

Draft Sept 5

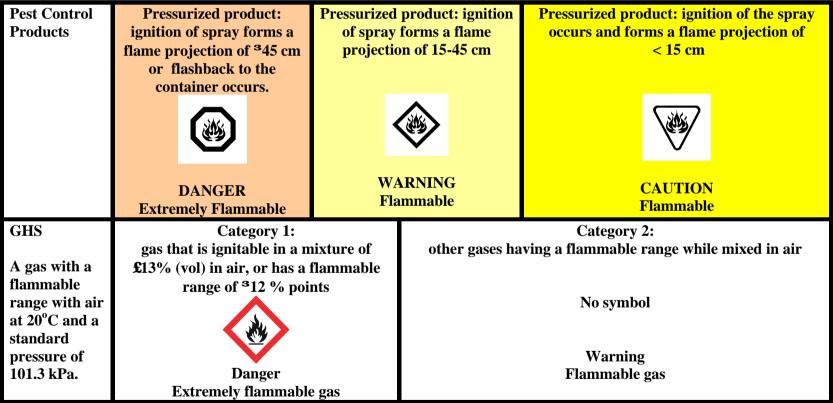
The Globally Harmonized System for the Classification and Labelling of Chemicals (The GHS)

Implementation of the GHS in Canada

Pest Control Products

TABLE 2 How hazards are identified and communicated in the GHS and for Pest Control Products

Flammable Gases



Comments: For any pressurized pest control product with a flame projection, the statement "Do not use in presence of open flame or spark" is required under the "Precautions" heading on the secondary panel of the label. All pressurized products require a statement regarding a maximum storage temperature. Products with a flame projection of >90 cm are not generally acceptable for registration, unless they are designed to be used >90 cm from the target.



File 08

Flammable Aerosols

Pest Control Products	spray forms a flame projection of ignit ³ 45 cm or flashback to the container occurs.		ressurized product: tion of spray forms a lame projection of 15-45 cm	Pressurized product: ignition of spray occurs and forms flame projection of < 15 cm	
	DANGER Extremely Flammable		WARNING Flammable	CAUTION Flammable	
GHS Aerosol dispenser: non-refillable receptacle containing a gas under pressure with a release device to eject solid or liquid particles in suspension in gas, as a foam, paste, powder, liquid or	Extremely Flammable Category 1 \geq 85% flammable components and Δ Hc ³ 30 kJ/g, or Ignition distance \geq 75 cm (spray aerosol), or in the foam test, flame height \geq 20 cm and flame duration \geq 2 s; or flame height \geq 4 cm and flame duration \geq 7 s		Category 2 Ignition distance ≥ 15 cm (spray aerosol), or $\Delta Hc \geq 20$ kJ/g (spray aerosol), or In the enclosed space ignition test, the time equivalent ≤ 300 s/m3 or deflagration density ≤ 300 g/m3 (spray), or In the foam test, flame height ≥ 4 cm and flame duration ≥ 2 s.		
gaseous state.	Danger Extremely flammable aerosol		F	Warning lammable aerosol	

Comments: For any pressurized pest control product with a flame projection, the statement "Do not use in presence of open flame or spark" is required under the "Precautions" heading on the secondary panel of the label. All pressurized products require a statement regarding a maximum storage temperature. Products with a flame projection of >90 cm are not generally acceptable for registration, unless they are designed to be used >90 cm from the target.

Gases Under Pressure

Pest Control Products	All pressurized products						
GHS Gas in a receptacle at a pressure ³ 280 kPa at 20°C or as a refrigerated liquid.	Compressed Gas	Liquified Gas	Refrigerated Liquified Gas	Dissolved Gas			
	Warning Contains gas under pressure; may explode if heated	Warning Contains gas under pressure; may explode if heated	Warning Contains refrigerated gas; may cause cryogenic burns or injury	Warning Contains gas under pressure; may explode if heated			

Comments: PMRA does not require a measure of the pressure in pressurized containers. All pressurized pest control products require a statement regarding a maximum storage temperature.

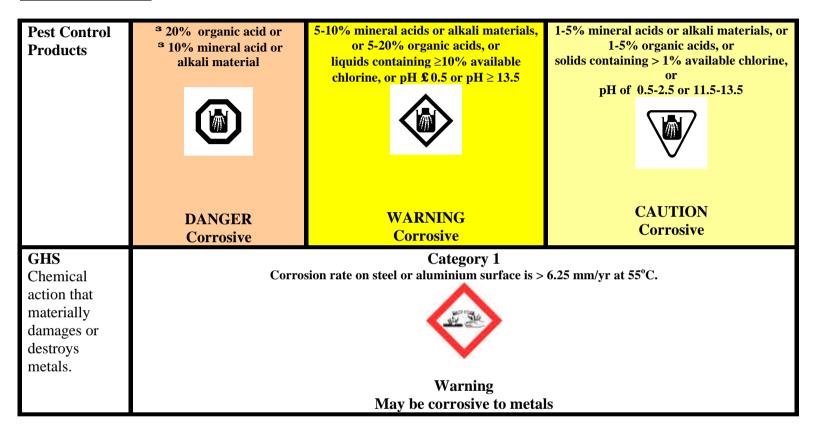
Flammable Liquids

Pest Control Products Non-pressurized					
products with flashpoint $\leq 27 ^{\circ}C$	DANGER	WARNING	CAUTION		
	Extremely Flammable	Flammable	Flammable		
Flashpoint (^O C)	-6	10	23 2	27	60

GHS	Category 1	Category 2	Category 3	Category 4
Liquid with flashpoint ≤93 °C			N	No symbol Warning
	Danger Extremely flammable liquid and vapour	Danger Highly flammable liquid and vapour	Warning Flammable liquid and vapour	Combustible liquid
Flashpoint (^O C) Initial Boiling Pt (^O		-23 <23 35	3	60 93

Comments:

Corrosive to Metals



Comments: PMRA requires information on the corrosivity of end-use products, unless a reasonable explanation of a lack of corrosivity is provided, e.g. lack of extreme pH, lack of reaction with container material.

Acute Toxicity

Regarding the labelling of acute health hazards, the following paragraphs describe (1) differences between the GHS and PMRA's current approach and (2) PMRA's proposal for labelling acute health hazards according to the GHS. Overall, the symbols for lower hazard pesticides and border shapes as well as the signal words would change. The use of a single symbol border shape (square on point) would replace the current three border shapes (octagon, square on point, inverted triangle).

Acute toxicity is one criterion used to ensure that the more hazardous products are not available in the DOMESTIC market class and that highly hazardous products are limited to the RESTRICTED market class. Market class LD_{50} cut-off values have been established for acute oral and dermal toxicity, but not for inhalation toxicity. There is, however, a provision that no special precautions or equipment (e.g. respirator) should be needed to mitigate hazard for a product destined for use in a domestic setting.

Under the GHS, mixtures are classified according to the same criteria as substances when data are available for the complete mixture and classification will always be based on that data. When data are not available for the complete mixture, bridging principles are then applied. If this approach is not viable, the GHS specifies methods to estimate the acute toxicity of a mixture based on a formula that sums the contribution of each hazardous ingredient. Pesticide petitioners usually produce test data on the active ingredient (substance) as well as the end-use products (mixture) or they bridge to other similar products in order to identify acute hazards and determine the appropriate hazard labelling.

Acute Toxicity: Oral

Pesticides		DANGER F			WARNING POISON	CAUTION POISON	No criteria
GHS	Category 1	Category 2	Category 3		Category 4	ļ	Category 5*
			Danger				No symbol
	Danger	Danger	Toxic if		Warning		Warning
	Fatal if swallowed	Fatal if swallowed	swallowed	Ha	Harmful if swallowed		May be harmful if swallowed
$LD_{50} \; (\text{mg/kg body weight})$		5 5	50 30)0	500 1	1000 20	00 5000

* GHS criteria for inclusion in Category 5 for oral, dermal and inhalation toxicity:

- indication of significant effect in humans
- any mortality at Category 4
- significant clinical signs at Category 4
- indication from other studies

Comments: Oral Toxicity LD50 Cut-off Values for current market classes: Commercial Class > 50 mg/kg; Domestic Class > 500 mg/kg.

Because the GHS cut-off value for oral toxicity for Category 4 is slightly lower than PMRA's current cut-off value for eligibility in the DOMESTIC market class (300 mg/kg body weight vs. 500 mg/kg body weight), it may be beneficial for PMRA to lower its cut-off value for eligibility in the DOMESTIC market class to that of the GHS in order to maintain correspondence with thresholds for symbol and signal word requirements under the GHS. Under the GHS, pesticides with LD₅₀ values between 301 - 500 mg/kg body weight would meet the GHS criteria to be labelled as "WARNING Harmful if swallowed" and carry the ! hazard symbol instead of "DANGER POISON" and the Skull and Crossbones symbol currently required by the PMRA. In 1998, the PMRA performed an inhouse analysis of acute oral toxicity data to gain a sense of the potential impact of this change. The assessment was based on a cut-off value of 200 mg/kg body weight (value under consideration at that time) and revealed that approximately 8% of pesticides bearing a COMMERCIAL market class designation could be considered eligible for the DOMESTIC market class by virtue of a change in cut-off value would be less. The remainder of DOMESTIC market class products which currently display the signal words (and accompanying symbols) "WARNING POISON" and "CAUTION POISON" would now require the ! symbol under the GHS as well as the signal word "WARNING". The signal words "WARNING May be harmful if swallowed" would be required for products in Category 5 (LD₅₀ 2000 - 5000 mg/kg body weight) which would represent a change from the current PMRA approach (no hazard labelling).

Acute Toxicity: Dermal

Pesticides	DANGER POISON		WARNING		CAUTION	No criteria		
GHS	Category 1	Category 2	(POISON Category 3	_	POISON Category 4	Category 5*	
							No symbol	
	Danger			\mathbf{V}		\mathbf{V}	Warning	
	Fatal in	Danger		Danger		Warning	May be harmful in contact with	
	contact with skin	Fatal in contact with skin	Toxic	in contact with skin		Harmful in contact with skin	skin	
LD ₅₀ (mg/kg body wei	5 ght)	0 200	5	00	1000		2000	5000

Comments: Acute dermal toxicity LD50 cut-off values for current market classes: Commercial Class > 100 mg/kg; Domestic Class > 1000 mg/kg.

For dermal toxicity under the GHS, Category 4 products (LD_{50} 1000 - 2000 mg/kg body weight) would be labelled with the GHS hazard symbol (!) and the signal words "WARNING Harmful in contact with skin", instead of the skull and crossbones symbol and current PMRA signal words "CAUTION POISON". The signal words "WARNING May be harmful in contact with skin" would be required for products in Category 5 (LD_{50} 2000 - 5000 mg/kg body weight) which would represent a change from the current PMRA approach (no hazard labelling).

Acute Toxicity: Inhalation - Dusts & Mists

Pesticides	DANGER POISON	WARNING POISON	CAUTION POISON		No criteria		
GHS	Category 1	Category 2	Category 3		Category 4	Category 5* No symbol	
	Danger Fatal if inhaled	Danger Fatal if inhaled	Danger Toxic if inhaled		Warning mful if inhaled	Warning May be harmful if inhaled	
LC ₅₀ (mg/L)	0	.05	0.5 1	.0 2.	0 5		

Comments: Restricted Class & Commercial Class Pesticides - no specific criteria defined; Domestic Class - there is no LC50 cut-off value, however, the inhalation hazard must be sufficiently low that they can be safety used without special precautions or equipment

The PMRA utilizes LC_{50} values to determine the appropriate hazard level as well as accompanying symbol for labelling purposes. PMRA does not require hazard labelling for pesticides with acute inhalation LC_{50} values exceeding 2 mg/l. As with other hazard classes with different GHS cut-off values than PMRA has used, this difference will represent a classification challenge for PMRA and pesticide registrants.

GHS Categories 1 and 2 correspond in terms of both LC_{50} cut-off values as well as hazard symbol with the higher levels of inhalation hazard currently identified by PMRA ($LC_{50} < 0.5 \text{ mg/l}$). Therefore, under the GHS, the skull and crossbones symbol would be retained for these highly toxic pesticides. Under the GHS, pesticides currently meeting the criteria for inclusion in Category 2 would require a change to their labels (from WARNING to DANGER). Likewise, in view of differences between cut-off values currently used by the PMRA hazard level identification with those established under the GHS, pesticides currently carrying the signal word CAUTION would fall within either GHS Category 3 or 4 and require either DANGER or WARNING , respectively, depending upon the LC_{50} value.

Many pesticides exist in a physical form which allows for the generation of dust, mists or aerosols when conducting acute inhalation toxicity testing. There are some pesticides, however, which exist in solid or liquid form but under conditions of use (e.g. fumigants) liberate volatiles or gases when in contact with water or other materials. The acute inhalation hazard classification would be based on the liberated gas which represents the active form of the pesticide. There are currently no specific classification criteria for gases and vapours, however, these pesticides would be restricted in use and the label would stipulate the requirement for the use of personal protective equipment to mitigate any inhalation hazard.

Market Classes

PMRA's current cut-off values for acute toxicity of products in the DOMESTIC market class are an oral $LD_{50} > 500$ mg/kg body weight and a dermal $LD_{50} > 1000$ mg/kg body weight. These values correspond to current thresholds for symbol and signal word requirements. As a result, DOMESTIC market class products currently bear the WARNING POISON or CAUTION POISON symbol and signal words, or no symbol or signal words at all. The acute oral and dermal toxicity of current DOMESTIC market class products correspond fairly well with GHS Categories 4 and 5. PMRA does not require hazard labelling for pesticides with acute oral or dermal LD_{50} values exceeding 2000 mg/kg body weight (corresponding to GHS Category 5).

On the basis of acute oral LD_{50} , the current COMMERCIAL market class pesticides ($LD_{50} \ge 50$ mg/kg body weight) would correspond with GHS Category 3 or higher. On the basis of acute dermal LD_{50} , these products would correspond with GHS Category 2 or higher. Under the GHS, the most toxic COMMERCIAL market class pesticides would maintain the Skull and Crossbones symbol and signal word DANGER which currently appear on these products.

Highly toxic pest control products with acute oral LD50 < 50 mg.kg or acute dermal LD50 < 100 mg/kg are currently restricted to the RESTRICTED market class. Under the GHS, the acute toxicity hazard of such products would be Category 1 or Category 2 and these

products would be labelled with the Skull and Crossbones symbol and signal word DANGER which currently appear on these products.

Skin Corrosion/Irritation

Pesticides:	DANGER SKIN IRRI	TANT	WARNING	G SKIN IRRITANT	CAUTION SKIN IRR	ITANT
Criteria using animal test data	Severely to extremely	irritating	Moderately irritating		Mildly irritating	
	for erythema/eschar and for oedema for 24, 48, and 72 hour assessments for all animals on test (usually 6)		for erythema/eschar and for oedema for 24, 48 and 72 hour assessments for all animals on test (usually 6)		Mean Draize scores of ³ 1.6 - 3.0 for erythema/eschar and for oedema for 24, 4 and 72 hour assessments for all animals on test (usually 6)	
Pesticides: Criteria using physical/chemical properties	DANGER CORROSIVE	WARNIN		CAUTION CORROSIVE	CAUTION IRRITANT	CAUTION
	Contains 10% or more mineral acids or alkali material; Contains 20% or more organic acids;	Contains 5 mineral ac alkali mat Contains 5 organic ac Liquids co ³ 10% ava chlorine; pH £ 0.5 o	cids or erials; 5-20% cids; ontaining	Contains 1-5% mineral acids or alkali materials; Contains 1-5% organic acids; Solids containing over 1% available chlorine pH between 0.5 - 2.5 or 11.5 - 13.5	Liquid products which contain ³ 4% - £ 10% available chlorine	Liquid products which contain ³ 1% - £4% available chlorine

	Category 1B	Category 1C	Category 2	Category 3
E.S.	528			(no symbol)
\sim	\sim			Warning
				Causes mild skin irritation
Danger	Danger	Danger	Warning	Mean Draize scores of ³ 1.5 - < 2.3 for
Causes severe skin burns and eye damage	Causes severe skin burns and eye damage	Causes severe skin burns and eye damage	Causes skin irritation	erythema/eschar or for oedema for 24, 48 and 72 hour assessments in at least
	8-	8-	Mean Draize scores of	2/3 animals ; gradings on 3
Corrosive in ³ 1/3 animals in £3 minutes (£1 hour observation)	Corrosive in ³ 1/3 animals in > 3 minutes - £1 hour	Corrosive in ³ 1/3 animals in >1 hour - £4 hours	³ 2.3 - < 4.0 for erythema/eschar or for oedema for 24, 48, and 72	consecutive days if reactions delayed (when not included in Category 2)
((£14 days observation)	(£14 days observation)	hour assessments in at least 2/3 animals;	
			days if reactions delayed - Persistence	
	Causes severe skin burns and eye damage Corrosive in ³ 1/3	Causes severe skin burns and eye damageCauses severe skin burns and eye damageCorrosive in 31/3 animals in £3 minutes (£1 hour observation)Corrosive in 31/3 animals in > 3 minutes - £1 hour (£14 days	Causes severe skin burns and eye damageCauses severe skin burns and eye damageCauses severe skin burns and eye damageCauses severe skin burns and eye damageCorrosive in 31/3 animals in £3 minutes (£1 hour observation)Corrosive in 31/3 animals in > 3 minutes - £1 hour (£14 daysCorrosive in 31/3 animals in > 1 hour - £4 hours (£14 days	Causes severe skin burns and eye damageCauses skin irritationCorrosive in 31/3 animals in £3 minutes (£1 hour observation)Corrosive in 31/3 minutes - £1 hour (£14 days observation)Corrosive in 31/3 animals in > 1 hour - £4 hours observation)Mean Draize scores of 32.3 - < 4.0 for erythema/eschar or for oedema for 24, 48, and 72 hour assessments in at least 2/3 animals; gradings on 3 consecutive days if reactions delayed

Current PMRA criteria are based on physical-chemical properties as well as biological response data (largely animal data). However, the criteria for both are not integrated and occasionally consultation with PMRA is required to determine appropriate hazard labelling. Signal word assignment is based on the biological response as well as the physical-chemical properties. However, the criteria for symbol selection as outlined in the Pesticide Registration Handbook take into account physical-chemical properties only. The PMRA would likely classify a pesticide as a skin corrosive if results from eye irritation testing demonstrate a corrosive response.

The PMRA and the GHS utilize the Draize scale of scoring (maximum of 8-points for skin reactions - 4 points for erythema/eschar response and 4 points for oedema response). However, the PMRA criteria are based on the average Draize scores for both erythema/eschar and oedema whereas the GHS criteria are based on the average Draize scores for either erythema/eschar or oedema. There are slight differences between the Draize score ranges used by the PMRA and those identified by the GHS, however, the classification outcome is not expected to differ to any significant extent.

With the adoption of the GHS, there would be an integration of physical-chemical properties and biological response data for selection of appropriate hazard symbol and signal word. The more irritating pesticides which, on the basis of animal Draize tests, currently require a signal word only (DANGER, WARNING or CAUTION), would now require a symbol (!) under the GHS and the words WARNING Causes mild skin irritation.

The GHS criteria to classify a chemical as Corrosive (Skin Category 1A, 1B, 1C) appear to encompass PMRA's current criteria for requiring the signal word CORROSIVE on a pesticide label, i.e. >1% mineral acids or alkalis, organic acids, solid chlorine; >10% liquid chlorine; pH <2 or > 11.5. Three current levels of corrosion hazard would compress into one GHS category. Likewise, the PMRA currently requires the corrosive symbol for liquid pesticides containing $^{3}1 - 10\%$ available chorine. Under the GHS, these pesticides would likely be classified as Corrosive (Skin Category 1). Consideration of GHS Skin Category 2 (reversible effects) may be justified, but would require supporting documentation.

Serious Eye Damage/Eye Irritation

Pesticides: Criteria using animal test data	DANGER CORROSIVE TO EYES* Severely to extremely irritating			WARNING EYE IRRITANT Moderately irritating			CAUTION EYE IRRITANT Mildly irritating	
	(including irreversibility)						windry initiating	
	Maximum average score of ³⁵⁰ - 110 for effects to cornea, iris and conjunctivae **		Maximum average score of ³ 25 - 49 for effects to cornea, iris and conjunctivae			Maximum average score of 3 15 - 24 for effects to cornea, iris and conjunctivae		
Pesticides:	DANGER	WARN	ING	CAUTION	C	AUTION	CAUTION	
Criteria using	CORROSIVE	CORRO	SIVE	CORROSIVE	IF	RRITANT		
physical/chemical properties			>					
	Contains 10% or more mineral acids or alkali material; Contains 20% or more organic acids;	Contains 5-1 mineral acids alkali materi Contains 5-2 organic acids Liquids cont 10% or more available chl pH £ 0.5 or ⁵	s or als; 0% s; aining orine;	Contains 1-5% mineral acids or alkali materials; Contains 1-5% organic acids; Solids containing over 1% available chlorine pH between 0.5 - 2.5 or 11.5 - 13.5	contain	products which a ³ 4% - £ 10% le chlorine	Liquid products which contain ³ 1% - £4% available chlorine	

GHS	Category 1	Category 2A	Category 2B
	LT BE		(No symbol)
			Warning
	Danger	Warning	Causes eye irritation
	Causes serious eye damage	Causes serious eye irritation	- same criteria as for Category 2A, however effects are fully reversible
	 in at least 1 animal, irreversible eye effects (or not expected to reverse) in 21 days, and/or mean scores (24, 48, 72 hours) in 2/3 animals consisting of corneal opacity ³³ and/or iritis ^{31.5} 	- eye effects, which fully reverse in 21 days, characterized by at least 2/3 animals with -corneal opacity ³ 1 and/or -iritis ³ 1, and/or	within 7 days
	and/or mus = 1.5	-conjunctival redness ³ 2 -conjunctival oedema (chemosis) ³ 2 calculated as mean scores of grading at 24, 48, and 72 hours	

* PMRA will consider use of DANGER EYE IRRITANT for pesticides with Maximum Average Scores >50 - 80 if the response is severe (i.e. opacity) but does demonstrate complete recovery within the study observation period

** The treated eye of each animal is scored using the standard Draize scale (cornea, iris, and conjunctival effects). These values are converted to an overall individual animal score based on a 110 point Draize rating scale. These converted animal scores are averaged for each of the 24, 48, and 72 hour observation periods. The observation period at which the average score is highest is then compared against either the Draize (1944) rating guide or Kay and Calandra rating guide (1962) to determine the appropriate level of eye irritation hazard.

Current PMRA criteria are based on physical-chemical properties as well as biological response data (largely animal data). However, the criteria for both are not integrated and occasionally consultation with PMRA is required to determine appropriate hazard labelling. Signal word assignment is based on the biological response as well as the physical-chemical properties. However, the criteria for symbol selection as outlined in the Pesticide Registration Handbook are based on physical-chemical properties only. The PMRA would classify a pesticide as an eye corrosive if results from skin irritation testing demonstrate a corrosive response. Therefore, pesticides meeting the criteria for classification as corrosive to skin on the basis of physical-chemical properties would also be considered corrosive to the eye and the label would carry the signal words DANGER CORROSIVE TO EYES.

There are slight differences between the animal test scoring approach used by the PMRA and that of the GHS, however, these differences are not anticipated to impact the classification outcome to any significant extent

The PMRA currently requires signal words to designate three levels of eye hazard: one for irreversible effects (DANGER CORROSIVE TO EYES) and two levels for reversible effects (WARNING EYE IRRITANT, CAUTION EYE IRRITANT). The GHS includes 3 comparable levels. Under the GHS, pesticides producing irreversible effects to the eye would be Category 1 (irreversible effects) and labelled with the corrosive symbol and signal words DANGER Causes severe eye damage". Pesticides which produce reversible effects would be Category 2 and, depending on the time required to reversal of effects, could be classified as Category 2A (within 21 days) or Category 2B (within 7 days). Under the GHS, pesticides currently labelled as CAUTION EYE IRRITANT would probably be in Category 2B with the signal words WARNING Causes eye irritation. No hazard symbol would be required for Category 2B.

Skin Sensitization

	No signal word
Pesticides	No hazard symbol
	POTENTIAL SKIN SENSITIZER
GHS	Category 1
	!
	Warning
	May cause an allergic skin reaction
	Evidence of sensitization - human or animal

The potential for skin sensitization is assessed by the PMRA and the hazard is communicated via the label phrase "POTENTIAL SKIN SENSITIZER". However, no hazard symbol or signal word is used to enhance the communication of this hazard. PMRA currently applies this approach to both pesticide active ingredients (substances) and formulated products (mixtures). Under the GHS, pesticides meeting the criteria for skin sensitization would require a symbol (!) as well as a signal word (WARNING) in addition to the text "May cause an allergic skin reaction".