products for the following hazards:

(1) A product is toxic if it can produce personal injury or illness to humans when it is inhaled, swallowed, or absorbed through the skin, while a product is highly toxic if its oral LD_{50} is < 50 mg/kg, if its dermal LD_{50} is <200 mg/kg, or if its 1-hour inhalation LC_{50} is <200 ppm (gas/vapor) or < 2 mg/L (mist/dust), as determined by animal tests specified in 16 CFR 1500.3(c)(1) and (2). In addition, a product is toxic if it can cause long-term chronic effects like cancer, birth defects, or neurotoxicity. Methodologies used to evaluate products for chronic hazards can be found at 16 CFR §1500.3(c)(2)(ii) and §1500.135 .

(2) A product is corrosive if it destroys living tissue such as skin or eyes by chemical action. Tests for assessing corrosivity are at 16 CFR §1500.41.

(3) A product is an irritant if it is not corrosive and causes an inflammatory reaction on the area of the body that it comes in contact with. Irritation can occur after immediate, prolonged, or repeated contact. Tests for skin and eye irritation are at 16 CFR §1500.41 and §1500.42, respectively.

(4) A strong sensitizer is a product that the CPSC declares by regulation to have a significant potential to cause hypersensitivity. Hypersensitivity does not happen when a person first comes in contact with the product, and only becomes evident after the person has been exposed to the product for a second time. A list of the chemicals that the Commission has classified as strong sensitizers can be found at 16 CFR §1500.13. None of these chemicals is present in the Entry ice melt formulation.

(5) The flammability of a product depends on the results of testing. The terms "extremely flammable", "flammable", and "combustible" as they apply to liquids, solids, and the contents of self-pressurized containers like aerosol cans are generally defined in 16 CFR 1500.3(c)(6) . For example, a flammable liquid can be:

a. Extremely flammable if, when tested, it has a flash point of below 20°F;

b. Flammable if it has a flash point above 20°F and below 100°F, or

c. Combustible if it has a flash point at or above 100°F, up to and including 150°F.

Please consult 16 CFR 1500.3(c)(6) for exceptions to these limits. Solid and self-pressurized products can be either extremely flammable or flammable. Please refer to 16 CFR 1500.3(c)(6(v)-(vii) for these definitions. The basic tests for determining the flammability of liquids and similar products are provided at 16 CFR §1500.43 and 43(a). The procedure for testing solid materials appears in 16 CFR §1500.44, while 16 CFR §1500.45 and 46 specify the procedures to use to test the contents of self-pressurized containers.

(6) Products that generate pressure, through decomposition, heat, or other means include aerosols, fireworks that contain explosive powder, and certain pool chemicals that, when their containers are heated by sunlight, for example, start to react and generate pressure in the containers. The FHSA does not have any tests to determine the amount of pressure that these types of products might generate.

The FHSA also requires specific labeling for products containing >10% diethylene glycol; >10% ethylene glycol; >5% benzene; >10% toluene, xylene, or petroleum distillates; >4% methanol; or >10% turpentine (16 CFR §1500.14).

REPORT APPROVALS

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This report has been finalized and authorized for release to the client.

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