SAFETY DATA SHEETS

This SDS packet was issued with item:

073241858

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

073241817 073241833

ZenithDental_Premium Dispersed Phase Alloy

Se ction 1: Identification

Product Identifier

Trade name:

Premium Dispersed Phase Alloy - Fast Set

Product Code: 61001, 61009, 61013, 61017, 61021, 61025, 61029, 61207, 61209, 61211

Relevant identified uses of the substance or mixture and uses advised against

No further relevant information available.

Application of the substance / mixture

Dental Amalgam

Details of the supplier of the safety data sheet

Manufacturer by: DMG America LLC

242 South Dean Street Englewood, NJ. 07631

Email: <u>info@dmg-america.com</u> Website: www.dmg-america.com

Emergency telephone number:

24 Hour emergency Assistance: **INFOTRAC US** + 1-800-535-5053

Information Department:

Quality Assurance / Regulatory Affairs

General SDS Assistance Information: + 1-800-662-6383

Se ction 2: Haz ard (s) Ide ntification

Classification of the substance or mixture:

GHS Label Elements

Pictogram: Health Hazard



GHS08

Danger



GHS06 Acute Toxicity



GHS05 Corrosive



Proposition 65

ZenithDental_Premium Dispersed Phase Alloy

Hazard Statement - determining components of labeling:

Danger; My Cause damage to kidneys and central nervous system through prolonger or repeated exposure. May cause harm to unborn child.

Toxic if inhaled; Avoid breathing vapors, use in a well-ventilated area.

IF INHALED; remove to fresh air and keep at rest in a position comfortable for breathing.

May be Corrosive to Metals; Keep only in original container, absorb spillage to prevent material damage, store in corrosive resistant container, with a resistant inner liner

Call a POISON CENTER or DOCTOR IF YOU FEEL UNWELL

• American Association of Poison Control Centers (800) 222-1222

Precautionary Statement

Avoid exposure - obtain special instructions before use.

Keep container in a well-ventilated place.

After contact with skin, wash immediately with plenty of soap and water.

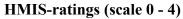
Wear suitable protective clothing, gloves and eye/face protection.

In case of accident or if you feel unwell, seek medical advice immediately (Show the label where possible).

Use appropriate container to avoid environmental contamination.

Classification system

NFPA ratings (scale 0 - 4)







Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable. **vPvB:** Not applicable.

Classification system

The classification was made according to the latest editions of international Substances list and expanded upon company literature and data.

Se ction 3: Composition/Information on Ingredients

Chemical characterization: Mixtures

Description:

Alloy powder and mercury in pre-dosed capsules. (this product consists of two parts pre-capsulated system; mercury and a metal alloy powder)

zenithDental_Premium Dispersed Phase Alloy

Hazardous Components	CAS Number	Exposure Limits	%
Mercury by Weight	7439-97-6	0.25mg/m3	50
Silver	7440-22-4	0.01 mg/m^3	53
Tin	7440-31-5	2 mg/m^3	23
Copper	7440-50-8	0.1 mg/m^3	24
Zinc	7440-66-6	Not established	5

Se ction 4: First-Aid Mea sure s

Description of first aid measures

General information:

Immediately remove any clothing soiled by the product.

After inhalation:

Supply fresh air or oxygen; call for doctor.

In case of unconsciousness place patient stably in side position for transportation

After skin contact:

Immediately wash with water and soap and rinse thoroughly.

After eye contact:

Rinse opened eye for several minutes under running water. Then consult a doctor.

After swallowing:

Rinse out mouth and then drink plenty of water.

Do not induce vomiting; immediately call for medical help.

Most important symptoms and effects, both acute and delayed:

No further relevant information available.

Indication of any immediate medical attention and special treatment needed

Antidote: DMPS

Se ction 5: Fire-Fighting Me as ure s

Extinguishing media

Suitable extinguishing agents:

The product is not flammable.

Use fire fighting measures that suit the environment.

Special hazards arising from the substance or mixture

In case of a fire very toxic mercury fumes will generate.

Fumes are heavier than air.

Advice for firefighters

Protective equipment:

Wear self-contained respiratory protective device.

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<u>Transport Canada – Guide 172</u>

Use extinguishing agent suitable for type of surrounding fire.

Do not direct water at the heated metal

Se ction 6: Accide nta l Re lea se Mea sure s

Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep unprotected persons away.

Environmental precautions

Do not allow product to reach sewage system or any water course.

Inform respective authorities in case of seepage into water course or sewage system.

Transport Canada – Guide 172: Spill or Leak

Do not touch or walk through spilled material.

Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.

Stop leak if you can do it without risk.

Prevent entry into waterways, sewers, basements or confined areas.

Do not use steel or aluminum tools or equipment.

Cover with earth, sand or other non-combustible material followed with plastic sheet to minimize spreading or contact with rain.

For mercury, use a mercury spill kit.

Mercury spill areas may be subsequently treated with calcium sulphide/calcium sulfide or with sodium thiosulphate/sodium thiosulfate wash to neutralize any residual mercury

Methods and material for containment and cleaning up

Spillages of mercury should be removed immediately, including from places which are difficult to access.

Use a plastic syringe to draw it up. Smaller quantities can be covered by sulphur

Powder and removed.

Avoid inhalation of vapors

Ensure adequate ventilation.

Dispose contaminated material as waste according to item 13.

Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

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Se ction 7: Handling and Storage

Precautions for safe handling

Only adequately trained personnel should handle this product.

Ensure good ventilation/exhaustion at the workplace.

For use in dentistry only

Information about protection against explosions and fires

Keep respiratory protective device available.

Conditions for safe storage,

Requirements to be met by storerooms and receptacles

Store only in unopened original receptacles

Keep receptacle tightly sealed.

Store receptacle in a well-ventilated area.

Se ction 8: Exposu re C ontrols/Pe rsonal Prote ction

Exposure Control

Components with limit values that require monitoring at the workplace

COMPONETS	OCCUPATIONAL EXPOSURE LIMITS:
MERCURY	OSHA PEL: TWA 0.01 mg/m ³
CAS NUMBER	CAL/OSHA PELs: 0.025 mg/m ³ TWA 0.1 mg/m ³ Ceiling
7439-97-6	NIOSH REL: 0.05 mg/m ³ TWA Skin
	NIOSH IDLH: 10 mg/m ³
	TLV: 0.025 mg/m ³ TWA
SILVER	OSHA PEL: TWA 0.01 mg/m ³
CAS NUMBER	NIOSH REL: TWA 0.01 mg/m ³
7440-22-4	NIOSH IDLH: 10 mg/m³ (as Ag)
	TLV (metal): 0.1 mg/m ³ (ACGIH 1997).
TIN	OSHA PEL*: TWA 2 mg/m ³ *Note: The PEL also applies to other inorganic tin compounds
CAS NUMBER	(as Sn) except tin oxides.
7440-31-5	NIOSH REL*: TWA 2 mg/m ³ *Note: The REL also applies to other inorganic tin
	compounds (as Sn) except tin oxides.
	NIOSH IDLH: 100 mg/m ³ (as Sn) Se e
	TLV: (as Sn) 2 mg/m ³ as TWA; (ACGIH 2004).
	MAK: IIb (not established but data is available); (DFG 2004).
COPPER	OSHA PEL*: TWA 1 mg/m ³ *Note: The PEL also applies to other copper compounds (as Cu)
CAS NUMBER	except copper fume.
7440-50-8	NIOSH REL*: TWA 1 mg/m ³ *Note: The REL also applies to other copper compounds (as Cu)
	except Copper fume.
	NIOSH IDLH: 100 mg/m ³ (as Cu)
	TLV: (Fume) 0.2 mg/m ³ ; TLV: (Dusts & mists as Cu) 1 mg/m ³ (ACGIH 2007). MAK: 0.1
	mg/m ³ (Inhalable fraction)
	Peak limitation category: II (2) Pregnancy risk group: C (DFG 2007).
ZINC	PEL; REL; TLV: Not established
CAS NUMBER	MAK: (as Zn, respirable fraction): 0.1 mg/m ³ ; peak limitation category: I (4); (as Zn, inhalable
7440-66-6	fraction): 2 mg/m ³ ; peak limitation category: I (1); pregnancy risk group: C; (DFG 2016)

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Appropriate engineering Controls:

Use only with adequate ventilation. Use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits.

Personal Protection

Recommendations for personal protective measures to prevent illness or injury from exposure to chemicals, such a personal protective equipment (PPE) needed based on hazards and potential exposure.











Safety Glasses

Dust Mask Hand Protection

Protective Clothing

Hygiene measures

Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

Eye protection

Tightly sealed goggles

Breathing equipment

Use sufficient natural or mechanical ventilation to keep vapor exposure level below PEL In case of brief exposure or low pollution use respiratory Mask, filter device. In case of intensive or longer exposure use respiratory device that is independent of Circulating air

Recommended filter device for short term use

Special gas filter Hg-P3

Protection of hands

Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation after use of gloves apply skin-cleaning agents and skin cosmetics.

Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacture.

Natural rubber, NR Nitrile rubber, NBR Butyl rubber, BR Fluorocarbon rubber (Viton)

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Penetration time of glove material

The exact break through time has to be found out by the manufacturer of Protective gloves and has to be observed.

Se ction 9: Physical and Chemical Properties

Information on basic physical and chemical properties

General Information

The physical and chemical properties in this section refer to the mercury.

Appearance Form: Fluid **Color:** Silver grey

Color: Silver grey Odor: Odorless

Odor threshold: Not determined. pH-value: Not determined. Change in condition

Melting point/Melting range: -38 °C (-36 °F) Boiling point/Boiling range: 356 °C (673 °F)

Flash point: Not applicable.

Auto igniting: Product is not self-igniting.

Danger of explosion: Product does not present an explosion hazard.

Explosion limits:

Lower: Not determined. Upper: Not determined.

Vapor pressure: Not determined.

Density at 20 °C (68 °F): 13.54 g/cm³ (112.991 lbs/gal)

Relative density: Not determined. Vapour density: Not determined. Evaporation rate: Not determined. Solubility in / Miscibility with

Water: Insoluble.

Partition coefficient (n-octanol/water): Not determined.

Viscosity:

Dynamic: Not determined. **Kinematic:** Not determined.

Other information No further relevant information available

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Se ction 10: Stabi lity and Rea ctivity

Reactivity

No further relevant information available.

Chemical stability

Stable under normal handling and storage conditions

Thermal decomposition / conditions to be avoided

No decomposition if used according to specifications.

Possibility of hazardous reactions

No dangerous reactions known.

Conditions to avoid

No further relevant information available.

Incompatible materials

No further relevant information available.

Hazardous decomposition products

None under normal conditions of storage and use

Additional information

Avoid contact with ammoniac, amines, metals and strong acids.

Se ction 11: Toxicological Information

Information on toxicological effects

Acute toxicity

Primary irritant effect

On the skin

No irritant effect.

On the eye

No irritating effect.

Sensitization

Mercury may have a sensitizing effect on the skin and lungs, or act as a nephrotoxin or neurotoxin.

Additional toxicological information

The product shows the following dangers according to internally approved calculation methods for preparation.

Harmful

Very toxic

Zenith Dental Premium Dispersed Phase Alloy

Alloy powder and mercury are pre-dosed in closed capsules, therefore the danger of exposition to mercury vapors are low.

Avoid exposure of mercury to pregnant person.

Carcinogenic categories

IARC (International Agency for Research on Cancer)

7439-97-6 mercury 3

NTP (National Toxicology Program)

None of the ingredients is listed

Se ction 12: Ecological Information

Toxicity

Aquatic toxicity

No further relevant information available.

Persistence and degradability

No further relevant information available.

Bio accumulative potential

No further relevant information available.

Mobility in soil

No further relevant information available.

Ecotoxical effects

Remark

Very toxic for fish

Additional ecological information



Signal Word: Warning – GHS09 Pictogram: Environmental

General notes

Water hazard class 3 (Self-assessment): extremely hazardous for water

Do not allow product to reach ground water, water course or sewage system,

Even in small quantities.

Danger to drinking water if even extremely small quantities leak into the ground

Also poisonous for fish and plankton in water bodies

Very toxic for aquatic organisms

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

Other adverse effects: No further relevant information available.

Revision Date: 01/31/2018 Version No. 5

Date of previous issue: 03/30/2014 Version No. 4

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Cons iderations Disposa 33 Se ction

Waste treatment methods

Recommendation

Must not be disposed of together with household garbage Must be specially treated adhering to official regulations. Do not allow product to reach sewage system.

Un-cleaned packaging

Recommendation: Disposal must be made according to official regulations.

Se ction 14: Transp ort Informat ion

	DOT	IMDG	IATA
UN-number	3506	3506	3506
Proper Shipping Name: M	Proper Shipping Name: MERCURY CONTAINED IN MANUFACTURED ARTICLES	NUFACTURED ARTICLES	
Class	8	8	8
Packing group	III	Ш	III
	8+6.1	8+6.1	8
(49CFR172.101) Environmental Hazards			
			5 L (Passenger & Cargo)
Limited quantity	5 kg		1 L (Passenger Aircraft)
			852 (Passenger & Caroo)
Packaging Instructions	P003		Y841 (Passenger Aircraft)
)			856 (Cargo aircraft only)
Special provisions	366, IB3, T7, TP1, TP28	223, 274	A3, A803
Additional Information	The marine pollutant mark is	The marine pollutant mark	The environmentally
	not required when	is not required when	hazardous substance mark
	transported on inland	transported in ≤ 5 L or ≤ 5	may appear if required by
	waterways in sizes of ≤ 5 L	kg.	other transportation
	or $\leq 5 \text{ kg.}$ or by road, rail, or	Emergency Schedules	regulation.
	inland air in non-bulk sizes	(EMS): F-A, S-B	<
		IMDG Code Segregation	>
		group:	
		7 – Heavy metals and their	
		salts (including their	
		organometallic	
		compounds)	
		11 – Mercury and mercury	
		compounds	

Special precaution for user: Transport within user's premises:

Always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code Not applicable

Date of previous issue: 03/30/2014 Version No. 4 Revision Date: 01/31/2018 Version No. 5

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Se ction 15: Re gulatory Information

Regulatory Information and Other regulations, limitations and prohibitive regulations

This product is classified as a medical device under US and Canadian regulations and by the US Food and Drug Administration and Health Canada. The SDS contains all the information required by OSHA/HCS, Canadian Controlled Product regulation and Harmonized System

US								
EPCRA - 302	RIGHT-to-KNOW, Mercury is on the following states Right to Know Lists: California, Massachusetts, Minnesota, New Jersey, Pennsylvania							
Section 313	Mercury subject to Annual release reporting requirements under SARA Title III, (40 CFR 372) Reportable Quantity 1 lbs. of mercury							
*CERCLA 103/CASRN/ CWA/RCRA/CAA 112/RQ	Hazardous Substance CASRN Statutory Code RCRA waste No. Final RQ Lbs. (Kg.)	Mercury 7439-97-6 2,3,4 U151 1 (0.454)	Silver 7440-22-4 2 - 1000 (454)	Tin 7440-31-5 - -	Copper 7440-50-8 2 - 5000 (227	Zinc 7440-66-6 2 - 0) 1000 (454)		
TRI Regulatory Matrix TRI Chemicals in other Federal Programs	Mercury * There are notification purposes Hazardous Substance/C Mercury – 7439-97-6 Silver – 7440-22-4 Tin – 7440-31-5 Copper – 7440-50-8 Zinc – 7440-66-6	s, Silver, Cop	per, Zinc - D	e Minimis 1.	0 Tin N/A (2	2017)		
OSHA	Does not consider Mercury Highly Hazardous							
OEHHA: Proposition 65	Mercury a chemical known to cause cancer, birth defects or other reproductive harm Developmental Toxicity (07-01-1990) AB-US-EPA							
CANADA								
WHMIS	Mercury classification D2A, E.							
Ingredients Disclosure List:	Mercury listed							
Domestic Substances List_Categorization DSL/NDSL_CAT	Mercury 7439-97-6, Silver 7440-22-4, Tin 7440-31-5, Copper 7440-50-8, Met the criteria under subsection 73(1) of the Canadian Environmental Protection Act, 1999 (CEPA). Zinc 7440-66-6 Did not meet the criteria under subsection 73(1) of the Canadian Environmental Protection Act, 1999 (CEPA)							

^{*}Note: The numbers under the column headed "CASRN" are the Chemical Abstracts Service Registry Numbers for each hazardous substance. The "Statutory Code" column indicates the statutory source for designating each substance as a CERCLA hazardous substance: "1" indicates that the statutory source is section 311(b)(2) of the Clean Water Act, "2" indicates that the source is section 307(a) of the Clean Water Act, "3" indicates that the source is section 112 of the Clean Air Act, and "4" indicates that the source is section 3001 of the Resource Conservation and Recovery Act (RCRA). The "RCRA Waste Number" column provides the waste identification numbers assigned to various substances by RCRA regulations. The "Pounds (kg)" column provides the reportable quantity adjustment for each hazardous substance in pounds and kilograms. Appendix A to §302.4, which lists CERCLA hazardous substances in sequential order by CASRN, provides a per-substance grouping of regulatory synonyms (i.e., names by which each hazardous substance is identified in other statutes and their implementing regulations):

 $\underline{https://www.ecfr.gov/cgi-bin/text\ idx?SID=5eb9206a60662143cb26a1b0a7263e74\&mc=true\&node=se40.28.302\\ \ 14\&rgn=div8acde+se40.28.302\\ \ 14\&rgn=div8acde+$

ZenithDental_Premium Dispersed Phase Alloy

Product related hazard information:

Hazard symbols:

GHS Label Elements

Pictogram:





Skull and





Signal Word: GHS08

GHS08 Danger

GHS06 Acute Toxicity GHS05 Corrosive

Proposition 65

Hazard-determining components of labeling

Mercury (hg). This product consists of a two-part pre-capsulated system: Mercury and a metal alloy powder. The health and physical hazards of this SDS are based Liquid elemental mercury

Risk phrases

May cause harm to the unborn child.

Also, very toxic by inhalation

Also, toxic: danger of serious damage to health by prolonged exposure through Inhalation

Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Safety phrases

Avoid exposure - obtain special instructions before use.

Keep container in a well-ventilated place.

After contact with skin, wash immediately with plenty of soap and water.

Wear suitable protective clothing, gloves and eye/face protection.

In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

Use appropriate container to avoid environmental contamination.

Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

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Section 16: Other Information

Disclaimer: The information contained herein is accurate to the best of our knowledge. My Company makes no warranty of any kind, express or implied, concerning the safe use of this material in your processor combination with other substances. This information is based on our present knowledge. Final determination of suitability of any material is the sole responsibility of the user. However, all materials may present unknown hazards and should be used with cautions. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist. this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

US.

- **(HCS) Hazard Communication Standard (2012)**This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200) https://www.osha.gov/dsg/hazcom/ https://www.osha.gov/SLTC/mercury/standards.html
- EPCRA 302: EPCRA section 302 (codified at 40 CFR Part 355), facilities with listed extremely hazardous substances (EHSs) in quantities greater than their Threshold Planning Quantities (TPQs) must report to the State Emergency Response Commission. TPQs are based on a combination of acute toxicity and ability of the substance to become airborne. The list of EHSs and their TPQs can be found at 40 CFR Part 355 Appendix A. For more information, contact the EPCRA Information Hotline: 1-800-535-0202.
- CAA 112: The Clean Air Act (CAA) section 112(b), National Emission Standards for Hazardous Air Pollutants (NESHAPS; codified at 40 CFR Part 61), lists the Hazardous Air Pollutants and includes emissions standards and monitoring requirements for plants with listed chemicals. Contaminant Levels (MCLs) for certain chemicals. The MCL is the maximum permissible level of a contaminant in public drinking water systems. MCLs are based on health factors but are also required by law to reflect the technological and economic feasibility of removing the contaminant from the water supply. Further information is available from the Safe Drinking Water Hotline: 1-800-424-4791.
- CERCLA: Under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA; 42 USC 9601 et seq.), releases of listed substances at or above their Reportable Quantities (RQs) must be reported to the National Response Center. RQs are set on the basis of aquatic toxicity, acute mammalian toxicity, ignitability, reactivity, chronic toxicity, and carcinogenicity, with possible adjustment on the basis of biodegradation, hydrolysis, and photolysis. The list of CERCLA hazardous substances and their RQs can be found at 40 CFR 302.4. For more information, contact the RCRA/Superfund Hotline: 1-800-424-9346
- NPDWR: The National Primary Drinking Water Regulations (NPDWR) under the Safe Drinking Water Act, Subparts B and G (codified at 40 CFR Part 141) list Maximum
- PPL: The Clean Water Act (CWA) regulates the discharge of pollutants into waterways by industrial sources, municipal sources, and other sources. These sources of water pollution are subject to effluent limitations based on guidelines and water quality standards. Approximately 125 pollutants make up a "Priority Pollutants List" (PPL). EPA has developed water quality criteria for all the priority pollutants
- RCRA (P/U): Under the Resource Conservation and Recovery Act (RCRA), hazardous waste is required to be managed "cradle to grave" (i.e., from the point of generation to the point of ultimate disposal). For a waste to be classified as hazardous, it can be an F, K, P, or U listed hazardous waste (40 CFR 261.30 261.33) or exhibit one of the following characteristics: ignitability, corrosivity, reactivity, or toxicity. The chemicals on the P and U list are commercial chemical products, off specification species, container residues, and spill residues. The chemicals on the P list have been identified as acute hazardous waste; those on the U list have been identified as toxic waste. For more information, contact the RCRA/Superfund Hotline: 1-800-424-9346.

https://www.epa.gov/sites/production/files/documents/94regmat.pdf

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CANADA:

 Hazardous Product Regulations (SOR/2015-17) http://laws-lois.justice.gc.ca/eng/regulations/SOR-2015-17/

• WHMIS – Workplace Hazardous Material Information System

Canada has aligned the (WHMIS) with the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). *Note:* The requirement to update safety data sheet every three years, as was the case under WHMIS 1988, no longer applies. For WHMIS 2015, the SDS must be accurate at the time of every sale or importation of the hazardous product. Suppliers have an ongoing responsibility to make sure SDSs and labels are accurate and compliant

https://www.ccohs.ca/oshanswers/chemicals/whmis ghs/sds.html

 $\frac{\text{https://www.canada.ca/en/health-canada/services/environmental-workplace-health/occupational-health-safety/workplace-hazardous-materials-information-system/whmis-2015/labelling-chemicals-workplace-chemicals/new-hazardous-products-regulations-requirements/whmis-2015-variances-between-united-states-hazard-communication-standard-2012-health-canada.html}$

Domestic Substances List_Categorization List (DSL/NDSL_CAT)
 https://pollution-waste.canada.ca/substances-search/Substance?lang=en

• Transport Canada - Emergency Transport Guide 2016

http://wwwapps.tc.gc.ca/saf-sec-sur/3/erg-gmu/erg/ergmenu.aspx http://wwwapps.tc.gc.ca/saf-sec-sur/3/erg-gmu/erg/guidepage.aspx/guide172/id1153/mnid1736