PART 1

TOXIC PRODUCTS

Classification of Toxic Products

Data sources

33. The person responsible for a toxic product must determine the appropriate sub-category for the product from one or more of the following data sources in the following order of precedence:

(*a*) human experience data pertaining to the toxic product;

(*b*) in the case of a toxic product that contains a substance of special concern, the table to subsection 34(1);

(*c*) in the case of a toxic product that poses a risk of exposure through an oral, a dermal or an inhalation route, the LD_{50} or LC_{50} or both, as the case may be, of the product as determined in accordance with the applicable table to subsections 34(2) to (4) and the data sources and formulas set out in sections 35 to 37; or

(*d*) in the case of a toxic product that poses an aspiration hazard, the properties set out in subsection 34(5).

Sub-categories - substance of special concern

34. (1) A chemical product that contains a substance of special concern set out in column 1 of the table to this subsection in a concentration set out in column 2 must be classified in the sub-category set out in column 3.

TABLE TO SUBSECTION 34(1)

SUB-CATEGORIES - SUBSTANCE OF SPECIAL CONCERN

	Column 1	Column 2	Column 3
Item	Substance of special concern*	Concentration	Sub-category
1.	Carbon tetrachloride	any concentration	Very Toxic
2.	Diethylene glycol	5% or more	Harmful
3.	Ethyl acetate	5% or more	Harmful
4.	Ethylene glycol	(*a*) 5% or more but less than 10%	Harmful
		(*b*) 10% or more	Toxic
5.	Hydrocyanic acid or a hydrocyanate salt	any concentration	Very Toxic

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TABLE TO SUBSECTION 34(1)

SUB-CATEGORIES - SUBSTANCE OF SPECIAL CONCERN

	Column 1	Column 2	Column 3
Item	Substance of special concern*	Concentration	Sub-category
6.	Methyl alcohol	1% or more and a total quantity of 5 mL or more	Toxic
7.	Nitrobenzene	5 mg/kg or more	Very Toxic
8.	1,1,2,2-tetrachloroethane	any concentration	Very Toxic
9.	1,2-dichloroethane	(*a*) 5% or more but less than 10%	Harmful
		(*b*) 10% or more	Toxic
10.	1,1,1-trichloroethane	5% or more	Harmful

*** These substances are of special concern because standard animal tests may not reflect the actual hazard posed by these substances to humans.**

Sub-categories - oral exposure

(2) A chemical product that poses a risk to a consumer through an oral route and has an LD_{50} set out in column 1 of the table to this subsection must be classified in the sub-category set out in column 2.

TABLE TO SUBSECTION 34(2)

SUB-CATEGORIES - ORAL EXPOSURE

	Column 1	Column 2
Item	LD_{50}	Sub-category
1.	not more than 50 mg/kg	Very Toxic
2.	more than 50 mg/kg but not more than 500 mg/kg	Toxic
3.	more than 500 mg/kg but not more than 2000 mg/kg	Harmful

Sub-categories - dermal exposure

(3) A chemical product that poses a risk to a consumer through a dermal route and has an LD_{50} set out in column 1 of the table to this subsection must be classified in the sub-category set out in column 2.

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TABLE TO SUBSECTION 34(3)

SUB-CATEGORIES - DERMAL EXPOSURE

Item	Column 1 LD_{50}	Column 2 Sub-category
1.	not more than 200 mg/kg	Very Toxic
2.	more than 200 mg/kg but not more than 1000 mg/kg	Toxic
3.	more than 1000 mg/kg but not more than 2000 mg/kg	Harmful

Sub-categories - inhalation exposure

(4) A chemical product that poses a risk to a consumer through inhalation, is in the state set out in column 1 of the table to this subsection and has a 4-hour LC_{50} set out in column 2 must be classified in the sub-category set out in column 3.

TABLE TO SUBSECTION 34(4)

SUB-CATEGORIES - INHALATION EXPOSURE

Item	Column 1 State of the chemical product	Column 2 4-hour LC_{50}	Column 3 Sub-category
1.	Gas	(*a*) not more than 2500 mg/m^3	Very Toxic
		(*b*) more than 2500 mg/m^3 but not more than 5000 g/m^3	Harmful
2.	Vapour	(*a*) not more than 1500 mg/m^3	Very Toxic
		(*b*) more than 1500 mg/m^3 but not more than 2500 mg/m^3	Toxic
		(*c*) more than 2500 mg/m^3 but not more than 10 000 mg/m^3	Harmful

TABLE TO SUBSECTION 34(4)

SUB-CATEGORIES - INHALATION EXPOSURE

Item	Column 1 State of the chemical product	Column 2 4-hour LC_{50}	Column 3 Sub-category
3.	Dust, mist or fume	(*a*) not more than 0.5 mg/L	Very Toxic
		(*b*) more than 0.5 mg/L but not more than 2.5 mg/L	Toxic
		(*c*) more than 2.5 mg/L but not more than 5.0 mg/L	Harmful

Sub-category - aspiration hazard

(5) A chemical product must be classified in the sub-category "toxic" if it has a viscosity of 14 mm^2/s or less at 40°C and 10% or more of the product is composed of hazardous ingredients that pose an aspiration hazard, including, in particular, any of the following substances:

(*a*) an n-primary alcohol with a composition of at least 3 carbon atoms but not more than 13;

(*b*) an isobutyl alcohol;

(*c*) a terpene alcohol;

(*d*) a ketone with a composition of at least 3 carbon atoms but not more than 13;

(*e*) a hydrocarbon with a composition of at least 3 carbon atoms but not more than 13; or

(*f*) a substance that has been determined to be an aspiration hazard based on its viscosity, surface tension and water solubility through the application of generally accepted standards of good scientific practices.

DISCUSSION OF CCCR, 2001 SECTIONS 33 AND 34

Definitions:

The following terms are defined in section 1 of the CCCR, 2001: aspiration, chemical product, dust, fume, good scientific practices, hazardous ingredient, human experience data, LC_{50}, LD_{50}, mist, person responsible, sub-category, toxic product, vapour.

Requirements:

Sections 33 and 34 set out the steps for classifying a product into the toxic product sub-categories: very toxic, toxic and harmful. The criteria describe products that are hazardous because of the immediacy of the harmful effect following exposure and because they can cause death. The distinction between sub-categories is the quantity of the product that is required to produce a harmful or fatal effect. The classification criteria do not include effects that occur over longer-term or repeated exposures, such as cancer, reproductive effects or skin sensitization.

The order of precedence for toxic product classification is:

1. Human experience data with the chemical product;
2. The presence of a substance of special concern;
3. The LD_{50} and LC_{50} of the product; and
4. The presence of a substance that poses an aspiration hazard.

Human experience with a product is the best indicator of its potential hazard, in view of the variability in response to materials between individuals and between species. However, reliable human experience data is not available for most products and substances, especially mixtures, making it necessary to accept animal test data.

If human experience data with the product is not available, the way to classify a product is by following section 34. That is, first examine whether there is a substance of special concern (subsection 34(1)), then assess the LD_{50} and LC_{50} of the product for the oral, dermal and inhalation routes of exposure (subsections 34(2) to (4)), then assess the aspiration hazard (subsection 34(5)). Despite the classification resulting from the application of section 34, if reliable data become available demonstrating that a product is more hazardous to a person when it is used under reasonably foreseeable conditions, then such human experience takes precedence and must be used to classify that product.

Topics

Route of Exposure:

During product classification, the person responsible must consider all possible routes through which a user could be exposed: oral, dermal, inhalation and aspiration. A product may only be accessible though one route of exposure or it may be accessible through multiple routes. If a chemical product falls into more than one sub-category, the product must be classified according to the most hazardous. However, the container must display the appropriate warnings for each applicable route of exposure. For example, if a product falls within the "toxic" sub-category via the oral route as well as the "harmful" sub-category via inhalation, then the product as a whole is classified as "toxic" (that is, the more severe sub-category), but both the warnings for the oral and inhalation exposures are required (see section 4).

Limited Exposure

The CCCR, 2001 do not apply if a consumer cannot be exposed to the product or any of its hazardous ingredients during reasonably foreseeable use (see subsection 2(2)).

Pens

Pens are included in this exception, if the ink is classified in the "harmful" sub-category, and the ink cartridge has a capacity of 2 grams or less and is constructed in such a way that, under reasonably foreseeable use, the ink will only emerge from the writing tip. This exception would not apply if the ink were classified as "toxic" or "very toxic".

Spray Containers

There is no exception from classifying a toxic product by the oral or aspiration route for spray containers that dispense the chemical product only as a mist.

As little as 10 drops of a product in the toxic sub-category could cause death to a 1-year-old child (15 drops for a 3-year old), for a product at the lower end of the toxic classification (half of the time, applying the criteria for a test animal). At the lower end of the harmful sub-category, only one swallow (5 mL or 1 teaspoon) of a product by a 3-year-old child could cause death, half of the time. Furthermore, as little as 2 or 3 mL of a chemical product that poses an aspiration hazard could prove fatal, if aspirated. Hence, it is necessary to maintain precautionary labelling to minimize the risk posed by toxic chemical products packaged in spray containers.

Human Experience:

Paragraph 33(a) gives preference to classifying a product based on human experience data with the whole product as used by the consumer. Reliable human experience data includes

epidemiological data and experience on the effects of chemicals on humans, such as occupational data, information from accident databases and clinical cases with a product. Market history data collected from company toll-free lines, or complaint databases from manufacturers may be useful, however these types of data may be less reliable than actual clinical cases collected from poison control centres or emergency wards in hospitals and clinics. Deliberate testing on humans solely for hazard identification purposes is discouraged for ethical reasons.

In order to make use of market history data, the person responsible must establish a mechanism to obtain complaints or feedback directly from the users of the product. However, once a product's formula is changed, there must be market history data on the new formulation in order to classify the modified product using human experience data.

Professional judgement must be used in making an assessment of what is sufficient data in each case and taking into account animal test results. For example, a single human experience result from exposure to a product may not be sufficient to warrant using that data instead of animal data, because there may be other contributory factors for the result in that particular case.

When human experience data give valid results different from results with animal data, the human experience data take precedence. Human experience data may be used to show that the product meets or does not meet a classification criterion.

Substances of Special Concern:

The list of substances of special concern was developed as an extension of the human experience criterion. Paragraph 33(b) applies to the ingredients in the product and reflects knowledge about human experience with these substances. The substances listed in subsection 34(1) are of special concern because standard animal tests may not reflect the actual hazard posed by these substances to humans. The list of substances permits specific concerns to be identified in the regulations while maintaining parallels to the criteria. This list ensures that the product is classified accurately and that the required labelling reflects the true hazard to the consumer.

The following table provides information on the toxic effect of substances included in the list of substances of special concern:

CCCR, 2001 Sections 33 and 34 - PART 1 - TOXIC PRODUCTS
Classification of Toxic Products

Substance of Special Concern	CCCR, 2001 Classification	Toxic Effect
Carbon tetrachloride	Very Toxic oral inhalation aspiration	Carbon tetrachloride is very toxic and poses a very high inhalation hazard. It very readily forms high vapour concentra-tions at room temperature. It is a central nervous system depressant causing symptoms such as headache, nausea, dizziness, vomiting, drunkenness and uncoordination. It can also cause kidney and liver damage following short-term exposure. Carbon tetrachloride is toxic following ingestion. Ingestion of 14-20 mL or 50-150 mL could be fatal, although 1.5 mL has caused death in a few cases. Based on its viscosity and surface tension, carbon tetrachloride can be aspirated, resulting in a life-threatening accumulation of fluid in the lungs. Severe lung damage, respiratory failure, cardiac arrest and death may result.
1,2-Dichloro-ethane	Harmful (5 to 10%) Toxic (≥ 10%) oral inhalation	The acute effect from inhalation of 1,2-dichloroethane is central nervous system depression, producing symptoms such as nausea, vomiting, headache, light-headedness, weakness, stupor, disequilibrium, coma and respiratory arrest. Excess ingestion produces widespread organ damage, especially to the kidney, liver and adrenal gland, as well as gastrointestinal bleeding. Death is usually due to circulatory or respiratory collapse. Death has resulted from the ingestion of 15 mL by a 14 year-old boy. Fatalities in adults have been reported after ingesting of 30 to 70 g.
Diethylene glycol	Harmful (≥ 5%) oral	Ingestion of diethylene glycol causes central nervous system depression and damage to the liver and kidneys. This renal effect leads to anuria which may prove fatal within days. The estimated acute oral lethal dose for humans is about 1 mL/kg. However, doses reported as fatal are highly variable, ranging from 5 to 120 mL in children and 20 to 240 mL in adults.
Ethyl acetate	Harmful (≥ 5%) oral	Ingested ethyl acetate may cause nausea, vomiting, shortness of breath, headache, drowsiness, dizziness and other signs of central nervous system depression. These effects may be caused in part by ethanol which is released when ethyl acetate is broken down in the body. The estimated lethal dose varies between 0.5 g/kg and 50 g/kg. High vapour concentrations may also cause headache, nausea, dizziness, uncoordination and confusion. One fatal poisoning has been reported as a result of painting the interior of a truck with a lacquer containing 80% ethyl acetate. Congestion of the upper respiratory tract, spleen and kidney and hemorrhaging in the lung tissue were observed.

CCCR, 2001 Sections 33 and 34 - PART 1 - TOXIC PRODUCTS
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Substance of Special Concern	CCCR, 2001 Classification	Toxic Effect
Ethylene glycol	Harmful (5 to 10%) Toxic (≥ 10%) oral	Ethylene glycol has a sweet, acrid taste which is alluring to children. When ingested, it is broken down in the body to produce oxalic acid, which can cause nausea, vomiting, abdom-inal pain and weakness, as well as drunkenness, dizziness, stupor, convulsions and coma (symptoms of depression of the central nervous system). Death could result from respiratory arrest or cardiovascular collapse. The mean lethal dose appears to be about 100 mL in adults. Death has been reported from drinking as little as 30 or 60 mL, although, in rare cases, people have survived ingestion of more than 2000 mL. Due to its low vapour pressure, ethylene glycol will not normally release enough vapour at room temperature to pose an inhalation hazard.
Hydrocyanic acid or a hydrocyanate salt	Very Toxic oral dermal inhalation	Cyanide is a potent and rapidly acting chemical asphyxiant, critically affecting the brain and heart. It is rapidly lethal: the inhalation of hydrogen cyanide commonly causes death within minutes and the ingestion of cyanide salts within an hour. Hydrocyanic acid is readily absorbed from the skin and mucous membranes, but the alkali salts are usually toxic only when ingested. The average lethal dose of HCN taken by mouth is believed to lie between 60 and 90 mg. (about one teaspoon of a 2% solution of hydrocyanic acid).
Methyl alcohol	Toxic (≥ 1% and ≥ 5 mL) oral inhalation	Ingestion of methanol causes initial mild inebriation, immediate or delayed (usually 18-24 hours) gastrointestinal symptoms (nausea, abdominal pain and cramps, vomiting), shortness of breath (due to metabolic acidosis), central nervous system effects (headache, dizziness, confusion, lethargy, slurred speech), eye effects (blurred vision, blindness due to optic nerve damage), prolonged coma, and respiratory failure and death due to lethal acidosis. Ingestion of methanol may also cause nec-rosis and hemorrhaging in the brain. Blindness has reportedly followed ingestion of about 4 mL of absolute methanol whereas 6 to 150 mL may be fatal. Methanol and can very readily form extremely high vapour concentrations at room temperature. It is absorbed readily following inhalation exposure and may cause central nervous system depression (fatigue, decreased concentration, impaired memory). An occupational fatality is recorded in which a female worker was exposed for about 12 hours at high concentrations, calculated to be between 4000 and 13,000 ppm.

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Substance of Special Concern	CCCR, 2001 Classification	Toxic Effect
Nitrobenzene	Very Toxic (≥ 5 mg/kg) oral dermal inhalation	Nitrobenzene (oil of mirbane) is an oily yellow liquid with an odour similar to that of oil of bitter almonds. Although nitrobenzene is absorbed by inhalation and ingestion, skin absorption poses the greatest threat of serious intoxication. The general symptoms of nitrobenzene intoxication, however absorbed, are changes in the blood, especially methaemoglobin formation, with cyanosis, headache, shortness of breath, weakness and ultimately coma and death.
1,1,2,2-Tetra-chloroethane	Very Toxic oral dermal inhalation	1,1,2,2-Tetrachloroethane is one of the most toxic of the chlorinated aliphatic hydrocarbons. Ingestion results in symptoms of central nervous system depression such as dizziness, loss of consciousness and death. Jaundice and other symptoms of severe liver injury have also occurred. A small oral dose, about 5 mL, can cause death. Acute poisoning by absorption of 1,1,2,2-tetrachloroethane through the skin has been reported. Symptoms of dermal exposure are similar to those resulting from inhalation and ingestion. One fatality has been attributed to skin absorption. Inhalation of 1,1,2,2-tetrachloroethane vapour results in nausea, vomiting, weight loss, anemia and liver injury with a sometimes fatal outcome. Damage to the peripheral nervous system is also seen in severe exposures. Many poisoning cases have observed a loss of feeling and tingling in the toes and fingers, pain in the extremities, hand tremors, difficulty walking and muscle weakness in the hands and feet. Severe acute inhalation exposure can cause depression of the central nervous system, including loss of consciousness, pulmonary edema (excessive fluid in the lungs) and kidney damage.
1,1,1-Trichloro-ethane	Harmful (≥ 5%) oral inhalation	Acute oral lethal doses are estimated at 500 to 5000 mg/kg. 1,1,1-Trichloroethane is well absorbed by the lung and produces central nervous system depression until coma or anesthia. Dizziness and light-headedness have been reported at 450 to 900 ppm. Disturbances in equilibrium occur at 1900 ppm with marked uncoordination at 5000 ppm. Higher exposures produce unconsciousness leading to death from respiratory failure or severe cardiac arrhythmia. 1,1,1-trichloroethane is very volatile, and its vapours are five times heavier than air. As a result, concentrations directly above a liquid surface, including solvent soaked rags and spills, may be much higher than elsewhere. Although there are no case reports of aspiration, it has been induced in rats.

Classification of Mixtures

The classification criteria in subsection 34(1) assume that the other ingredients in the product are benign. However, if a product contains ingredients in addition to the substance of special concern that would make the product more hazardous, then the product must be classified into the higher sub-category (see subsection 4(3)). This means that the product will at least be classified according to subsection 34(1) and may be classified into a higher subcategory if other hazardous ingredients are present.

When other hazardous ingredients are present, apply subsections 34(2) to (5) using animal data, compositional information and physical properties, and compare the resulting classification to that in subsection 34(1). The product is then classified according to the greatest hazard. Note, however, that the container must display the required information for each route of exposure (see subsection 4(5)).

The LD_{50} and LC_{50} of the Product:

The classification criteria based on the LD_{50} and LC_{50} of the product for the oral, dermal and inhalation routes of exposure, are given in the tables to subsections 34(2) to (4). The determination of the LD_{50} and LC_{50} values for the whole chemical product can use the data sources listed in section 35, or they can be estimated from the product's ingredients using the additivity formulas in section 36.

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Minimum Amount Exemption

As per subsection 40.(1) product that are classified in the sub-category 'Toxic' must be packaged in a child-resistant container. However, if the quantity of toxic product is so low that it may not pose a hazard will it be exempt from this requirement? Yes, if the total amount present in the container or in the layer for separable mixtures is less than 1/20 of the LD_{50} for a 10 kg child. This is the limit that was used when first drafting the CCCR, 2001 and although this limit is not recognised in legislation, it still can be used when making policy decisions.

Mixtures That Separate

In the case of a mixture that separates, the product must be assigned the LD_{50} and LC_{50} of the most toxic layer. A mixture that separates is a liquid or semi-liquid that separates into two or more distinct layers if left standing undisturbed for a period of 30 days at 20˚C. (See subsections 35(3) and (4)).

Inhalation Toxicity - Gas and Vapour LC_{50}

The units for the LC_{50} criteria for gases and vapours should be mL/m^3, not mg/m^3. The toxicity limits that were developed in collaboration with all stakeholders were harmonized with *WHMIS*

and other Canadian and international systems, in order to avoid redundant toxicity evaluations. The recommended limits were expressed in the units of parts per million by volume. In the drafting of the CCCR, 2001, it was intended to express the units in clear and unambiguous terms. However, the units were inadvertently printed as mg/m^3 rather than mL/m^3. As a result, the values are no longer harmonized with other systems and the criteria numbers are not what was agreed. The CCCR, 2001 will be amended to change all references from mg/m^3 to mL/m^3 in section 11 and the table to subsection 34(4).

The difference in units is related to the molecular weight of the substance relative to the molar volume of air. This means that higher molecular weight gases and vapours, such as toluene and xylene, would be excluded from classification when they were intended to be captured, whereas those with a lower molecular weight, such as ammonia, would be inappropriately classified into a higher sub-category.

Inhalation Toxicity - Four-hour Conversion

Four-hour exposure periods are specified in subsection 34(4). Since LC_{50} determinations may be conducted over various periods of time, the formulas in section 37 may be used to extrapolate such data to four-hour exposure periods. These formulas assume a simple linear relationship between times of exposure and concentration in the animal chamber for dusts, mists and fumes, and a square-root function for gases and vapours. Exposure times of longer than 10-hours are not permitted. However, caution should be used to avoid data from exposure times of less than 1-hour because, at this extreme, the conversion may not be as reliable.

Inhalation Toxicity - Saturated Vapour Concentration

The saturated vapour concentration (SVC) is the maximum concentration of the vapour of a liquid or solid that can exist in air at a particular temperature. It is a function of the vapour pressure of the substance. The SVC is important as an indicator of how readily a lethal concentration could be reached during use or in the event of a spill. For example, a substance with a high SVC relative to the LC_{50} of a substance may readily exceed the lethal concentration and may be capable of causing death in a short time. On the other hand, a substance with an SVC of the same order of magnitude as the LC_{50} would probably not reach the lethal concentration.

The vapour toxicity criteria in the CCCR, 2001 do not include the SVC. However, professional judgement may be used to downgrade the classification to a less toxic sub-category for those products whose LC_{50} is similar to the saturated vapour concentration. (See paragraphs 46(d) and 49(c) of the *Controlled Products Regulations* as a guide for professional judgement when the SVC is of the same order of magnitude as the LC_{50}.)

Mineral Spirits

Mineral spirits are a complex mixture: a petroleum distillate, generally characterized as having a minimum flash point of 37.7˚C and a distillation range of approximately 149 to 205˚C. Mineral spirits are also known as Stoddard Solvent, white spirits or safety solvent naphtha.

Mineral spirits have a low saturation vapour concentration in relation to the acute effects of inhaling the vapour. To date, an LC_{50} has not been achieved in animal studies, as long as the following conditions are met: there is an absence of smaller carbon-chain components (C-8 and below), it contains less than 0.5% of benzene and toluene, and it contains a low proportion of 1,2,4-trimethylbenzene.

In view of this, the presence of mineral spirits in a consumer chemical product does not contribute to the inhalation toxicity of that product. That is, when calculating the LC_{50} of the product using the formula in subsection 36(1), the term for mineral spirits should be disregarded much as one would do the inhalation toxicity of water.

However, if other substances are present that do contribute to the inhalation toxicity of the product, such as 1,2,4-trimethylbenzene, then the product must be classified using the reported toxicological data for those substances.

Aspiration Hazard:

The term “aspiration” means the entry of a liquid or solid into the lungs either directly through the mouth or nose or indirectly through vomiting. Once aspirated, small amounts of certain substances can significantly injure the lung. Thus, aspiration toxicity occurs when the aspiration of a substance results in severe acute effects, such as chemical pneumonia, other pulmonary injury or death.

There are two conditions that must be met in order to classify a product as toxic by aspiration: the product must have a viscosity of 14 mm^2/s or less at 40˚C and it must be composed of at least 10% of ingredients that pose an aspiration hazard.

Four principal families of chemicals have been shown to pose aspiration toxicity: ketones, hydrocarbons (including petroleum distillates and turpentine), primary alcohols and carbon tetrachloride. There is human evidence mainly for petroleum products, turpentine, pine oil (a natural mixture of terpene alcohols and hydrocarbons) and carbon tetrachloride. Both animal and human data show that the effective oral LD_{50} of these liquids, when aspirated, is below 500 mg/kg.

Low viscosity and low surface tension favour the flow and spread, respectively, of a liquid through the lower parts of the respiratory tract. But the single most important physical property is the viscosity of the product. Water solubility and surface tension seem to be modifying factors. For example, a hydrocarbon-containing product with a viscosity below 14 mm^2/sec at 40˚C is

considered to be highly toxic by aspiration. Whereas viscous materials such as paints and glues may contain high hydrocarbon concentrations but do not represent a very great aspiration hazard, since the materials are not readily atomized and, therefore, not easily aspirated.

However, viscosity alone is not a sufficient condition for a product to pose an aspiration hazard. Water has a low viscosity (1 mm^2/s) and can produce low-viscosity solutions or emulsions of many organic compounds by dilution. Many common organic compounds have viscosities below 10 mm^2/s, but have not demonstrated aspiration toxicity.

The viscosity is expressed in kinematic units. Kinematic viscosity is the ratio of absolute viscosity to density. No test method to determine the viscosity is specified; any test method which conforms to the requirements of good scientific practices may be used. Note that one centistoke equals one mm^2/s. At 40˚C, 14 mm^2/s is equivalent to 73.4 Saybolt Seconds (SUS).

Isopropyl Alcohol

Isopropyl alcohol is not specifically named in paragraphs 34(5)(a) to (e), the list of substances that are toxic by aspiration. However, isopropyl alcohol is included in the classification criteria in paragraph 34(5)(f) because it is considered to be toxic by aspiration at 100% concentration.

Isopropanol has a viscosity of 2.3 mm^2/s and a surface tension of 21.7 dynes/cm. A paper by Gerarde and Ahlstrom ("*The Aspiration Hazard and Toxicity of a Homologous Series of Alcohols,"* Arch Environ Health, v 13, October 1966) presented the following animal test results: 6 out of 10 rats died as a result of aspiration of 100% isopropanol; 1 out of 10 rats died from this cause at 85% and at 70% concentration. There have been no documented reports of aspiration in humans from this substance.

Thus, 100% isopropanol is considered to pose a high risk for aspiration toxicity, but 85% and 70% isopropanol have a low propensity to be toxic by aspiration. Rubbing alcohol (70% isopropyl alcohol) has been used in the home for many years without indication from poison control centres that it poses an aspiration hazard. However, between 85% and 100% concentration, the aspiration hazard is unclear. Professional judgement according to good scientific practices must be used to assess products in this range.

Turpentine and Pine Oil

Turpentine is an oleoresin, a derivative of the Pinus tree species, manufactured by the steam distillation of their resins. The chief ingredient of turpentine is α-pinene, but it also contains terpenes, dipentene and sylvestrene. Turpentine is captured in the aspiration hazard criteria under paragraph 34(5)(e): "a hydrocarbon with a composition of at least 3 carbon atoms but not more than 13".

Pine oil is extracted from the same pine wood as turpentine, as the less volatile fraction. It consists mainly of α-turpineol plus turpene hydrocarbons, borneol and terpene ethers. Pine oil is considered to pose an aspiration hazard, as turpene alcohol is included in paragraph 34(5)(c), and terpene hydrocarbons in paragraph 34(5)(e).

Mixtures That Separate

In the case of a mixture that separates, it is recommended that the aspiration toxicity of each layer be assessed according to the criteria of subsection 34(5). The toxic product should be assigned the classification of the most toxic layer.

Harmonization With the Controlled Products Regulations (WHMIS):

The CCCR, 2001 classification criteria for toxic products in subsections 34(2) to (4) are harmonized with those for workplace chemicals under the requirements of *WHMIS* for acute toxicity. The "very toxic" sub-category is equivalent to *WHMIS* D1A (class D, division 1, subdivision A), and the "toxic" sub-category is equivalent to *WHMIS* D1B (class D, division 1, subdivision B). However, since children and other vulnerable people may be exposed to consumer chemical products, but not likely exposed to workplace chemicals, the CCCR, 2001 have a third sub-category for "harmful", which is not included in *WHMIS*. Note also that the *WHMIS* criteria do not classify based on the aspiration hazard (subsection 34(5)) or the substances of special concern (subsection 34(1)).

However, the CCCR, 2001 do not include criteria for chronic toxic effects that would develop over time, following a single exposure to a substance, or from the prolonged or repeated exposure to a substance. Hence there is no equivalent CCCR, 2001 classification for toxic products in class D division 2 of *WHMIS*. (Note, see section 42 regarding the harmonization of *WHMIS* D2B concerning irritants.)

MEKP (Methyl ethyl ketone peroxide) Curing Agents:

MEKP is a highly reactive, colourless liquid organic oxidizer, with a pungent burning odour. It is strongly irritating to the nose, throat and lungs and upon exposure to skin can cause defatting leading to dermatitis. Inhalation studies in the past had shown that this chemical would be classified in the sub-category "very toxic" according to the criteria set out within subsection 34(4), thus prohibiting its use in consumer chemical products. However, a toxicological review showed that the more likely hazard was not from inhalation but rather ingestion exposure. This review of more recent exposure data concluded that MEKP would more accurately be classified in the sub-category "toxic" for ingestion (LC_{50} and LD_{50} values). The substance would also be classified in the sub-category "corrosive" for ingestion and ocular exposure (based on the percentage on MEKP in the product (greater than 5%) and its ability to cause necrosis of epithelial tissue and eyes.

It should be noted that as a result of this review, additional requirements, such as child-resistant containers, would now be required in addition to the required labelling.

Determination of Toxicity

Data sources

35. (1) The person responsible for a toxic product must determine, from one or more of the following data sources in the following order of precedence, its toxicity or, in the case of a mixture that separates, the toxicity of each layer of the mixture:

(*a*) the LD_{50} or LC_{50} or both, as the case may be, of the product or of the layer as determined by the peer-reviewed results of acute toxicity tests using the product on animals, which tests were conducted in accordance with the OECD Test Guidelines for acute toxicity testing;

(*b*) if tests on animals using the product have not been conducted in accordance with the OECD Test Guidelines for acute toxicity testing, the LD_{50} or LC_{50} or both, as the case may be, of the product or of the layer as determined by

(i) peer-reviewed results of acute toxicity tests of the product or the layer, which tests were conducted on animals in accordance with

(A) a National standard or an international standard recognized by the Standards Council of Canada, or

(B) a generally accepted procedure that conformed with good scientific practices at the time the tests were conducted,

(ii) if the product is a mixture, other than a mixture that separates, section 36,

(iii) peer-reviewed results of tests of a chemical product or a substance that has similar properties to those of the product or of the layer under examination, which tests were conducted on animals in accordance with

(A) OECD Test Guidelines for acute toxicity testing,

(B) a National standard or an international standard recognized by the Standards Council of Canada, or

(C) a generally accepted procedure that conformed with good scientific practices at the time the tests were conducted, or

(iv) other current, peer-reviewed information about the product or the layer; or

(*c*) the LD_{50} or LC_{50} or both, as the case may be, of the product or of the layer as determined by the results of tests conducted with the toxic product by the person responsible in accordance with a test methodology that conforms with good scientific practices.

Differing data sources

(2) In the case of differing data sources,
(*a*) an original literature source must be used in preference to a literature source that refers to the original study; and
(*b*) a source that reports test results that conform with good scientific practices and that disclose the greatest hazard must be used.

Mixture that separates

(3) In the case of a mixture that separates, the toxic product must be assigned the LD_{50} or LC_{50} or both, as the case may be, of the most toxic layer.

Definition of "mixture that separates"

(4) In this section, "mixture that separates" means a chemical product in a liquid or semiliquid state that separates into two or more distinct layers if left standing undisturbed for a period of 30 days at 20˚C.

Additivity formulas - LD_{50} or LC_{50} of mixtures

36. (1) The LD_{50} or LC_{50} of a mixture may be determined from the LD_{50} or LC_{50} of its ingredients that are present in a concentration of 1% or more, using one of the following additivity formulas, as the case may be:

(*a*) for a solid or a liquid

$$LD_{50} \quad \frac{1}{\frac{P_a}{LD_{50a}} \quad \frac{P_b}{LD_{50b}} \quad \cdots \quad \frac{P_n}{LD_{50n}}}$$

where
LD_{50} represents the LD_{50} of the mixture,
LD_{50a} to LD_{50n} represent the LD_{50} of each ingredient that is present in a concentration of 1% or more, and
P_a to P_n represent the proportion by weight of each ingredient that is present in a concentration of 1% or more; or

(*b*) for a gas, vapour, dust, mist or fume

$$LC_{50} \quad \frac{1}{\frac{P_a}{LC_{50a}} \quad \frac{P_b}{LC_{50b}} \quad \cdots \quad \frac{P_n}{LC_{50n}}}$$

where
LC_{50} represents the LC_{50} of the mixture,
LC_{50a} to LC_{50n} represent the LC_{50} of each ingredient that is present in a concentration of 1% or more, and
P_a to P_n represent the proportion by weight of each ingredient that is present in a concentration of 1% or more.

Complex mixture

(2) For the purposes of the additivity formulas set out in subsection (1), "ingredient" includes a complex mixture.

When LD_{50} or LC_{50} of ingredient is not known but can be estimated

(3) When the LD_{50} or LC_{50} of one or more ingredients present in a chemical product in a concentration of 1% or more is not known, the person responsible may, in the additivity formulas set out in subsection (1), use an estimated LD_{50} or LC_{50} determined in accordance with good scientific practices.

When LD_{50} or LC_{50} of ingredient is not known and cannot be estimated

(4) When the LD_{50} or LC_{50} of one or more ingredients present in a chemical product is not known and cannot be estimated from information referred to in paragraph 35(1)(*b*) or (*c*), the person responsible, in the additivity formulas set out in subsection (1), must substitute for the LD_{50} or LC_{50} of the ingredient, the LD_{50} or LC_{50} of the most toxic known ingredient that is present in the product at a concentration of 1% or more.

Conversion to a 4-hour LC_{50}

37. An LC_{50} obtained during a duration of exposure of other than four hours must be converted to an LC_{50} equivalent to a duration of exposure of four hours by using one of the following formulas, as the case may be:
(*a*) for a gas or vapour

$$LC_{50\,of\,4\,hours} \quad LC_{50y} \sqrt{\frac{y}{4}}$$

where
$LC_{50\ of\ 4\ hours}$ represents the LC_{50} of the mixture for a duration of exposure of four hours,
LC_{50y} represents the LC_{50} of the mixture for a duration of exposure of y hours, and
y represents the actual duration of exposure expressed in hours and must be no greater than 10 hours; or

(*b*) for a dust, mist or fume

$$LC_{50 of\ 4\ hours} \quad LC_{50\,y} \quad \frac{y}{4}$$

where
$LC_{50\ of\ 4\ hours}$ represents the LC_{50} of the mixture for a duration of exposure of four hours,
LC_{50y} represents the LC_{50} of the mixture for a duration of exposure of y hours, and
y is the actual duration of exposure expressed in hours and must be no greater than 10 hours.

DISCUSSION OF CCCR, 2001 SECTIONS 35 TO 37

Definitions:

The following terms are defined in section 1 of the CCCR, 2001: chemical product, complex mixture, dust, fume, good scientific practices, LC_{50}, LD_{50}, mist, mixture, National Standard, OECD Test Guidelines, person responsible, toxic product, vapour.

Topics

Requirements:

Sections 35 to 37 are used in the determination of a product's LD_{50} and LC_{50} for the oral, dermal and inhalation routes of exposure (refer to paragraph 33(c) and subsections 34(2) to (4)). This classification step is performed after examining human experience data with the chemical product and after assessing the presence of substances of special concern.

Section 35 provides the order of precedence of the data required to assess the LD_{50} and LC_{50} of the product. If the product is a mixture that separates into layers, then the determination must be done on each layer and the product is classified according to the most hazardous layer. Only acute toxicity test data using the product or layer on animals are acceptable.

Precedence is given to data from an assessment of the whole product or layer by using animal test results from OECD tests for acute toxicity (paragraph 35(1)(a)).

Paragraph 35(1)(b) sets out the four steps available to assess the data determined using animal test results other than OECD Tests. Sub-paragraph (i) allows a manufacturer to use toxicity data for the product or layer from animal test results from non-OECD acute toxicity tests. Subparagraph (ii) refers to section 36, the additivity formulas that may be used for mixtures that do not separate. Sub-paragraph (iii) allows for the bridging of data from a similar product or substance using OECD tests or non-OECD tests. And, sub-paragraph (iv) would be applicable if no animal tests had been conducted but there was still information on the toxicity.

Paragraph 35(1)(c) gives a person responsible the flexibility to conduct animal tests on their product or layer, if data do not already exist according to paragraphs 35(1)(a) and (b). However, Health Canada does not encourage conducting animal tests for the purposes of classifying a product. There is enough published data on commonly used chemicals, and the precedence for using the additivity formulas in 35(1)(b)(ii) should reduce the need to conduct animal tests unnecessarily.

The term “peer-reviewed” does not mean that a study must be published in a journal or other similar scientific publication; it is more flexible. A peer-reviewed study can be external or internal to an organization, but it must be reviewed by competent and appropriate people. Health Canada’s evaluators should be able to come to the same conclusions after reviewing all of the same information as the peer-review team. If there are any discrepancies, then the data are questionable and would not be acceptable for classification purposes.

Animal Testing:

As with Section 6, section 35 does not mean that a manufacturer or importer must conduct animal tests. Rather, if toxicological data on a product’s ingredients are already available, or can be estimated using good scientific practices, then this information can be used for classification purposes. The CCCR, 2001 were designed to make the best use of existing toxicological data in order to assess a product’s potential hazard. Acute toxicity data in the form of LD_{50} and LC_{50} values have been produced for tens of thousands of chemicals and are widely available in handbooks, data banks, and manufacturers' material data safety sheets (MSDS's). This published data has been peer-reviewed, which is a requirement prior to acceptance in most scientific journals and publications. See section 6 for a list of reliable reference sources.

Differing Data Sources:

Discrepancies in reported values for the test data for some substances, especially toxicity data, may arise. The variance is in some cases due to errors rather than differences in actual test results. For example, the originally published value for the LC_{50} of mineral spirits, a common solvent and thinner, was “much greater than 1400 ppm”. This value was later reproduced in many references as being equal to 1400 ppm, resulting in a different classification of a product containing this substance. Subsection 35(2) ensures that disputes over the classification of a product may be settled by reference to a single source, subject to professional review.

Mixtures That Separate:

Components of consumer chemical products may separate out over time, especially in the case of emulsions of petroleum distillates. Estimation of the toxicity of the product as a whole in such cases may significantly misrepresent the hazard when the upper layer that separates, or supernatant layer, will be accessible as a distinct mixture or solution and may be so ingested by a child.

Subsections 35(3) and (4) address this concern by specifying a test to determine if a mixture separates into layers during the likely storage conditions in the home. The test procedure assesses if a product separates after standing for 30 days at 20˚C. Where the product separates into layers, the toxicity of each layer must be assessed and the product must be assigned the LD_{50} and LC_{50} of the most toxic layer. The term supernatant mixture was not used because it implies only the top layer of the separated mixture. If no separation occurs, then the toxicity classification is determined from the entire product.

Subparagraph 35(1)(b)(ii) specifies that the additivity formulas of section 36 apply only to mixtures that do not separate. However, if the precise composition of each layer has been ascertained, the additivity formulas can be used to estimate the LD_{50} and LC_{50} of each layer, based on its chemical composition (35(1)(b)(iii) or (iv)).

Untested Mixtures:

Most products are mixtures, formed as the result of the combination of specific ingredients in definite proportions. Since most formulations are not tested for toxicity, their toxicity must be estimated from the ingredients.

The additivity formulas of section 36 assume that the components act by similar mechanisms at the same sites, but toxicokinetic or toxicodynamic interactions are negligible. Substances with similar uses and properties, for example, various petroleum solvents, often have approximately additive toxicity. The available information indicates that the acute toxicity of mixtures of chemicals for consumer products is reasonably well predicted by the additivity formulas.

When the Toxicity of All Ingredients is Known

Subsections 36(1) and (2) are used when the LD_{50} or LC_{50} values are known for each ingredient. The cut-off concentration for including an ingredient is 1%. A complex mixture is treated as a single ingredient.

When the Toxicity of an Ingredient is Not Known

Where information about the LD_{50} or LC_{50} of an ingredient is limited or not available, subsection 36(3) allows an estimate of the value in accordance with good scientific practices. The additivity formula is then adapted to use the estimated value. Some examples are as follows:

1. The LD_{50} or LC_{50} has been estimated in an alternative test, such as the Fixed Dose Method. The LD_{50} or LC_{50} is known to exceed one of the fixed doses. The calculation can be performed as an inequality.

   For example, component A (40%) has an LD_{50} = 300 mg/kg and
   component B (60%) has an LD_{50} > 2000 mg/kg.

   $$\frac{1}{LD_{50}} = \frac{0.4}{300} + \frac{0.6}{(> 2000)}$$

   $$= 0.00133 + (< 0.0003)$$

   $$= 0.00133 \text{ to } 0.00163$$

   $$LD_{50} = 613 \text{ to } 752 \text{ mg/kg}$$

2. The LD_{50} or LC_{50} can be estimated by a comparison to similar substances. By professional judgement, it is often possible to estimate that the LD_{50} or LC_{50} exceeds a certain value. For example, if the known LC_{50}'s of several members of a family of solvents all exceed 6000 mL/m^3, then one may judge that an untested member of the family with similar properties has an LC_{50} exceeding 6000 mL/m^3. This value can be used in the formula as in the above example.

3. The LD_{50} of a substance is not known, but testing shows that serious non-lethal effects occur. By professional judgement, this dose could be substituted into the formula.

NEW▸ **Determination of p-value**

In order to properly use the additivity formula set out in s.36(a) and (b), the p-value for each component must be entered correctly into the equation. The p-value is a decimal representation of the percentage of a certain ingredient in the whole final product. For example, if a given ingredient X constituted 60% of the total product, then we would use the number Px = 0.60.

When the Toxicity of an Ingredient is Not Known and Cannot Be Estimated

When the toxicity of a component of a consumer chemical product is completely unknown and cannot be estimated, subsection 36(4) assumes that the LD_{50} or LC_{50} of that component is equal to the value for the most toxic component present in the mixture at a concentration of 1% or more. This is unlike *WHMIS*, where the whole product takes on the value of the most toxic known component present at over 1%.

Inhalation Toxicity - Four-hour Conversion:

Four-hour exposure periods are specified in subsection 34(4). Since the LC_{50} determinations may be conducted over various periods of time, the formulas in section 37 may be used to extrapolate such data to four-hour exposure periods. These formulas assume a simple linear relationship between times of exposure and concentration in the animal chamber for dusts, mists and fumes, and a square-root function for gases and vapours. Exposure times of longer than 10-hours are not permitted. However, caution should be used to avoid data from exposure times of less than 1-hour because at this extreme, the conversion may not be as reliable.

NEW▸ ## Haber's Rule - LC_{50} 4-hour Conversion:

The reason behind the square root function being present in the formula in s.37(a) and absent in the formula in 37(b) is due to the application of Haber's Rule when the CCCR, 2001 was being initially drafted. This Rule states that the application of certain mathematical operations (such as square root functions) to a set of data can make the data closer reflect what is seen in reality. In other words, the square root function is applied to gases and vapours because this make the data fit what is seen in real life, and it is removed from the formula for dusts, mists, and fumes for the same reason.

CCCR, 2001 Section 38- PART 1 - TOXIC PRODUCTS
Very Toxic Products - Prohibition

Very Toxic Products

Prohibition

38. The advertising, sale or importation of a chemical product that is classified under section 33 in the sub-category "very toxic" is prohibited.

DISCUSSION OF CCCR, 2001 SECTION 38

Definitions:

The following terms are defined in section 1 of the CCCR, 2001:
chemical product, sub-category.

Topics

Requirements:

Products classified as very toxic are too hazardous to be routinely made available to consumers who lack the specialized knowledge and training to use such products. No known consumer products currently on the market would fall into this sub-category. Various ingredients of several consumer products would be captured by the very toxic sub-category if sold in pure form. However, these ingredients are usually mixed with other less toxic ingredients, rendering the product as a whole less toxic.

Exceptions

All products classified as very toxic are prohibited from advertisement, sale or importation into Canada. There are no exceptions.

However, Health Canada will accept submissions to request an exception from prohibition. The granting of such an exception involves a regulatory amendment to the CCCR, 2001 in accordance with the Canadian Federal Regulatory Process. A submission to Health Canada to request an exception from prohibition must clearly show the following:

- no other less hazardous alternative exists and is readily available or technically feasible;
- the benefits of the product outweigh the high degree of hazard to the user; and
- any other information which supports the request to allow a very hazardous product into the hands of the general public.

Health Canada will exercise its discretionary authority regarding the request and may make its permission subject to restrictions on the packaging, labelling or conditions of sale. Once the Regulations have been amended, the exception would apply to all products meeting the amendment conditions.

CCCR, 2001 Section 39- PART 1 - TOXIC PRODUCTS Required Information

Required Information

Required information - sub-category "toxic"

39. (1) Subject to subsection (3), the container of a chemical product that is classified in the sub-category "toxic" under section 33 must display, for each type of information set out in column 1 of the table to this subsection, and for each applicable route of exposure set out in column 2, the information set out in columns 3 and 4, other than the instructions set out in italics.

TABLE TO SUBSECTION 39(1)

REQUIRED INFORMATION - SUB-CATEGORY "TOXIC"

Item	Column 1 Type of information	Column 2 Applicable route of exposure	Column 3 English information	Column 4 French information
1.	Hazard symbol	All		
2.	Signal word	All	DANGER	DANGER
3.	Primary hazard statement	All	POISON	POISON
4.	Specific hazard statement	(*a*) Oral or aspiration	CONTENTS HARMFUL	CONTENU NOCIF
		(*b*) Dermal	CONTENTS HARMFUL	CONTENU NOCIF
		(*c*) Inhalation	CONTENTS HARMFUL	CONTENU NOCIF
			or, if only the vapour or fume poses a hazard:	*or, if only the vapour or fume poses a hazard:*
			FUMES HARMFUL	ÉMANATIONS NOCIVES
5.	Negative instructions	(*a*) Oral or aspiration	Do not swallow.	Ne pas avaler.
		(*b*) Oral and contains 1% or more methyl alcohol and a total quantity of 5 mL or more	May cause blindness if swallowed.	L'ingestion peut causer la cécité.

CCCR, 2001 Section 39- PART 1 - TOXIC PRODUCTS Required Information

TABLE TO SUBSECTION 39(1)

REQUIRED INFORMATION - SUB-CATEGORY "TOXIC"

Item	Column 1 Type of information	Column 2 Applicable route of exposure	Column 3 English information	Column 4 French information
		(*c*) Dermal	**Do not get in eyes or on skin or clothing.**	**Éviter tout contact avec les yeux, la peau et les vêtements.**
		(*d*) Inhalation	**Do not breathe fumes.**	**Ne pas respirer les émanations.**
6.	Positive instructions	(*a*) All	**Keep out of reach of children.**	**Tenir hors de la portée des enfants.**
		(*b*) Oral or aspiration	**Wear** [*Insert description of the specific safety equipment relevant to the hazard, e.g., a mask.*].	**Porter** [*Insert description of the specific safety equipment relevant to the hazard, e.g., un masque.*].
		(*c*) Dermal	**Wear** [*Insert description of the specific safety equipment relevant to the hazard, e.g., rubber gloves, safety glasses.*].	**Porter** [*Insert description of the specific safety equipment relevant to the hazard, e.g., des gants de caoutchouc, des lunettes de sécurité.*].
		(*d*) Inhalation	**Use only in a well-ventilated area.**	**N'utiliser que dans un endroit bien aéré.**
			Wear [*Insert description of the specific safety equipment relevant to the hazard, e.g., a mask, a respirator.*].	**Porter** [*Insert description of the specific safety equipment relevant to the hazard, e.g., un masque, un respirateur.*].
7.	First aid statement	(*a*) All	**FIRST AID TREATMENT**	**PREMIERS SOINS**
			Contains [*name of hazardous ingredients in descending order of proportion*].	**Contient** [*name of hazardous ingredients in descending order of proportion*].

CCCR, 2001 Section 39- PART 1 - TOXIC PRODUCTS Required Information

TABLE TO SUBSECTION 39(1)

REQUIRED INFORMATION - SUB-CATEGORY "TOXIC"

Item	Column 1 Type of information	Column 2 Applicable route of exposure	Column 3 English information	Column 4 French information
			If swallowed, call a Poison Control Centre or doctor immediately.	En cas d'ingestion, appeler immédiatement un centre antipoison ou un médecin.
		(*b*) Oral or aspiration	If person is [*Insert instructions for administering first aid, e.g., for methyl alcohol: If person is alert, induce vomiting.*].	Si la personne est [*Insert instructions for administering first aid, e.g., for methyl alcohol: Si la personne est consciente, provoquer le vomissement.*].
		(*c*) Dermal	If in eyes or on skin, rinse well with water. If on clothes, remove clothes.	En cas de contact avec les yeux ou la peau, bien rincer avec de l'eau. En cas de contact avec les vêtements, enlever ceux-ci.
		(*d*) Inhalation	If breathed in, move person into fresh air.	En cas d'inhalation, transporter à l'air frais la personne exposée.

Required information - sub-category "harmful"

(2) Subject to subsection (3), the container of a chemical product that is classified in the sub-category "harmful" under section 33 must display, for each type of information set out in column 1 of the table to this subsection, and for each applicable route of exposure set out in column 2, the information set out in columns 3 and 4, other than the instructions set out in italics.

CCCR, 2001 Section 39- PART 1 - TOXIC PRODUCTS Required Information

TABLE TO SUBSECTION 39(2)

REQUIRED INFORMATION - SUB-CATEGORY "HARMFUL"

Item	Column 1 Type of information	Column 2 Applicable route of exposure	Column 3 English information	Column 4 French information
1.	Hazard symbol	All		
2.	Signal word	All	CAUTION	ATTENTION
3.	Primary hazard statement	All	POISON	POISON
4.	Specific hazard statement	(*a*) Oral or aspiration	CONTENTS MAY BE HARMFUL	LE CONTENU PEUT ÊTRE NOCIF
		(*b*) Dermal	CONTENTS MAY BE HARMFUL	LE CONTENU PEUT ÊTRE NOCIF
		(*c*) Inhalation	CONTENTS MAY BE HARMFUL *or, if only the vapour or fume poses a hazard:* FUMES MAY BE HARMFUL	LE CONTEN PEUT ÊTRE NOCIF *or, if only the vapour or fume poses a hazard:* LES ÉMANATIONS PEUVENT ÊTRE NOCIVES
5.	Negative instructions	(*a*) Oral or aspiration	Do not swallow.	Ne pas avaler.
		(*b*) Dermal	Do not get in eyes or on skin or clothing.	Éviter tout contact avec les yeux, la peau et les vêtements.
		(*c*) Inhalation	Do not breathe fumes.	Ne pas respirer les émanations.
6.	Positive instructions	(*a*) All	Keep out of reach of children.	Tenir hors de la portée des enfants.
		(*b*) Oral or aspiration	Wear [*Insert description of the specific safety equipment relevant to the hazard, e.g., a mask.*].	Porter [*Insert description of the specific safety equipment relevant to the hazard, e.g., un masque.*].

CCCR, 2001 Section 39- PART 1 - TOXIC PRODUCTS Required Information

TABLE TO SUBSECTION 39(2)

REQUIRED INFORMATION - SUB-CATEGORY "HARMFUL"

Item	Column 1 Type of information	Column 2 Applicable route of exposure	Column 3 English information	Column 4 French information
		(*c*) Dermal	**Wear** [*Insert description of the specific safety equipment relevant to the hazard, e.g., rubber gloves, safety glasses.*].	**Porter** [*Insert description of the specific safety equipment relevant to the hazard, e.g., des gants de caoutchouc, des lunettes de sécurité.*].
		(*d*) Inhalation	**Use only in a well-ventilated area.**	**N'utiliser que dans un endroit bien aéré.**
			Wear [*Insert description of the specific safety equipment relevant to the hazard, e.g., a mask, a respirator.*].	**Porter** [*Insert description of the specific safety equipment relevant to the hazard, e.g., un masque, un respirateur.*].
7.	First aid statement	(*a*) All	**FIRST AID TREATMENT**	**PREMIERS SOINS**
			Contains [*name of hazardous ingredients in descending order of proportion*].	**Contient** [*name of hazardous ingredients in descending order of proportion*].
			If swallowed, call a Poison Control Centre or doctor immediately.	**En cas d'ingestion, appeler immédiatement un centre antipoison ou un médecin.**
		(*b*) Oral or aspiration	**If person is** [*Insert instructions for administering first aid, e.g., for methyl alcohol: If person is alert, induce vomiting.*].	**Si la personne est** [*Insert instructions for administering first aid, e.g., for methyl alcohol: Si la personne est consciente, provoquer le vomissement.*].
		(*c*) Dermal	**If in eyes or on skin, rinse well with water. If on clothes, remove clothes.**	**En cas de contact avec les yeux ou la peau, bien rincer avec de l'eau. En cas de contact avec les vêtements, enlever ceux-ci.**

CCCR, 2001 Section 39- PART 1 - TOXIC PRODUCTS Required Information

TABLE TO SUBSECTION 39(2)

REQUIRED INFORMATION - SUB-CATEGORY "HARMFUL"

Item	Column 1 Type of information	Column 2 Applicable route of exposure	Column 3 English information	Column 4 French information
		(*d*) Inhalation	If breathed in, move person into fresh air.	En cas d'inhalation, transporter à l'air frais la personne exposée.

Exception - fuels

(3) Subsections (1) and (2) do not apply to a container of a fuel, such as gasoline, ethanol or propane, if the container is directly connected to an internal combustion engine, a gas turbine or an appliance that uses the fuel.

DISCUSSION OF CCCR, 2001 SECTION 39

Definitions:

The following terms are defined in section 1 of the CCCR, 2001: aspiration, chemical product, container, first aid statement, fume, fumes, hazard symbol, hazardous ingredients, sub-category, vapour.

Topics

Requirements:

The wording for the warnings was developed through a consensus process, with the active collaboration of interested stakeholders, including the medical profession and public health organizations, the chemical industry, consumers' and seniors' groups, academia, technical experts and various federal government departments. During the label development, all sectors involved agreed that the regulations should prescribe mandatory warnings for the various hazard categories and sub-categories. The label statements are generic in terms of the hazard in order to be applicable to all types of consumer chemical products which fall within a particular sub-category. This ensures a constancy in the messages seen by consumers as well as a consistent set of rules for all companies. In addition, the general nature of the statements eliminates the need for ongoing regulatory amendments, but still provides the flexibility to add more specific information that may be appropriate to the chemical product.

CCCR, 2001 Section 39- PART 1 - TOXIC PRODUCTS Required Information

All of the appropriate statements are required for all applicable routes of exposure. Statements may be combined. However, if a person under reasonably foreseeable use of the product cannot be exposed through a specific route, then it is not considered applicable, and the warnings are not required for that route of exposure.

Presentation Requirements:

See sections 17 to 32 of the CCCR, 2001 for the presentation format of the required information.

"Fumes":

The term "fumes" is used on a product label to reflect the hazards arising from vapours, gases, fumes or mists. In focus group testing among Canadian consumers, the term "fumes" was preferred, because it best conveyed in the popular, although not technical, usage, the sense of airborne material which may not be visible. No one word is technically correct for gases, fumes, mists and vapours. Since "fumes" communicates the hazard best, its use on a label leads to appropriate behaviour during the use and storage of a consumer chemical product.

Protective Equipment:

The positive instructions include a requirement to prescribe specific safety equipment relevant to the hazard, such as rubber gloves or a mask. However, the specific protective equipment must address the nature of the hazard during reasonably foreseeable use of the product.

First Aid Statement:

Only those hazardous ingredients present at least at 1% and which directly contribute to the classification of the product must be listed immediately after the words "**FIRST AID STATEMENT**" and "**PREMIERS SOINS**". The use of the words "may contain" and other phrases which leave some ambiguity as to the composition and, consequently, the health hazard of the product, is discouraged.

Instructions for administering first aid for the oral or aspiration routes of exposure are required only when appropriate to the hazard. The person responsible should consult a Poison Control Centre for the latest medical advice to get the appropriate recommendation on inducing vomiting for their product. For example, to avoid the risk of aspiration, products that pose an aspiration hazard should bear the instruction "do not induce vomiting" and "ne pas faire vomir".

New →

Methanol

The example provided in the instructions for administering first aid is no longer appropriate, in light of current treatment practices. Traditionally, vomiting was recommended in the treatment of methyl alcohol poisoning. However, current practice does not recommend inducing vomiting because methanol is absorbed so rapidly that there would be little opportunity to prevent absorption, and inducing vomiting may introduce the risk of aspirating the gastric contents. The CCCR, 2001 will be amended to correct this first aid instruction.

Wiping Cloths

Oral exposure to a chemical absorbed into a wiping cloth is not likely. For example, it is unlikely that a polish absorbed into a cloth would be ingested, as long as the mixture cannot be squeezed-out. In view of this, the statement "If swallowed, call a Poison Control Centre or doctor immediately" is not required for products in which a liquid is absorbed onto a solid, semi-solid or fibrous material, as long as the liquid cannot be released from the substrate material with any reasonably foreseeable conditions of use or manipulation.

It is recommended that written records be kept of the decisions and justifications taken in this regard, so that, if necessary, a Product Safety inspector may review the rationale for these actions.

Additional Information:

The required labelling is the minimum necessary, and is an indication of the minimum standard of care imposed on a person responsible. Manufacturers and importers can add, and are encouraged to add, information considered necessary to fully inform the public of the hazards of using their products (see subsection 15(2)). In composing these statements, use short, simple sentences. Complex conditional sentences, particularly those containing negations, should be avoided. In addition, a person will remember the important product related information better, if fewer dimensions or items are listed.

However, the person responsible is discouraged from deliberately over-stating the hazards posed by a product. If unwarranted warnings are added to products, it may lead to potentially lengthy and unnecessary or inappropriate treatment upon exposure to the product. Furthermore, such a practice minimizes the perception of risk for those products which actually need the warnings, leading to potential injuries from a lack of concern or precaution by the user.

Exception - Fuel Tanks:

Subsection 39(3) allows an exception from labelling on a permanently attached fuel tank, such as an automobile, lawn mower or home heating fuel tank. This is due to the limited exposure to the chemical product during reasonably foreseeable use of the engine or appliance.

Spray Containers:

There is no exception from the toxic product labelling requirements for spray containers (see section 33).

CCCR, 2001 Section 40- PART 1 - TOXIC PRODUCTS
Child-resistant Containers

Child-resistant Containers

Sub-category "toxic"

40. (1) Subject to subsection (2) and section 14, a chemical product that is classified under section 33 in the sub-category "toxic" must be in a child-resistant container that complies with sections 9 to 13.

Exceptions - spray container and single-drop dispenser

(2) Subsection (1) does not apply to a chemical product classified under section 33 in the sub-category "toxic" that is in

(*a*) a spray container that cannot be opened and that disperses the product as a mist; or

(*b*) a container that

(i) dispenses only one drop of the product at a time, and

(ii) displays the following primary hazard statement in the manner set out in sections 17 to 20, subsections 24(1) and (3) and sections 25 and 26:

"THIS CONTAINER IS NOT CHILD-RESISTANT. KEEP OUT OF REACH OF CHILDREN."

"CE CONTENANT N'EST PAS UN CONTENANT PROTÈGE-ENFANTS. TENIR HORS DE LA PORTÉE DES ENFANTS."

DISCUSSION OF CCCR, 2001 SECTION 40

Topics

Definitions:

The following terms are defined in section 1 of the CCCR, 2001: chemical product, container, mist, spray container, sub-category.

Requirements:

Chemical products that are classified as toxic are required to be packaged in child-resistant containers because of the likelihood of death or severe injury should a child come into contact with the product.

See sections 9 to 13 for the design and performance requirements for child-resistant containers. In general, these requirements make it difficult for a child under five years of age to open the container and obtain a toxic amount within a reasonable time. This requirement means that some children may still be able to open a container if given sufficient time to do so.

Exceptions:

Large Containers

Containers of toxic chemical products that are greater than 5L in capacity need not be child-resistant (see section 14).

Spray Containers

For toxic products, a spray container that dispenses only as a mist need not be child-resistant (40(2)(a)). It would be difficult for a child to manipulate such a container, and the risk is lessened by the toxic product labelling on the container. There is no similar exception for corrosive products or quick skin-bonding adhesives (see sections 47 and 57).

It must not be possible to open the container any other way. If a container has a detachable sprayer, for example: a re-fillable pump-spray container, the outlet between the bottle and the sprayer must be child-resistant.

The exception does not apply if the product may also be dispensed in a stream form, since the stream provides more product that is easier to ingest or aspirate.

New →

Tube Attachments

Certain spray containers, such as automotive lubricants, are packaged with a tube that is intended to be inserted into the nozzle to confine the application of the product. Without the tube, the spray is a mist and the product qualifies for the exemption of paragraph 40(2)(a). However, with the tube inserted, the product is released as a stream and, if the user leaves the tube in the nozzle, the contents are readily available to a child. In order to maintain the exception of paragraph 40(2)(a), the container must be designed so that the tube can stored when the lid is closed. In addition, the label should include instructions to remove the tube from the nozzle when storing. For example, the following instructions could be used:

> "THIS CONTAINER IS NOT CHILD-RESISTANT WHEN THE TUBE IS USED. REMOVE AND STORE TUBE IN THE HOLDER PROVIDED."
>
> "AVEC LE TUBE, LE CONTENANT N'EST PLUS UN CONTENANT PROTÈGE-ENFANTS. RETIRER LE TUBE ET LE PLACER DANS LE SUPPORT FOURNI."

Single Drop Dispensers

Paragraph 40(2)(b) allows single-drop dispensers of toxic products to not be child-resistant when the main display panel bears the primary hazard statements "THIS CONTAINER IS NOT CHILD-RESISTANT. KEEP OUT OF REACH OF CHILDREN." and "CE CONTENANT N'EST

PAS UN CONTENANT PROTÈGE-ENFANTS. TENIR HORS DE LA PORTÉE DES ENFANTS." Such metered outlet nozzles are commonly used for lighter fluids and penetrating oils, such as sewing-machine oil.

This exception does not exist for corrosive products or quick skin-bonding adhesives (see sections 47 and 57).

This exception applies to containers where the single-drop dispenser is the only outlet. It must not be possible to unscrew the nozzle or remove the insert that releases the contents in single drops.

The container must dispense only one drop of the chemical product at a time. To assess a container, invert it without agitation or squeezing, and examine the flow. In order for the exception to apply, the contents must be released in single drops under their own weight.

Since the main display panel must bear the primary hazard statement "KEEP OUT OF REACH OF CHILDREN" and "TENIR HORS DE LA PORTÉE DES ENFANTS", the requirement for this statement in the positive instructions within the border (usually on the back of the container) need not be repeated.

Limited Free Flow

This exception also applies to products from which the liquid cannot flow freely, including but not limited to: paint markers and battery terminal cleaners.

Limited Flow Orifices

Limited flow orifices are not included in this exception, since they may allow up to 2 mL of the contents to be dispensed at a time.

PART 2

CORROSIVE PRODUCTS

Classification of Corrosive Products

Data sources

41. (1) The person responsible for a corrosive product must determine the appropriate sub-category for the product from one or more of the following data sources in the following order of precedence:

(*a*) subject to subsection (2), human experience data for the corrosive product;

(*b*) the table to subsection 42(1), in the case of a corrosive product that contains a substance of special concern;

(*c*) one or more of the following sources in the following order of precedence, in the case of a corrosive product that contains one or more acids or one or more bases:

(i) the data sources set out in paragraph 6(1)(*b*), (*c*) or (*e*), or

(ii) the pH and, if applicable, the acid reserve or the alkali reserve of the corrosive product as set out in the tables to subsections 42(2) and (3), determined using the test methods set out in section 44;

(*d*) the table to subsection 42(4), in the case of a corrosive product that contains a substance, other than an acid or a base, that is capable of inducing necrosis or ulceration of epithelial tissue at the site of application determined using the data sources set out in subsection 43(1); or

(*e*) subsection 42(5), in the case of a corrosive product that contains a substance, other than an acid or a base, that is capable, when tested when using the test methods set out in subsection 43(2), of causing any of the following at the site of application, namely,

(i) an erythema or edema of the skin graded at 2 or more,

(ii) corneal damage graded at 2 or more,

(iii) iris damage graded at 1 or more, or

(iv) conjunctival swelling or redness graded at 2.5 or more.

Classification using human experience data

(2) If the human experience data for a corrosive product demonstrates that the product is capable of causing an effect described in

(*a*) paragraph (1)(*d*), the product must be classified in the sub-category "corrosive"; or

(*b*) any of subparagraphs (1)(*e*)(i) to (iv), the product must be classified in the sub-category "irritant".

CCCR, 2001 Sections 41 and 42 - PART 2 - CORROSIVE PRODUCTS
Classification of Corrosive Products

Sub-categories - substance of special concern

42. (1) A chemical product that contains one or more of the substances of special concern set out in column 1 of the table to this subsection in a concentration set out in column 2 must be classified in the sub-category set out in column 3.

TABLE TO SUBSECTION 42(1)

SUB-CATEGORIES - SUBSTANCE OF SPECIAL CONCERN

Item	Column 1 Substance of special concern	Column 2 Concentration	Column 3 Sub-category
1.	Ethyl bromoacetate	any concentration	Very Corrosive
2.	Fluoride	0.5% or more of available fluoride ions	Very Corrosive

Sub-categories - one or more acids

(2) A chemical product that contains one or more acids, is in the state set out in column 1 of the table to this subsection and has the properties set out in column 2, as determined under section 44, must be classified in the sub-category set out in column 3.

TABLE TO SUBSECTION 42(2)

SUB-CATEGORIES - ONE OR MORE ACIDS

Item	Column 1 State	Column 2 Properties	Column 3 Sub-category
1.	Liquid	(*a*) a pH of not more than 1.0	Corrosive
		(*b*) a pH of more than 1.0 but not more than 3.0, and an acid reserve of 5.0 or more	Corrosive
		(*c*) a pH of more than 1.0 but not more than 3.0, and an acid reserve of 3.0 or more but less than 5.0	Irritant
2.	Solid, paste or gel	(*a*) a pH of not more than 1.0	Corrosive
		(*b*) a pH of more than 1.0 but not more than 3.0, and an acid reserve of 10.0 or more	Corrosive
		(*c*) a pH of more than 1.0 but not more than 3.0, and an acid reserve of 5.0 or more but less than 10.0	Irritant

Sub-categories - one or more bases

(3) A chemical product that contains one or more bases, is in the state set out in column 1 of the table to this subsection and has the properties set out in column 2, as determined under section 44, must be classified in the sub-category set out in column 3.

TABLE TO SUBSECTION 42(3)

SUB-CATEGORIES - ONE OR MORE BASES

Item	Column 1 State	Column 2 Properties	Column 3 Sub-category
1.	Liquid	(*a*) a pH of 13.0 or more	Corrosive
		(*b*) a pH of less than 13.0 but not less than 11.0, and an alkali reserve of 5.0 or more	Corrosive
		(*c*) a pH of less than 13.0 but not less than 12.0, and an alkali reserve of less than 5.0	Irritant
		(*d*) a pH of less than 12.0 but not less than 11.0, and an alkali reserve of less than 5.0 but not less than 3.0	Irritant
2.	Solid, paste or gel	(*a*) a pH of 13.0 or more	Corrosive
		(*b*) a pH of less than 13.0 but not less than 11.0, and an alkali reserve of 10.0 or more	Corrosive
		(*c*) a pH of less than 13.0 but not less than 12.0, and an alkali reserve of less than 10.0	Irritant

Sub-categories - substances causing necrosis or ulceration

(4) A chemical product that contains substances described in paragraph 41(1)(*d*) that are capable of causing necrosis or ulceration, in a total concentration set out in column 1 of the table to this subsection, must be classified in the sub-category set out in column 2.

CCCR, 2001 Sections 41 and 42 - PART 2 - CORROSIVE PRODUCTS
Classification of Corrosive Products

TABLE TO SUBSECTION 42(4)

SUB-CATEGORIES - SUBSTANCES CAUSING NECROSIS OR ULCERATION

Item	Column 1 Total concentration of the substances	Column 2 Sub-category
1.	5% or more	Corrosive
2.	1% or more but less than 5%	Irritant

Sub-category - substances causing other effects

(5) A chemical product that contains substances that are capable of causing an effect described in paragraph 41(1)(*e*) in a total concentration of 5% or more must be classified in the sub-category "irritant".

DISCUSSION OF CCCR, 2001 SECTIONS 41 AND 42

Definitions:

The following terms are defined in section 1 of the CCCR, 2001:
acid reserve, alkali reserve, chemical product, corrosive product, human experience data, person responsible, sub-category.

A corrosive substance is capable of causing necrosis or ulceration of epithelial tissue. Necrosis means the death of cells or tissues, and ulceration means the development of a lesion of the skin or a mucous membrane that causes necrosis of the surrounding tissue. Epithelial tissue refers to the covering of most of the internal and external surfaces of the body and its organs, and it includes the skin as well as the throat. Hence, contact with a corrosive substance results in significant and permanent tissue destruction.

Topics

An irritant substance can induce erythema, edema, or eye irritation, but the effect is reversible. Erythema is a sign of inflammation; it is a redness of the skin caused by dilatation and congestion of the capillaries. Edema means swelling due to abnormally large amounts of fluid in the tissue spaces of the body. The terms "cornea", "iris", and "conjunctive" all refer to eye tissue.

CCCR, 2001 Sections 41 and 42 - PART 2 - CORROSIVE PRODUCTS Classification of Corrosive Products

Requirements:

Sections 41 and 42 set out the steps for classifying a product into the corrosive product sub-categories: very corrosive, corrosive and irritant. The criteria describe products that are hazardous because they can cause a chemical burn. The distinction between sub-categories is the degree of injury and whether permanent damage results.

The order of precedence for corrosive product classification is:

1. Human experience data with the chemical product;
2. The presence of a substance of special concern;
3. The presence of acids or bases;
4. The presence of a corrosive substance that can induce necrosis or ulceration; and
5. The presence of an irritant substance that can induce erythema, edema, or eye irritation.

If human experience data with the chemical product is not available, the way to determine the corrosive product classification is to follow section 42. That is, first examine whether there is a substance of special concern (subsection 42(1)), then assess the pH and acid/alkali reserve (subsections 42(2) and (3)), then assess the presence of a corrosive substance (subsection 42(4)) and finally assess the presence of an irritant substance (subsection 42(5)).

Despite the classification resulting from the application of section 42, if reliable data become available demonstrating that a product causes more harm to a person when it is used under reasonably foreseeable conditions, then such human experience takes precedence and must be used to classify that product.

Route of Exposure:

During product classification, the person responsible must consider all possible routes through which a consumer could be exposed -- oral, dermal, eye contact and inhalation. If a chemical product falls into more than one sub-category, the product must be classified according to the most hazardous. However, the container must display the appropriate warnings for each applicable route of exposure. For example, if a product falls within the "corrosive" sub-category via the oral route as well as the "irritant" sub-category via skin contact, then the product as a whole is classified as "corrosive" (that is, the more severe sub-category), but both the warnings for oral and dermal are required (see section 4).

Human Experience:

Subsection 41(2) gives the classification for a product based on human experience data. The human experience data must be for the chemical product as it is used by the consumer, not just on certain ingredients.

CCCR, 2001 Sections 41 and 42 - PART 2 - CORROSIVE PRODUCTS
Classification of Corrosive Products

Human experience with a product is the best indicator of its potential hazard. A corrosive effect results from an interaction between the corrosive substance and the site of application. The complexity and variability of living tissue means that the results of any specific test does not always accord with other tests or known exposure outcomes. Some products produce corrosive effects due to the action of strong acids or bases, while others function through more complex interactions with specific tissue types.

The ingestion of a corrosive substance may cause serious effects, such as circulatory collapse, asphyxia (due to edema of the larynx and glottis), mediastinitis (inflammation of the tissues and organs separating the two lungs), peritonitis (inflammation of the serous membrane lining the abdominopelvic walls), infection and stricture (narrowing) of the esophagus and stomach. Stricture is a complication that occurs more commonly in alkali poisoning than in acid poisoning. Strong mineral acids would be swallowed less often than caustic alkalis because the acids produce intense and immediate pain when taken into the mouth, and the spasm after the first swallow tends to prevent further ingestion.

The effect of skin contact with a corrosive substance is also more intense with alkalis than with acids. This is because, in general, acids cause coagulation of the tissue proteins which tends to protect the underlying tissues. In contrast, alkalis dissolve tissue proteins and collagen, the main supportive protein of skin, tendon, bone, cartilage and connective tissue, thereby liquefying the tissue and promoting deeper penetration by the corrosive chemical.

An irritant effect involves tissue damage from minor to severe, but short of necrosis or ulceration. Irritation may cause discomfort or may lead to tissue destruction indirectly, for example, by severe coughing on exposure to a respiratory irritant, by the scratching or rubbing of irritated tissue, or by making it easier for bacteria or other infectious agents to invade.

Classification

Subsection 41(2) gives the classification criteria for a product based on human experience data. Reliable human experience data includes epidemiological data and experience on the effects of chemicals on humans, such as occupational data, information from accident databases and clinical cases with a product. Market history data collected from company toll-free lines, or complaint databases from manufacturers may be useful, however these types of data may be less reliable than actual clinical cases collected from poison control centres or emergency wards in hospitals and clinics. Deliberate testing on humans solely for hazard identification purposes is discouraged for ethical reasons.

In order to make use of market history data, the person responsible must establish a mechanism to obtain complaints or feedback directly from the users of the product. However, once a product's formula is changed, there must be market history data on the new formulation in order to classify the modified product using human experience data.

Professional judgement must be used in making an assessment of what is sufficient data in each case and taking into account animal test results. For example, a single human experience result from exposure to a product may not be sufficient to warrant using that data instead of animal data, because there may be other contributory factors for the result in that particular case.

When human experience data give valid results different from results with animal data, the human experience data take precedence. Human experience data may be used to show that the product meets or does not meet a classification criterion.

A corrosive substance causes tissue destruction, or necrosis, from skin or eye contact or from ingestion. A test material is considered to be corrosive if there is extensive damage, such as scarring, ulceration or necrosis, which constitutes irreversible tissue destruction. In addition, corrosion occurs when the exposure of the eye to the material under the specified conditions results in significant tissue destruction (necrosis) and that the injuries persist or are expected to persist for twenty-one days or more.

With regard to the irritant criteria, *OECD No. 404* is used to determine whether there is an erythema or edema of the skin graded at 2 or more (see section 43). This test method grades skin reaction on a scale of 0 to 4, where 0 means no erythema and 4 means severe erythema (beet red) to scab formation (eschar) which prevents the grading of erythema. *OECD No. 405* evaluates corneal damage, iris damage and conjunctival swelling or redness. Corneal damage is graded from 0 to 4 (2 or more is irritant), where 0 means no ulceration or opacity, and 4 means that the cornea is opaque and the iris is not discernible through the opacity. Iris damage is graded from 0 to 2 (1 or more is irritant), where 0 means normal and 2 means that there is no reaction to light, hemorrhage, or gross destruction. Conjunctive damage is graded from 0 to 4 (2.5 or more is irritant), where 0 means that the blood vessels are normal, and 4 means that there is swelling with lids more than half closed.

Substances of Special Concern:

Paragraph 41(1)(b) includes two items: ethyl bromoacetate and fluoride. They are both classified as very corrosive.

Ethyl Bromoacetate

Ethyl bromoacetate vapours are irritant to all mucous membranes, especially the eyes, and are unbearable for more than a minute at a concentration of 8 ppm in air. When liquid ethyl bromoacetate comes into contact with the eyes, permanent damage may result. In the past, this chemical was sold to consumers as a tear gas, intended as a joke or novelty product.

Elemental Fluoride

Hydrofluoric acid is the principle source of available fluoride ions. Other sources of fluoride ions, such as sodium fluoride, sodium and ammonium bifluoride, and fluorosylicic acid, produce hydrofluoric acid in aqueous solutions. These chemicals have been used in metal cleaners, rust removers, bathtub etchants and glass etchants.

Deep and extremely painful burns can result from contact with products containing relatively low concentrations of hydrofluoric acid. Serious skin damage is the result of the fluoride ions which have a unique ability to penetrate through body tissue, including bone. In addition, substantial damage can occur prior to the appearance of physical symptoms, which leads to delays in seeking medical treatment. Unlike other acids that are neutralized quickly, fluoride ion reactions in the body can continue for several days.

Products That Contain Acids or Bases:

The classification of a product that contains acids or bases may be determined from animal tests on the chemical product according to paragraphs 6(1) (b), (c) or (e), or from the pH and acid/alkali reserve of the product using the test methods in section 44.

The classification criteria for pH and acid/alkali reserve are given in the tables to subsections 42(2) and (3). The application of the pH and acid/alkali reserve criteria of subsections 42(2) and (3) are intended to minimize the need for animal testing, and do not require animal testing for enforcement purposes. According to *OECD No. 404*, materials that have predictable corrosive potential based on structure-activity relationships and/or physicochemical properties such as strong acidity or alkalinity, for example, when the material to be applied has a pH of 2 or less or 11.5 or greater, should not be tested on animals for dermal irritation/corrosion; -- alkaline or acidic reserve should also be taken into account. Hence the criteria support the concepts of *OECD No. 404*.

Acid Reserve and Alkali Reserve

The acid reserve and alkali reserve measures the capacity of a product to maintain its pH. It is an important factor in the evaluation of the degree of damage that can occur on exposed tissue. The concept of acid reserve and alkali reserve is that any product can be titrated to a predetermined uniform pH value to obtain its equivalence in grams of sodium hydroxide (NaOH). Thus the acid reserve and alkali reserve provides a finer appraisal of the degree of product's acidity or alkalinity than pH alone. Values at both ends of the pH scale may be sufficient for identifying corrosive materials. However, as the pH moves from the highly acidic and highly alkaline extremes, the distinction between borderline corrosive and irritant substances, and between the moderate and weak irritants, becomes less obvious. This difficulty may be the result of the logarithmic basis of the pH scale, where 1 pH unit corresponds to a factor of 10 in hydrogen ion concentration. Also, the pH alone may not always

determine the total acid or alkali in a solution. The acid reserve and alkali reserve criteria thus supplement the pH criteria. This is particularly important in the low-to-moderate acid range and the moderate-to-high alkaline range.

The acid reserve and alkali reserve criteria for liquid products are more stringent than for products in the form of a solid, paste or gel. The potential for harmful effects from liquids is greater in case of ingestion, since a liquid is swallowed more readily and is more hazardous to the esophagus and stomach lining. Ingesting a solid, paste or gel tends to result in local injury to the oropharynx and upper esophagus.

Corrosive and Irritant Substances:

The classification of a product that contains substances other than acids or bases may be determined from paragraphs 41(1)(d) and (e) using the test methods in section 43. The classification criteria for these products are given subsections 42(4) and (5).

Some substances are known to have a corrosive or irritant potential unrelated to pH and acid reserve or alkali reserve. Examples of known corrosive or irritant substances that are not acids or bases are: silver salts, peroxides (organic and inorganic), halogens, isocyanates, phenols, amines, iodine and zinc chloride.

The criteria of subsections 42(4) and (5) require that the total concentration of corrosive or irritant substances be used. That is, if a product contains two corrosive substances that are not acids or bases, the total concentration of these substances is used.

Alternatives to Animal Tests

Historically, the classification of substances as corrosive to tissue has been based on the results of animal tests, primarily the Draize Test. The need to minimize or eliminate tests involving living animals has led to the development of alternative in-vitro tests which use tissue cultures or tissue substitutes. These alternative in-vitro tests also systematically correlate fundamental properties of materials with corrosive effects, eliminating the need for direct testing. The use of tissue substitutes or cultured tissue shows great promise, but has not yet sufficiently matured to serve as the basis for criteria.

CCCR, 2001 Sections 41 and 42 - PART 2 - CORROSIVE PRODUCTS
Classification of Corrosive Products

Harmonization With the WHMIS Controlled Products Regulations:

In general, the CCCR, 2001 classification criteria for corrosive products are harmonized with those for workplace chemicals under the requirements of the *Controlled Products Regulations* (*CPR*) of *WHMIS*. The "corrosive" subcategory is generally equivalent to *WHMIS* Class E - Corrosive Material. For example, CCCR, 2001 subsections 42(2) and (3) expand on the *OECD No. 404* requirement of *CPR* paragraph 65(b), with regard to acid reserve and alkali reserve. However, the *WHMIS* criteria for mixtures containing a corrosive substance, in *CPR* paragraph 65(f), is more stringent, in that it applies when the substance is present at 1% concentration, rather than at 5% (total amount of all corrosive substances) in the CCCR, 2001. Note also that the *WHMIS* Class E criteria include the corrosion of metal, which is not included in the CCCR, 2001.

The CCCR, 2001 classification criteria for skin or eye irritants in paragraph 41(1)(e) are harmonized with those for *WHMIS* in *CPR* section 60.

Test Methods

Determination - necrosis and ulceration

43. (1) The capability of a substance in a corrosive product to induce necrosis or ulceration of epithelial tissue at the site of application must be determined from an applicable data source set out in paragraphs 6(1)(*a*) to *(c*) or (*e*).

Determination - other effects

(2) The capability of a substance in a corrosive product to cause an erythema or edema of the skin, corneal or iris damage or conjunctive swelling or redness at the site of application, to the grade specified in paragraph 41(1)(*e*), must be determined from the applicable data source set out in paragraphs 6(1)(*a*) to *(c*) or (*e*), including

(*a*) the Draize Test;

(*b*) in the case of an erythema or an edema, OECD No. 404; and

(*c*) in the case of corneal or iris damage or conjunctive swelling or redness, OECD No. 405.

Determination of the pH

44. (1) The person responsible for a corrosive product must determine the pH of the product by using good scientific practices that are in accordance with a procedure similar to that described in ASTM D 1293, from

(*a*) in the case of a product in the form of a liquid, the product as it is dispensed from its container; and

(*b*) in the case of a product in the form of a solid, paste or gel, or in a form otherwise unsuitable for direct measurement of the pH, a 10% aqueous solution of the product.

Determination of acid reserve or alkali reserve

(2) The person responsible for a corrosive product must determine, where applicable, the acid reserve or the alkali reserve of the product by

(*a*) titrating, in accordance with the OECD Principles of Good Laboratory Practice,

(i) in the case of a product in the form of a liquid, a suitable aliquot of the product as it is dispensed from its container, and

(ii) in the case of a product in the form of a solid, paste or gel, or in a form otherwise unsuitable for direct measurement of the pH, a suitable aliquot of a 10% aqueous solution of the product; and

(*b*) calculating

(i) in the case of an acidic product, the amount of an alkali, expressed in grams of sodium hydroxide, that is required to bring 100 mL of the product in the form of a liquid, or 100 g of the product in the form of a solid, paste or gel, to a pH of 4.00 ± 0.05, and

(ii) in the case of a basic product, the amount of an alkali, expressed in grams of sodium hydroxide, that is neutralized when 100 mL of the product in the form of a liquid, or 100 g of the product in the form of a solid, paste or gel, is brought to a pH of 10.00 ± 0.05 by the addition of hydrochloric acid.

Unstable end point

(3) If the end point of the titration referred to in subsection (2) is unstable and exhibits drifting, the pH end point reached within 30 seconds after the last addition of titrant is to be used as the effective end point for classification purposes.

DISCUSSION OF CCCR, 2001 SECTIONS 43 AND 44

Definitions:

The following terms are defined in section 1 of the CCCR, 2001: acid reserve, alkali reserve, container, corrosive product, good scientific practices, person responsible, ASTM D 1293, Draize Test, OECD No. 404, OECD No. 45, OECD Principles of Good Laboratory Practice.

Topics

Requirements:

Sections 43 and 44 provide the test methods and data sources for assessing and classifying corrosive products.

Corrosive Effects:

Subsection 43(1) gives the data sources for determine the capability of a substance to induce tissue destruction. A corrosive substance causes tissue destruction, or necrosis, from skin or eye contact or from ingestion. A test material is considered to be corrosive if there is extensive damage, such as scarring, ulceration or necrosis, which constitutes irreversible tissue destruction. In addition, corrosion occurs when the exposure of the eye to the material under the specified conditions results in significant tissue destruction (necrosis) and that the injuries persist or are expected to persist for twenty-one days or more.

The data sources for determining the capabiity of a substance in a chemical product to induce a corrosive effect are 6(1)(a) (human experience data pertaining to the product), 6(1)(b) (existing

data from tests conducted in accordance with the *OECD Test Guidelines)*, 6(1)(c) (existing data from tests other than OECD), and 6(1)(e) (the results of tests conducted by the person responsible).

If human experience data for the whole product demonstrates that it is capable of causing necrosis or ulceration, then the product is classified as corrosive. If data on the whole product is lacking, but the product contains 5% or more of substances (in total), other than acids or bases, that are capable of causing necrosis or ulceration, then the product is classified as corrosive (see sections 41 and 42).

Irritant Effects:

Subsection 43(2) gives the data sources for determine the capability of a substance to produce an irritant effect, which are 6(1)(a) (human experience data pertaining to the product), 6(1)(b) (existing data from tests conducted in accordance with the *OECD Test Guidelines*), 6(1)(c) (existing data from tests other than OECD), and 6(1)(e) (the results of tests conducted by the person responsible), including *OECD Nos. 404*, *405* and the *Draize Test*.

The classification criteria in paragraph 41(e) are that the substance is not an acid or a base and it is capable of causing any of the following at the site of application:

(i) an erythema or edema of the skin graded at 2 or more,
(ii) corneal damage graded at 2 or more,
(iii) iris damage graded at 1 or more, or
(iv) conjunctival swelling or redness graded at 2.5 or more.

The result should be measured at any of the times specified in the test, usually 24, 48 and 72 hours after patch removal; it is not a mean score value over the test times. This harmonizes the criteria with *WHMIS* (see section 60 of the *Controlled Products Regulations*).

If human experience data for the whole product demonstrates that it is capable of causing an irritant effect, then the product is classified as irritant. If data on the whole product is lacking, but the product contains 5% or more of substances (in total), other than acids or bases, that are capable of causing an irritant effect, then the product is classified as irritant. In addition, if the product contains 1 to 5% of substances (in total), other than acids or bases, that are capable of causing a corrosive effect (necrosis or ulceration), then the product is classified as irritant (see sections 41 and 42).

Descriptive Statements:

Where irritant results have been indicated as descriptive statements rather than a grading value, the following guide has been taken from *OECD Nos. 403, 404* and from the *Draize Test* literature:

Descriptive Statement		Grade
OECD Nos. 404, 405	*DraizeTest*	
Effect: erythema and eschar formation (where erythema means "abnormal redness of the skin due to capillary congestion (as in inflammation)" and eschar means "a scab formed especially after a burn")		
no erythema		0
very slight erythema (barely perceptible)	very slight erythema (barely perceptible)	1
well defined erythema	well defined erythema	2
moderate to severe erythema	moderate to severe erythema	3
severe erythema (beet redness) to eschar formation prevents grading of erythema	severe erythema (beet redness) to eschar formation (injuries in depth)	4
Effect: edema formation (where edema means "an abnormal excess accumulation of serous fluid in connective tissue or in a serous cavity called also *dropsy*")		
no edema		0
very slight edema (barely perceptible)	very slight edema (barely perceptible)	1
slight edema (edges of area well defined by definite raising	slight edema (edges of area well defined by definite raising	2
moderate edema (raised approx. 1 mm)	moderate edema (raised approx. 1 mm)	3
severe edema (raised more than 1 mm and extending beyond area of exposure)	severe edema (raised more than 1 mm and extending beyond area of exposure)	4
Effect: corneal damage (Opacity: degree of density (area most dense taken for reading))		
no ulceration or opacity		0
scattered or diffuse area of opacity (other than slight dulling or normal lustre), details of iris clearly visible	scattered or diffuse area, details of iris clearly visible	1
easily discernible translucent area, details of iris slightly obscured	easily discernible translucent areas, details of iris slightly obscured	2
nacrous area, no details of iris visible, size of pupil barely discernible	opalescent areas, no details of iris visible, size of pupil barely discernible	3
opaque cornea, iris not discernible through the opacity	opaque, iris invisible	4

CCCR, 2001 Sections 43 and 44 - PART 2 - CORROSIVE PRODUCTS Test Methods

Descriptive Statement		Grade
OECD Nos. 404, 405	*DraizeTest*	
Effect: iris damage		
normal		0
markedly deepened rugae, congestion, swelling, moderate circumcorneal hyperaemia, or injection, any of these or combination of any thereof, iris still reacting to light (sluggish reaction is positive)	folds above normal, congestion, swelling, circumcorneal injection (any one or all of these or combination of any thereof, iris still reacting to light, sluggish reaction is positive)	1
no reaction to light, haemorrhage, gross destruction (any of these)	no reaction to light, haemorrhage; gross destruction (any of these)	2
Effect: conjunctival damage (redness (refers to palpebral and bulbar conjunctivae, cornea and iris)		
blood vessels normal		0
some blood vessels definitely hyperaemic (injected)	vessels definitely injected above normal	1
diffuse, crimson colour, individual vessels not easily discernible	more diffuse, deeper crimson red, individual vessels not easily discernible	2
diffuse beefy red	diffuse beefy red	3
Effect: conjunctival damage (chemosis: lids and/or nictitating membranes)		
no swelling		0
any swelling above normal (includes nictitating membranes)	any swelling above normal (includes nictitating membranes)	1
obvious swelling with partial eversion of lids	obvious swelling with partial eversion of the lids	2
swelling with lids about half closed	swelling with lids about half closed	3
swelling with lids more than half closed	swelling with lids about half closed to completely closed	4

PH Test Method:

Although ASTM D1293 (*Standard Test Methods for pH of Water*) has been specified, subsection 44(1) allows other similar test methods to be used.

Acid Reserve and Alkali Reserve:

The acid reserve is required for products with a pH of 1 to 3; the alkali reserve for products with a pH of 11 to 13. Products with a pH at the extremes (that is, a pH of 1.0 or less or of 13.0 or more) are classified as corrosive regardless of the acid reserve or alkali reserve.

The acid reserve and alkali reserve of a product is derived directly from a titration. The results of titration of any product are expressed in terms of the equivalent amount of sodium hydroxide used or neutralized to bring the pH of a set amount of product to the end point. The set amount of product is 100 mL for liquids and 100 g for solids, pastes or gels. During the test, it is not necessary to use 100 mL or 100 g of the product, but the results must be reported in terms of these amounts.

The testing of products in the form of a solid, paste or gel is performed on a 10% w/w aqueous solution of the product. The weight of product is used rather than the volume, to avoid introducing uncertainty due to the variability of the bulk density of a solid product, for example, from compaction or settling of a powder during shipment or storage. However, the result must be expressed in terms of 100 g of the product.

The titration end point is set at a pH of 4.0 for an acid. When titrating an acid, the result is expressed as the quantity, in grams, of sodium hydroxide that is required to bring the pH up to 4.0.

For a base, the titration end point is set at a pH of 10.0. When titrating an alkali, the result is expressed as the equivalent quantity of sodium hydroxide that is neutralized to bring the pH down to 10.0. The alkali reserve is not the quantity of acid used in the titration -- it is based on the amount of sodium hydroxide that is neutralized and is expressed as grams of sodium hydroxide.

Subsection 44(3) sets out a time period of 30 seconds to record the result, so that the tester is not waiting an extensively long period for stability to occur.

Calculation

1. Liquid products:
   (Grams of soduim hydroxide per 100 mL of liquid product)

$$\left[\frac{g\ NaOH}{100\ mL}\right] = \frac{(N_{A\,or\,B})(V_{A\,or\,B}) \times 100}{V_S} \times \frac{40\ g}{1000\ mL}$$

   Where: $N_{A\ or\ B}$ = Normality of HCl or NaOH
   $V_{A\ or\ B}$ = Volume of HCl or NaOH (mL)
   V_s = Volume of sample (mL)

2. Solids, pastes or gels:
   (Grams of sodium hydroxide per 100 grams of product (solid, paste or gel))

$$\left[\frac{g\ NaOH}{100\ g}\right] = \frac{(N_{A\,or\,B})(V_{A\,or\,B})\ Wt_w \times 100}{V_S \times Wt_s} \times \frac{40\ g}{1000\ mL}$$

   Where: $N_{A\ or\ B}$ = Normality of HCl or NaOH
   $V_{A\ or\ B}$ = Volume of HCl or NaOH (mL)
   V_s = Volume of sample (mL)
   Wt_s = Weight of sample (g)
   Wt_w = Weight of distilled water

CCCR, 2001 Section 45 - PART 2 - CORROSIVE PRODUCTS
Very Corrosive Products

. *Very Corrosive Products*

Prohibition and exception

45. The advertising, sale or importation of a corrosive product that is classified in the sub-category "very corrosive" under section 41 is prohibited unless it is set out in column 1 of the table to this section and meets the conditions set out in column 2.

TABLE TO SUBSECTION 45

CONDITIONS FOR ADVERTISING, SELLING OR IMPORTING VERY CORROSIVE PRODUCTS

	Column 1	Column 2
Item	**Chemical product**	**Conditions**
1.	**A product that contains a concentration of 0.5% or more of available fluoride ions**	**Product is in the form of a paste or a gel, is used for etching glass and its container** **(*a*) displays the information set out in the table to subsection 46(1); and** **(*b*) is child-resistant as required by section 47.**

DISCUSSION OF CCCR, 2001 SECTION 45

Topics

Definitions:

The following terms are defined in section 1 of the CCCR, 2001: chemical product, container, corrosive product, sub-category.

Requirements:

Products classified as very corrosive are too hazardous to be routinely made available to consumers who lack the specialized knowledge and training to use such products.

Ethyl Bromoacetate

In the past, ethyl bromoacetate was sold as a joke product: a tear gas, known as "Ondes Lacrymogènes". The product was packaged in a vial that, when broken, released the liquid which immediately vaporized to produce tears. The problem was resolved by the removal of the product from the market and the prohibition of ethyl bromoacetate in 1974. (See section 42 for a description of the health effects of ethyl bromoacetate.)

Glass Etchants

(See section 42 for a description of the health effects of elemental fluoride.)

Consumer chemical products that contain 0.5% or more of available fluoride ions are prohibited, except for glass etchants that meet the conditions of the table to section 45. Products used for glass etching are not included in the prohibition, since there is no effective substitute for the frosting of glass, a technique used by artists and artisans. Fluoride-containing glass etchants must be in the form of a paste or gel, must be packaged in a child-resistant container and must be labelled according to the table to subsection 46(1). This promotes a controlled application and reduces the possibility of splashing.

The child-resistant packaging requirement is harmonized with the United States' *Poison Prevention Packaging Act*, where child-resistant packaging is required for household products containing more than 0.5 % and more than 50 mg of elemental fluoride. However, unlike Canada, other household products are not prohibited from containing fluoride ions in the U.S.

Toothpaste contains around 0.2% fluoride, and the Canadian Dental Association recognizes these products as safe and effective when used as directed. In Canada, consumer chemical products that contain more than 0.5% of available fluoride ion are prohibited, unless they are used for etching glass.

Exceptions:

An exception from prohibition may be requested, but the granting of such an exception involves a regulatory amendment to the CCCR, 2001 in accordance with the Canadian Federal Regulatory Process. A submission to Health Canada to request an exception from prohibition must clearly show the following:

- no other less hazardous alternative exists and is readily available or technically feasible;
- the benefits of the product outweigh the high degree of hazard to the user; and
- any other information which supports the request to allow a very hazardous product into the hands of the general public.

Health Canada will exercise its discretionary authority regarding the request and may make its permission subject to restrictions on the packaging, labelling or conditions of sale. Once the Regulations have been amended, the exception would apply to all products meeting the amendment conditions.

CCCR, 2001 Section 46 - PART 2 - CORROSIVE PRODUCTS Required Information

Required Information

Required information - sub-category "very corrosive"

46. (1) When a corrosive product classified in the sub-category "very corrosive" under section 41 has an information requirement under the table to section 45, the container of the product must display, for each type of information set out in column 1 of the table to this subsection and for each applicable route of exposure set out in column 2, the information set out in columns 3 and 4, other than the instructions set out in italics.

TABLE TO SUBSECTION 46(1)

REQUIRED INFORMATION - SUB-CATEGORY "VERY CORROSIVE"

	Column 1	Column 2	Column 3	Column 4
Item	Type of information	Applicable route of exposure	English information	French information
1.	Hazard symbol	All		
2.	Signal word	All	EXTREME DANGER	DANGER EXTRÊME
3.	Primary hazard statement	All	VERY CORROSIVE	TRÈS CORROSIF
4.	Specific hazard statement	(*a*) All	CAUSES SEVERE BURNS	PROVOQUE DE GRAVES BRÛLURES
		(*b*) Dermal and contains a concentration of 0.5% or more of available fluoride ions	SYMPTOMS MAY NOT APPEAR IMMEDIATELY	LES SYMPTOMES PEUVENT NE PAS SE MANIFESTER IMMÉDIATEMENT
		(*c*) Inhalation	DANGEROUS FUMES FORM WHEN MIXED WITH OTHER PRODUCTS	DÉGAGE DES ÉMANATIONS DANGEREUSES LORSQUE MÉLANGÉ AVEC D'AUTRES PRODUITS
5.	Negative instructions	(*a*) All	*When appropriate and before the other negative instructions*:	*When appropriate and before the other negative instructions*:

CCCR, 2001 Section 46 - PART 2 - CORROSIVE PRODUCTS Required Information

TABLE TO SUBSECTION 46(1)

REQUIRED INFORMATION - SUB-CATEGORY "VERY CORROSIVE"

Item	Column 1 Type of information	Column 2 Applicable route of exposure	Column 3 English information	Column 4 French information
			Do not mix with [*Insert description of other products that react with the chemical product, such as toilet bowl or drain cleaners, bleach or ammonia.*].	**Ne pas mélanger avec [*Insert description of other products that react with the chemical product, such as des nettoyants pour cuvettes de toilette ou tuyaux d'évacuation, des agents de blanchiment ou de l'ammoniaque.*].**
		(*b*) Oral	**Do not swallow.**	**Ne pas avaler.**
		(*c*) Eyes	**Do not get in eyes.**	**Éviter tout contact avec les yeux.**
		(*d*) Dermal	**Do not get on skin or clothing.**	**Éviter tout contact avec la peau ou les vêtements.**
		(*e*) Inhalation	**Do not breathe fumes.**	**Ne pas respirer les émanations.**
6.	**Positive instructions**	**(*a*) All**	**Handle with extreme care. Keep out of reach of children.**	**Manipuler avec grand soin. Tenir hors de la portée des enfants.**
		(*b*) Oral	**Wear [*Insert description of the specific safety equipment relevant to the hazard, e.g., a mask.*].**	**Porter [*Insert description of the specific safety equipment relevant to the hazard, e.g., un masque.*].**
		(*c*) Dermal	**Wear [*Insert description of the specific safety equipment relevant to the hazard, e.g., rubber gloves, safety glasses.*].**	**Porter [*Insert description of the specific safety equipment relevant to the hazard, e.g., des gants de caoutchouc, des lunettes de sécurité.*].**
		(*d*) Inhalation	**Use only in a well-ventilated area.**	**N'utiliser que dans un endroit bien aéré.**

CCCR, 2001 Section 46 - PART 2 - CORROSIVE PRODUCTS Required Information

TABLE TO SUBSECTION 46(1)

REQUIRED INFORMATION - SUB-CATEGORY "VERY CORROSIVE"

Item	Column 1 Type of information	Column 2 Applicable route of exposure	Column 3 English information	Column 4 French information
			Wear [*Insert description of the specific safety equipment relevant to the hazard, e.g., a mask, a respirator*].	**Porter** [*Insert description of the specific safety equipment relevant to the hazard, e.g., un masque, un respirateur.*].
7.	First aid statement	(*a*) All	**FIRST AID TREATMENT**	**PREMIERS SOINS**
			Contains [*name of hazardous ingredients in descending order of proportion*].	**Contient** [*name of hazardous ingredients in descending order of proportion*].
			If swallowed, call a Poison Control Centre or doctor immediately. Do not induce vomiting.	**En cas d'ingestion, appeler immédiatement un centre antipoison ou un médecin. Ne pas provoquer le vomissement.**
		(*b*) Eyes	**If in eyes, rinse with water for** [*Insert appropriate period of time.*].	**En cas de contact avec les yeux, rincer avec de l'eau pendant** [*Insert appropriate period of time.*].
		(*c*) Dermal	**If on skin, rinse well with water. If on clothes, remove clothes.**	**En cas de contact avec la peau, bien rincer avec de l'eau. En cas de contact avec les vêtements, enlever ceux-ci.**
		(*d*) Inhalation	**If breathed in, move person to fresh air.**	**En cas d'inhalation, transporter à l'air frais la personne exposée.**

Required information - sub-category "corrosive"

(2) The container of a corrosive product that is classified in the sub-category "corrosive" under section 41 must display, for each type of information specified in column 1 of the table to this subsection and for each applicable route of exposure set out in column 2, the information set out in columns 3 and 4, other than the instructions set out in italics.

CCCR, 2001 Section 46 - PART 2 - CORROSIVE PRODUCTS Required Information

TABLE TO SUBSECTION 46(2)

REQUIRED INFORMATION - SUB-CATEGORY "CORROSIVE"

Item	Column 1 Type of information	Column 2 Applicable route of exposure	Column 3 English information	Column 4 French information
1.	Hazard symbol	All		
2.	Signal word	All	DANGER	DANGER
3.	Primary hazard statement	All	CORROSIVE	CORROSIF
4.	Specific hazard statement	(*a*) All	CAUSES BURNS	PROVOQUE DES BRÛLURES
		(*b*) Inhalation	DANGEROUS FUMES FORM WHEN MIXED WITH OTHER PRODUCTS	DÉGAGE DES ÉMANATIONS DANGEREUSES LORSQUE MÉLANGÉ AVEC D'AUTRES PRODUITS
5.	Negative instructions	(*a*) All	*When appropriate and before the other negative instructions:* Do not mix with [*Insert description of other products that react with the chemical product, such as toilet bowl or drain cleaners, bleach or ammonia.*].	*When appropriate and before the other negative instructions:* Ne pas mélanger avec [*Insert description of other products that react with the chemical product, such as des nettoyants pour cuvettes de toilette ou tuyaux d'évacuation, des agents de blanchiment ou de l'ammoniaque.*].
		(*b*) Oral	Do not swallow.	Ne pas avaler.
		(*c*) Eyes	Do not get in eyes.	Éviter tout contact avec les yeux.
		(*d*) Dermal	Do not get on skin or clothing.	Éviter tout contact avec la peau ou les vêtements.
		(*e*) Inhalation	Do not breathe fumes.	Ne pas respirer les émanations.

CCCR, 2001 Section 46 - PART 2 - CORROSIVE PRODUCTS Required Information

TABLE TO SUBSECTION 46(2)

REQUIRED INFORMATION - SUB-CATEGORY "CORROSIVE"

Item	Column 1 Type of information	Column 2 Applicable route of exposure	Column 3 English information	Column 4 French information
6.	Positive instructions	(*a*) All	Handle with care. Keep out of reach of children.	Manipuler avec soin. Tenir hors de la portée des enfants.
		(*b*) Oral	Wear [*Insert description of the specific safety equipment relevant to the hazard, e.g., a mask.*].	Porter [*Insert description of the specific safety equipment relevant to the hazard, e.g., un masque.*].
		(*c*) Dermal	Wear [*Insert description of the specific safety equipment relevant to the hazard, e.g., rubber gloves, safety glasses.*].	Porter [*Insert description of the specific safety equipment relevant to the hazard, e.g., des gants de caoutchouc, des lunettes de sécurité.*].
		(*d*) Inhalation	Use only in a well-ventilated area.	N'utiliser que dans un endroit bien aéré.
			Wear [*Insert description of the specific safety equipment relevant to the hazard, e.g., a mask, a respirator.*].	Porter [*Insert description of the specific safety equipment relevant to the hazard, e.g., un masque, un respirateur.*].
7.	First aid statement	(*a*) All	FIRST AID TREATMENT	PREMIERS SOINS
			Contains [*name of hazardous ingredients in descending order of proportion*].	Contient [*name of hazardous ingredients in descending order of proportion*].
			If swallowed, call a Poison Control Centre or doctor immediately. Do not induce vomiting.	En cas d'ingestion, appeler immédiatement un centre antipoison ou un médecin. Ne pas provoquer le vomissement.
		(*b*) Eyes	If in eyes, rinse with water for [*Insert appropriate period of time.*].	En cas de contact avec les yeux, rincer avec de l'eau pendant [*Insert appropriate period of time.*].

CCCR, 2001 Section 46 - PART 2 - CORROSIVE PRODUCTS Required Information

TABLE TO SUBSECTION 46(2)

REQUIRED INFORMATION - SUB-CATEGORY "CORROSIVE"

Item	Column 1 Type of information	Column 2 Applicable route of exposure	Column 3 English information	Column 4 French information
		(*c*) Dermal	If on skin, rinse well with water. If on clothes, remove clothes.	En cas de contact avec la peau, bien rincer avec de l'eau. En cas de contact avec les vêtements, enlever ceux-ci.
		(*d*) Inhalation	If breathed in, move person to fresh air.	En cas d'inhalation, transporter à l'air frais la personne exposée.

Required information - sub-category "irritant"

(3) Subject to subsection (4), the container of a corrosive product that is classified in the sub-category "irritant" under section 41 must display, for each type of information specified in column 1 of the table to this subsection and for each applicable route of exposure set out in column 2, the information set out in columns 3 and 4, other than the instructions set out in italics.

TABLE TO SUBSECTION 46(3)

REQUIRED INFORMATION - SUB-CATEGORY "IRRITANT"

Item	Column 1 Type of information	Column 2 Applicable route of exposure	Column 3 English information	Column 4 French information
1.	Signal word	Dermal	CAUTION	ATTENTION
2.	Primary hazard statement	Dermal	IRRITANT	IRRITANT
3.	Specific hazard statement	(*a*) Eye	MAY IRRITATE EYES	PEUT IRRITER LES YEUX
		(*b*) Dermal	MAY IRRITATE SKIN	PEUT IRRITER LA PEAU

CCCR, 2001 Section 46 - PART 2 - CORROSIVE PRODUCTS Required Information

TABLE TO SUBSECTION 46(3)

REQUIRED INFORMATION - SUB-CATEGORY "IRRITANT"

Item	Column 1 Type of information	Column 2 Applicable route of exposure	Column 3 English information	Column 4 French information
		(*c*) Inhalation	**DANGEROUS FUMES FORM WHEN MIXED WITH OTHER PRODUCTS**	**DÉGAGE DES ÉMANATIONS DANGEREUSES LORSQUE MÉLANGÉ AVEC D'AUTRES PRODUITS**
4.	Negative instructions	(*a*) All	*When appropriate and before the other negative instructions*:	*When appropriate and before the other negative instructions*:
			Do not mix with [*Insert description of other products that react with the chemical product, such as toilet bowl or drain cleaners, bleach or ammonia.*].	Ne pas mélanger avec [*Insert description of other products that react with the chemical product, such as des nettoyants pour cuvettes de toilette ou tuyaux d'évacuation, des agents de blanchiment ou de l'ammoniaque.*].
		(*b*) Eyes	Do not get in eyes.	Éviter tout contact avec les yeux.
		(*c*) Dermal	Do not get on skin or clothing.	Éviter tout contact avec la peau ou les vêtements.
		(*d*) Inhalation	Do not breathe fumes.	Ne pas respirer les émanations.
5.	Positive instructions	All	Keep out of reach of children.	Tenir hors de la portée des enfants.
6.	First aid statement	(*a*) All	**FIRST AID TREATMENT**	**PREMIERS SOINS**
			Contains [*name of hazardous ingredients in order of decreasing proportion*].	Contient [*name of hazardous ingredients in order of decreasing proportion*].

CCCR, 2001 Section 46 - PART 2 - CORROSIVE PRODUCTS Required Information

TABLE TO SUBSECTION 46(3)

REQUIRED INFORMATION - SUB-CATEGORY "IRRITANT"

Item	Column 1 Type of information	Column 2 Applicable route of exposure	Column 3 English information	Column 4 French information
			If swallowed, call a Poison Control Centre or doctor immediately. Do not induce vomiting.	**En cas d'ingestion, appeler immédiatement un centre antipoison ou un médecin. Ne pas provoquer le vomissement.**
		(*b*) Eyes	**If in eyes, rinse with water for [*Insert appropriate period of time*.].**	**En cas de contact avec les yeux, rincer avec de l'eau pendant [*Insert appropriate period of time*.].**
		(*c*) Dermal	**If on skin, rinse well with water.**	**En cas de contact avec la peau, bien rincer avec de l'eau.**

Exception - another primary hazard statement

(4) The primary hazard statement set out in columns 3 and 4 of item 2 of the table to subsection (3) may be omitted when other provisions in these Regulations require another primary hazard statement to be displayed on the container.

DISCUSSION OF CCCR, 2001 SECTION 46

Topics

Definitions:

The following terms are defined in section 1 of the CCCR, 2001: container, corrosive product, first aid statement, hazard symbol, hazardous ingredients, sub-category.

Requirements:

The wording for the warnings was developed through a consensus process, with the active collaboration of interested stakeholders, including the medical profession and public health

organizations, the chemical industry, consumers' and seniors' groups, academia, technical experts and various federal government departments. During the label development, all sectors involved agreed that the regulations should prescribe mandatory warnings for the various hazard categories and sub-categories. The label statements are generic in terms of the hazard in order to be applicable to all types of consumer chemical products which fall within a particular sub-category. This ensures a constancy in the messages seen by consumers as well as a consistent set of rules for all companies. In addition, the general nature of the statements eliminates the need for ongoing regulatory amendments, but still provides the flexibility to add more specific information that may be appropriate to the chemical product.

All of the appropriate statements are required for all applicable routes of exposure. Statements may be combined. However, if a person under reasonably foreseeable use of the product cannot be exposed through a specific route, then it is not considered applicable, and the warnings are not required for that route of exposure.

Presentation Requirements:

See sections 17 to 32 of the CCCR, 2001 for the presentation format of the required information.

Irritants:

Unlike corrosive materials, the irritant hazard does not warrant the use of a symbol, due to the reversible nature of health effects upon exposure. The signal word "CAUTION" indicates the lower degree of hazard associated with exposure to the product. This signal word and primary hazard statement are not required for products that are an eye irritant only. In addition, the primary hazard statement "IRRITANT" may be omitted for products which already require a primary hazard statement from another sub-category. The intent of labelling on the main display panel is to direct a user to the safe usage and first aid labelling elsewhere on the product. This objective will have been met by the signal word and primary hazard statement for toxicity, corrosivity or flammability that already appears on the main display panel.

Mixing:

The specific hazard statement and negative instructions related to mixing is intended to warn of the hazard when a consumer chemical product is mixed with another product, such as bleach and household ammonia, or acidic toilet-bowl cleaner and bleach. These are documented foreseeable uses of consumer chemical products. The intent is to discourage a user from mixing any product not specifically identified as suitable for mixing on the directions for use.

These statements are only required when appropriate to the product. If there is no mixing issue with the product, then the specific hazard statement need not be used. This is consistent with the negative instruction, where the “do not mix with ...” statement is only used when appropriate.

First Aid Statement:

Only those hazardous ingredients present at least at 1% and which directly contribute to the classification of the product must be listed immediately after the words “**FIRST AID TREATMENT**” and “**PREMIERS SOINS**”. The use of the words “may contain” and other phrases which leave some ambiguity as to the composition and, consequently, the health hazard of the product, is discouraged.

Wiping Cloths

A wiping cloth that contains a consumer chemical product may not pose a significant oral hazard. For example, it is unlikely that a cleanser absorbed into a cloth would be ingested, as long as the mixture cannot be squeezed-out. The statement "If swallowed, call a Poison Control Centre or doctor immediately" is not required for products in which a liquid is absorbed onto a solid, semi-solid or fibrous material, as long as the liquid cannot be released from the substrate material with any reasonably foreseeable conditions of use or manipulation.

It is recommended that written records be kept of the decisions and justifications taken in this regard, so that, if necessary, a Product Safety inspector may review the rationale for this action.

Additional Statements:

The required labelling is the minimum necessary, and is an indication of the minimum standard of care imposed on a person responsible. Manufacturers and importers can add, and are encouraged to add, information considered necessary to fully inform the public of the hazards of using their products (see subsection 15(2)). In composing these statements, use short, simple sentences. Complex conditional sentences, particularly those containing negations, should be avoided. In addition, a person will remember the important product related information better, if fewer dimensions or items are listed.

However, the person responsible is discouraged from deliberately over-stating the hazards posed by a product. If unwarranted warnings are added to products, it may lead to potentially lengthy and unnecessary or inappropriate treatment upon exposure to the product. Furthermore, such a practice minimizes the perception of risk for those products which actually need the warnings, leading to potential injuries from a lack of concern or precaution by the user.

Cement

To assist consumers who are working with cement, containers of dry cement may add the phrase “forms calcium hydroxide when wet / fait de l’hydroxyde de calcium lorsque trempé”, or a similar phrase that conveys the same meaning.

Inhalation Hazards

When a corrosive product poses an inhalation hazard, a specific hazard statement such as “IRRITATING FUMES RELEASED WHEN USED / DÉGAGE DES ÉMANATIONS LORS DE SON UTILISATION” may be added. This would not contradict the CCCR, 2001 labelling, but it would help the person responsible meet their obligations to warn of the hazards posed by their product.

CCCR, 2001 Section 47 - PART 2 - CORROSIVE PRODUCTS Child-resistant Containers

Child-resistant Containers

Sub-categories "very corrosive" and "corrosive"

47. Subject to section 14, a corrosive product must be in a child-resistant container that complies with sections 9 to 13 if the product has been classified in accordance with section 41

(*a*) in the sub-category "very corrosive" and is listed in the table to section 45; or

(*b*) in the sub-category "corrosive".

DISCUSSION OF CCCR, 2001 SECTION 47

Topics

Definitions:

The following terms are defined in section 1 of the CCCR, 2001:
container, corrosive product, sub-category.

Requirements:

Chemical products that are classified as very corrosive or corrosive are required to be packaged in child-resistant containers because of the likelihood to death or severe injury should a child come into contact with the product.

See sections 9 to 13 for the design and performance requirements for child-resistant containers. In general, these requirements make it difficult for a child under five years of age to open the container and make contact with the corrosive product within a reasonable time. This requirement means that some children may still be able to open a container if given sufficient time to do so.

Exceptions:

Large Containers

Containers of chemical products classified in the "corrosive" subcategory need not be child-resistant if they have a capacity of greater than 5L. This exception does not apply to products classified in the "very corrosive" subcategory (see section 14).

PART 3

FLAMMABLE PRODUCTS

Classification of Flammable Products

Data sources and tests

48. (1) The person responsible for a flammable product must determine the appropriate sub-category for the product in accordance with section 49 using human experience data or the results of tests conducted in accordance with the test methods set out in sections 50 to 52 and Schedule 1.

Exemption

(2) A flammable product that is classified in the sub-category "combustible" is exempt from the requirements of this Part if it

(*a*) is composed of 50% or more of water and 50% or less of water-miscible solvent; and

(*b*) does not sustain combustion when tested in accordance with Test L.2.

Sub-categories of hazard category "Category 3, flammable products"

49. (1) A flammable product described in column 1 of the table to this subsection must be classified in the sub-category set out in column 2.

TABLE TO SUBSECTION 49(1)

SUB-CATEGORIES OF HAZARD CATEGORY "CATEGORY 3, FLAMMABLE PRODUCTS"

	Column 1	Column 2
Item	Product Description	Sub-category
1.	A product that spontaneously combusts under reasonably foreseeable conditions of use	Spontaneously Combustible
2.	A product that heats spontaneously on contact with air to the point that it begins to burn	Spontaneously Combustible

CCCR, 2001 Sections 48 and 49 - PART 3 - FLAMMABLE PRODUCTS
Classification of Flammable Products

TABLE TO SUBSECTION 49(1)

SUB-CATEGORIES OF HAZARD CATEGORY "CATEGORY 3, FLAMMABLE PRODUCTS"

Item	Column 1 Product Description	Column 2 Sub-category
3.	A liquid, other than a liquid in a spray container, that has a flash point, determined in accordance with one of the standards set out in section 50, of	
	(*a*) less than -18.0˚C;	Very Flammable
	(*b*) -18.0ºC or more but not more than 37.8˚C; or	Flammable
	(*c*) more than 37.8˚C but not more than 60.0˚C	Combustible
4.	A solid, paste or gel that emits a vapour that has a flash point, determined in accordance with the standard set out in section 51, of	
	(*a*) less than -18.0˚C;	Very Flammable
	(*b*) -18.0˚C or more but not more than 37.8˚C; or	Flammable
	(*c*) more than 37.8˚C but not more than 60.0˚C	Combustible
5.	A gas, other than a gas in a spray container, that forms a flammable mixture with air at a concentration of 13% or less by volume at normal atmospheric pressure	Flammable
6.	A gas, other than a gas in a spray container, that forms a flammable mixture with air over a concentration range of 12% or more by volume at normal atmospheric pressure	Flammable
7.	A liquid or gas in a spray container that, when tested in accordance with the procedure set out in Schedule 1,	
	(*a*) has a flame projection of 100 cm or more;	Very Flammable
	(*b*) has a flame projection of 15 cm or more but less than 100 cm; or	Flammable
	(*c*) exhibits a flashback	Very Flammable

Flammable liquid in a refillable spray container

(2) In the case of a liquid flammable product in a refillable spray container, the person responsible must

(*a*) determine both the product's flash point, in accordance with section 50, and its flame projection and flashback, in accordance with section 52; and

(*b*) classify the product in the most flammable sub-category of the applicable sub-categories as determined under items 3 and 7 of the table to subsection (1).

DISCUSSION OF CCCR, 2001 SECTIONS 48 and 49

Definitions:

The following terms are defined in section 1 of the CCCR, 2001: flammable product, flame projection, flash point, flashback, human experience data, normal atmospheric pressure, person responsible, spray container, sub-category, Test L.2, vapour.

Topics

Requirements:

Sections 48 and 49 set out the steps for classifying a product into the flammable product sub-categories: spontaneously combustible, very flammable, flammable and combustible. The criteria describe products that are hazardous because they can catch fire. The distinction between sub-categories is the ease of ignition or length of flame projection.

Spontaneous Combustion:

Many liquid or paste products are intended to be used with a rag for cleaning, rubbing or polishing purposes. A used rag that is not washed right away or not disposed of properly may create the conditions for a fire caused by spontaneous combustion. Spontaneous combustion means that the rag may begin to burn by itself, without a source of ignition. It is a complex process, involving the ignition of a combustible material through the heat of a chemical reaction.

One of the best known examples of spontaneous combustion is when a drying oil, such as linseed oil, is absorbed on a cotton rag. The drying oil slowly takes oxygen from the air to form a solid skin. This is an oxidation reaction, which produces heat. If the oil is spread over a surface, such as wood, the heat from oxidation is dissipated quickly. However, if the oil is absorbed into a crumpled-up rag, the heat cannot escape very well, and the temperature of the rag rises. This, in turn, speeds-up the rate of oxygen absorption and further increases the temperature. If this process continues, the temperature of the oil-soaked rag may gradually rise enough for it to ignite.

Some common drying oils are: linseed oil, tung oil, cottonseed oil, corn oil, soybean oil, safflower oil, walnut oil and poppyseed oil. Not all products containing these substances are prone to spontaneous combustion, especially if they have been mixed with anti-oxidant substances which inhibit drying. Furthermore, the criteria are limited to product uses that would cause spontaneous combustion under reasonably foreseeable conditions, for example, a product that must be applied with a rag or other combustible material.

Since spontaneous combustion poses a distinct flammability hazard from ignition by a flame, labelling for spontaneous combustion must be present in addition to that for another flammable sub-category, if required (see subsection 4(4)).

Human Experience

Subsection 48(1) allows a classification based upon human experience data with the product. Fire investigation reports are a useful source of information on the initial sources of a fire. This may be particularly useful in classifying a product as a spontaneous combustion hazard under reasonably foreseeable conditions of use.

Combustible:

Combustible products do not ignite readily but may add to the fire load, and should therefore not be stored in areas prone to fires, such as in furnace or electrical rooms. Canadian Fire Service organizations have expressed concern about combustible materials, and suggested households be informed that combustible products must be stored properly. The criteria classifies a product that may flash at normal living temperatures, with 60.0˚C being considered at the outside range of "normal" in Canada. For example, this temperature can easily be reached in a car's trunk on a warm sunny day.

Exemption - Water-Based Products

Certain water-based products will not sustain combustion after the initial surface flash. For example, many dishwashing liquids contain a moderate amount of low molecular weight alcohols and will flash between 37.8 and 60˚C, but will not continue to burn. Subsection 48(2) allows an exemption for water-based products that flash in the "combustible" range so long as they are made-up mostly of water ($\geq$ 50%) and will not sustain combustion according to Test L.2.

The Product Safety Laboratory has tested various mixtures of water and methanol, as well as water and acetone. The test results indicate that products with a greater than 70/30 mix of water/methanol would not sustain combustion. As the water content was reduced, combustion was sustained for progressively longer periods of time. It was also observed that the flame colour was blue and not easily visible in daylight, creating a hidden hazard since a user may not be aware that the product has caught fire. A similar result occurred for acetone, though the flame was a common yellow colour, which was more visible during daylight.

Solids/Pastes/Gels:

This item captures only products which emit vapours during testing. These vapours may flash, and if so, the results determine if the product meets the criteria. Products which are rigid solids that do not emit vapours, such as paper products, would not be classified.

Gases:

Items 5 and 6 of the table to subsection 49(1) capture compressed gas cylinders, such as propane for barbeques and butane curling-iron cartridges. Three conditions have to be met in order to ignite a flammable gas:

- the concentration of the gas has to be within the range that the gas is capable of igniting, meaning between the lower and upper flammable limits of the gas;
- an oxidizing gas, such as air, must be present; and
- a source of ignition has to be available.

The lower flammable limit is the minimum concentration (% by volume) of a gas in air below which a flame is not generated when an ignition source is present. That is, the mixture is "too lean" to burn. Similarly, the upper flammable limit is the maximum concentration above which the mixture is "too rich" to burn. The flammable limits are sometimes also referred to as the “explosive limits”.

The greater the range or spread over which a gas forms a flammable mixture, the greater the likelihood is that such conditions may occur. Similarly, gases which can ignite at relatively low concentrations (13% or less) in air would be particularly hazardous because of the likelihood that a potential flammable mixture can occur, such as in the event of a leak. For example, hydrogen, with flammability limits of 4-75%, meets both items 5 and 6, but 1,3-butadiene, with flammability limits of 2-12%, meets only item 5. Other examples of flammable gases include: propane (flammable at 2.3-9.5%), butane (flammable at 1.9-8.5%) and acetylene (flammable at 2.5-82%).

Spray Containers:

Spray containers are classified based on the flame projection and flashback of the product, and not by the flammable gas used as a propellant. The flame projection test considers the design of the entire product, including the propellant, if present, as well as the spray characteristics from the nozzle or trigger design.

A pump-spray container can significantly increase the flammability of a substance by producing a mixture of the substance with air that is much more flammable than the substance alone, even though no propellant is used. For example, a ski care product packaged in a pump-spray container was tested by the Product Safety Laboratory in 1990. This product had a flash point of more than 65.5˚C, but the flame projection from the container was between 15 and 45 cm.

A refillable spray container usually refers to a pump-spray container, where the nozzle apparatus can be unscrewed at the neck and the contents poured-in through the neck opening. Since a person may be exposed to the product or to the spray, it must be tested for both the flash point as well as the flame projection and flashback, and the product is classified into the higher level of hazard (subsection 49(2)).

Aerosol Foams, Caulking, and Spray-String Products

Not all pressurized containers are spray containers, only those containers that permit release in the form of a mist are included in item 7 to the table to subsection 49(1). Mist is defined as:

> "droplets of liquid suspended in air that are produced by the condensation of vapourized liquid or by the dispersion of a liquid by a spray container".

A pressurized container that emits a product only in the form of foam, paste or string would not be considered to be a spray container. Hence, the flame projection and flash back criteria do not apply to an insulating foam, a caulking product or a novelty string packaged in an aerosol container, unless it is also possible to release the contents in the form of a mist.

However, the flame projection test is appropriate to assess the hazard posed by aerosol products that are released in the horizontal plane, like a conventional aerosol spray container (for example, novelty string products). Such products should be assessed in a similar way as re-fillable spray containers (s. 49(2)): determine the product's flammability using the flame projection and flash back criteria (item 7) as well as the flash point of the solid emitted (item 4) and the flammable gas criteria, if it is possible for pure propellant to be released (items 5 and 6), and classify into the most flammable sub-category. This gives the safest classification.

Aerosol products that are not released horizontally can represent a greater flammability hazard than conventional aerosol containers. For example, the container for foams or mousses are generally operated from the upside-down position. Operating such products in the upright position could cause pure propellent, such as propane or butane, to be released, since the foam or caulking product would be settled at the bottom of the container. It is often the practice to expel pure propellant to clean the nozzle after using such products. As a result, consumers would unexpectedly encounter a situation where pure highly flammable hydrocarbon gas is expelled from the container. To classify such products, it is recommended that both the flash point criteria for the solid, paste or foam, be assessed (item 4) as well as the flammable gas criteria for the propellant, if it is possible for pure propellant to be released (items 5 and 6), and classify into the most flammable sub-category.

CCCR, 2001 Sections 48 and 49 - PART 3 - FLAMMABLE PRODUCTS
Classification of Flammable Products

Harmonization with the WHMIS Controlled Products Regulations:

The CCCR, 2001 criteria for gases are exactly the same as those for workplace chemicals under the requirements of *WHMIS* Division 1 of Class B (flammable gases).

For liquids, the "flammable" classification has the same limit as *WHMIS* Division 2 of Class B (flammable liquids), however *WHMIS* does not distinguish a "very flammable" subcategory. The sub-category "very flammable" is intended for products which are too hazardous to be routinely made available to consumers who lack the specialized knowledge and training to use such products. The average household does not have in place the engineering controls necessary to react to the hazards posed by these products. The upper flash point criteria for the "combustible" sub-category harmonizes with the *Transportation of Dangerous Goods Regulations*, but the *WHMIS* criteria for Division 3 of Class B (combustible liquids) sets the upper limit at 93.3˚C, which is inappropriate for household conditions. Temperatures of 93.3˚C, while being encountered in industrial settings, would rarely be met in the consumer environment.

With respect to solids, the CCCR, 2001 are not harmonized with *WHMIS* Division 4 of Class B (flammable solids).

For spray containers, *WHMIS* classifies aerosol containers according to the same flame-projection test in Division 5 of Class B (flammable aerosols), but not pump-spray containers. Furthermore, *WHMIS* does not distinguish a "very flammable" subcategory for aerosol sprays.

Finally, the criteria for spontaneous combustion in the CCCR, 2001 is also included in *WHMIS* Division 6 of Class B (reactive flammable materials).

Test Methods

Flash point - liquids

50. A flammable product in the form of a liquid must be tested for its flash point in accordance with the following standards:
(*a*) for liquids that have a viscosity of less than 5.8 mm^2/s at 37.8˚C, ASTM D 56 or ASTM D 3828; and
(*b*) for liquids that have a viscosity of 5.8 mm^2/s or more at 37.8˚C, ASTM D 93.

Flash point - solids, pastes and gels

51. A flammable product in the form of a solid, paste or gel must be tested for its flash point in accordance with ASTM D 56.

Flame projection and flashback - spray container

52. A flammable product that is enclosed in a spray container must be tested for its flame projection and flashback in accordance with the procedure set out in Schedule 1.

DISCUSSION OF CCCR, 2001 SECTIONS 50 to 52

Topics

Definitions:

The following terms are defined in section 1 of the CCCR, 2001: flame projection, flashback, flammable product, flash point, spray container, ASTM D 56, ASTM D 93, ASTM D 3828.

Requirements:

Sections 50 to 52 provide the test methods for assessing and classifying flammable products.

Flash point:

All of the methods specified for flash point are closed-cup techniques in which the vapour is enclosed in the space above the product being tested. Open-cup techniques, where the vapour can dissipate, tend to yield flash points with values higher than those obtained with closed-cup methods. The liquid test methods are the same methods that suppliers have used to comply with the *Controlled Products Regulations* (*WHMIS*).

Section 50 recognizes that the viscosity of a liquid influences the choice of test most appropriate for measuring an accurate flash point. Although the ASTM standards express kinematic viscosity in the units of centistokes (cSt) or stokes, one centistoke equals one mm^2/s. No test method for viscosity is specified because this is a standard laboratory practice. Any test method which conforms to the principals of good laboratory practices may be used to determine the viscosity.

Paragraph 50(a) is used for liquids which are very fluid and pourable, whereas paragraph 50(b) is used for liquids which are thicker. Very thick substances will, by their nature, inhibit free solvent evaporation and the stirring capabilities of the test apparatus in paragraph 50(b) will alleviate this restriction. Stirring ensures a uniform distribution of heat. In addition, sample pre-conditioning will take care of the difficulties of mixing too viscous of a product at very low temperatures. Sampling section 8.5 in ASTM D 93 states that:

> "...samples of very viscous materials can be warmed until they are reasonably fluid before they are tested. However, no sample should be heated more than is absolutely necessary."

There are two different procedures in the test method to address various conditions of samples: one is for fuel oils, lubricating oils and other homogeneous liquids; and the other is for liquids that tend to form a surface film, liquids with suspensions of solids and non-homogeneous liquids.

Section 51, for solids, pastes and gels, is a variation of the flammable liquid method. It classifies only products which emit vapours during testing. These vapours may flash, and if so, the results determine if the product meets the criteria. Products which are rigid solids that do not emit vapours, such as paper products, would not be classified.

Estimation of Flash Point

The practice of estimating the flash point of the finished product, based on the flash points of the individual components, is not acceptable. These physical properties may not always be accurately extrapolated from similar products or individual ingredients. Sections 50 to 52 give standard test methods to ensure that all manufacturers are testing and classifying products in the same manner, thus resulting in similar labelling for the same hazards.

Spray Containers:

The flame projection and flashback test in Schedule 1 assesses a spray container when it is in the upright position and the spray is emitted horizontally.

Pump-spray containers are evaluated at each nozzle position. If a spray container is packaged with a tube that is intended to be inserted into the nozzle, such as certain automotive lubricants, the container is evaluated with and without the tube.

At present, the criteria are limited to spray containers, and do not apply to insulating foams or caulking products, unless it is possible to release the contents in the form of a mist. However, when these containers are in the upright position, pressing the nozzle could release pure propellant. This situation could be hazardous, if the propellant is highly flammable, such as propane or dimethyl ether. In such cases, it is recommended that both the flash point criteria for the product be assessed as well as the flammable gas criteria for the propellant, if it is possible for pure propellant to be released, and classify into the most flammable sub-category (see section 49 of the CCCR, 2001).

NEW▸ **Solid Impregnated with Liquid (ie. Wetnap):**

A solid product that is impregnated (or soaked) in a liquid chemical product is treated as a flammable solid when tested according to s.51. This is because the final product is in the form of a solid; similarly, s.51 applies to pastes and gels and they too are solids which have been impregnated with liquids, but are mixed and given a gel/paste consistency.

CCCR, 2001 Section 53 - PART 3 - FLAMMABLE PRODUCTS
Very Flammable Products

Very Flammable Products

Prohibition and exceptions

53. The advertising, sale or importation of a flammable product that is classified in the sub-category "very flammable" under section 48 is prohibited unless the product is set out in column 1 of the table to this section and meets the conditions set out in column 2.

TABLE TO SUBSECTION 53

CONDITIONS FOR ADVERTISING, SELLING OR IMPORTING A VERY FLAMMABLE PRODUCT

	Column 1	Column 2
Item	Chemical product	Conditions
1.	A fuel, such as gasoline, ethanol or propane	The container of the fuel (*a*) is permanently attached to an internal combustion engine, a gas turbine or an appliance that uses the fuel; or (*b*) is separate or detachable from the internal combustion engine, gas turbine or appliance that uses the fuel and displays the information set out in the table to subsection 54(1).
2.	A product that exhibits a flashback	The container of the product displays the information set out in the table to subsection 54(1).

DISCUSSION OF CCCR, 2001 SECTION 53

Definitions:

The following terms are defined in section 1 of the CCCR, 2001: chemical product, container, flammable product, flashback, sub-category.

Topics

Requirements:

Chemical products classified as very flammable are prohibited in general, because they are too hazardous for household use without specialized training and equipment.

The following table lists examples of very flammable substances. These substances may also be classified and restricted by other hazard criteria.

CCCR, 2001 Section 53 - PART 3 - FLAMMABLE PRODUCTS
Very Flammable Products

Table: Examples of Very Flammable Substances

Substance	Flash point (˚C) (closed cup)	Substance	Flash point (˚C) (closed cup)
Acetaldehyde	-38	Isopropylamine	-37
2-Butanethiol	-23	Methylcyclopentane	-23
Carbon Disulphide	-30	2-Methyl-2-Propanethiol	< - 29; - 24
Cyclohexane	-20	Methyl Formate	-20
Cyclopentane	-37	Isopentane	-51
Diethylamine	- 28; - 23	Jet B	- 23 to - 1
Diethyl Ether	-45	JP Fuel	- 23 to - 1
Dimethylamine 40%	-18	Gasoline	-43
60%	-51.7	n-Hexane	-21.7
2,2-Dimethyl Butane	-48	Methyl tertiary Butyl Ether	-28
Ethylamine (anhydrous)	< - 18 (liquid: < - 16.6˚C)	Methyl Formate	-19
		n-Pentane	-49
Ethylamine solutions: 70%	-25	1-Propanethiol	-20.6
Ethyl Mercaptan (ethanethiol)	-48.3	2-Propanethiol	-35
Isoheptane	-3; -1; < -18	n-Propylamine	-37
Isohexane	-32		

New →

Acetone

The flash point for acetone is often reported as -18˚C. The Product Safety Laboratory has tested various brands of acetone available for consumer use. The test results indicate that the flash points of these products were above -18.0˚C. Hence these products were not classified as very flammable. However, the results were so close to the classification limit, that the confidence intervals for some products included values below -18˚C. It is the responsibility of the manufacturer or importer of acetone that is destined for consumer use to ensure that their products have a flash point of -18˚C or greater.

Exceptions:

Fuels

Very flammable fuel, such as gasoline, is not prohibited. If the fuel tank is directly connected to the engine or appliance that uses the fuel, such as an automobile, lawn mower or home heating fuel tank, then no precautionary labelling is required. This is due to the limited exposure to the chemical product during reasonably foreseeable use of the engine or appliance and since there are standards commonly set in other legislation, such as the *Motor Vehicle Safety Act* and Regulations.

However, fuel containers that are detached or able to be detached must be appropriately labelled. Such containers include naphtha reservoirs for camp stoves, small propane tanks for welding, barbecue cylinders, bench-top brulé apparatuses, and butane tanks for lighters and hair curling irons. If the fuel container can be separated from the appliance by the consumer, then it is likely to be stored separately from the appliance, and so it must be labelled for the flammability of the substances within.

Flashback

The exception of item 2 to the table to section 53 applies only to products that are classified as "very flammable" because they have a flashback. If a flashback is recorded during testing, the product is not prohibited if it meets the required labelling.

The exception does not apply to products classified by the other "very flammable" criteria in addition to flashback, for example, spray containers that have a flame projection of 100 cm or more, or refillable spray containers that contain a liquid with a flash point of less than -18˚C.

Other exceptions from prohibition may be requested, but the granting of such an exception involves a regulatory amendment to the CCCR, 2001 in accordance with the Canadian Federal Regulatory Process. A submission to Health Canada to request an exception from prohibition must clearly show the following:

- no other less hazardous alternative exists and is readily available or technically feasible;
- the benefits of the product outweigh the high degree of hazard to the user; and
- any other information which supports the request to allow a very hazardous product into the hands of the general public.

Health Canada will exercise its discretionary authority regarding the request and may make its permission subject to restrictions on the packaging, labelling or conditions of sale. Once the Regulations have been amended, the exception would apply to all products meeting the amendment conditions.

CCCR, 2001 Section 54 - PART 3 - FLAMMABLE PRODUCTS Required Information

Required Information

Required information - sub-category "very flammable"

54. (1) When a flammable product classified in the sub-category "very flammable" under section 48 has an information requirement under the table to section 53, the container of the product must display, for each type of information set out in column 1 of the table to this subsection, the information set out in columns 2 and 3, other than the instructions set out in italics.

TABLE TO SUBSECTION 54(1)

REQUIRED INFORMATION - SUB-CATEGORY "VERY FLAMMABLE"

	Column 1	Column 2	Column 3
Item	Type of information	English information	French information
1.	Hazard symbol		
2.	Signal word	EXTREME DANGER	DANGER EXTRÊME
3.	Primary hazard statement	VERY FLAMMABLE	TRÈS INFLAMMABLE
4.	Specific hazard statement	CONTENTS MAY CATCH FIRE *or, when only the vapour or fume poses a hazard:* FUMES MAY CATCH FIRE	LE CONTENU PEUT S'ENFLAMMER *or, when only the vapour or fume poses a hazard:* LES ÉMANATIONS PEUVENT S'ENFLAMMER
5.	Negative instructions	Do not smoke.	Ne pas fumer.
6.	Positive instructions	Use only in a well-ventilated area. Keep away from flames, such as a pilot light, and any object that sparks, such as an electric motor.	N'utiliser que dans un endroit bien aéré. Tenir loin des flammes, telle une flamme pilote, et de tout objet produisant des étincelles, tel un moteur électrique.

CCCR, 2001 Section 54 - PART 3 - FLAMMABLE PRODUCTS Required Information

Required information - sub-category "flammable"

(2) The container of a flammable product that is classified in the sub-category "flammable" under section 48 must display, for each type of information set out in column 1 of the table to this subsection, the information set out in columns 2 and 3, other than the instructions set out in italics.

TABLE TO SUBSECTION 54(2)

REQUIRED INFORMATION - SUB-CATEGORY "FLAMMABLE"

Item	Column 1 Type of information	Column 2 English information	Column 3 French information
1.	Hazard symbol		
2.	Signal word	DANGER	DANGER
3.	Primary hazard statement	FLAMMABLE	INFLAMMABLE
4.	Specific hazard statement	CONTENTS MAY CATCH FIRE *or, when only the vapour or fume poses a hazard:* FUMES MAY CATCH FIRE	LE CONTENU PEUT S'ENFLAMMER *or, when only the vapour or fume poses a hazard:* LES ÉMANATIONS PEUVENT S'ENFLAMMER
5.	Negative instructions	Do not smoke.	Ne pas fumer.
6.	Positive instructions	Use only in a well-ventilated area. Keep away from flames, such as a pilot light, and any object that sparks, such as an electric motor.	N'utiliser que dans un endroit bien aéré. Tenir loin des flammes, telle une flamme pilote, et de tout objet produisant des étincelles, tel un moteur électrique.

Required information - sub-category "spontaneously combustible"

(3) The container of a flammable product that is classified in the sub-category "spontaneously combustible" under section 48 must display, for each type of information set out in column 1 of the table to this subsection, the information set out in columns 2 and 3.

CCCR, 2001 Section 54 - PART 3 - FLAMMABLE PRODUCTS Required Information

TABLE TO SUBSECTION 54(3)

REQUIRED INFORMATION - SUB-CATEGORY "SPONTANEOUSLY COMBUSTIBLE"

	Column 1	Column 2	Column 3
Item	Type of information	English information	French information
1.	Hazard symbol		
2.	Signal word	CAUTION	ATTENTION
3.	Primary hazard statement	READ INSTRUCTIONS BEFORE USING	LIRE LES INSTRUCTIONS AVANT USAGE
4.	Specific hazard statement	DANGER OF COMBUSTION	DANGER DE COMBUSTION
5.	Positive instructions	Materials such as rags used with this product may begin to burn by themselves. After use, put rags in water or lay flat to dry, then discard.	Les matériaux, utilisés avec ce produit, tels les chiffons, peuvent s'enflammer spontanément. Après utilisation, mettre les chiffons dans l'eau ou les sécher à plat, puis les jeter.

Required information - sub-category "combustible"

(4) The container of a flammable product that is classified in the sub-category "combustible" under section 48 must display, for each type of information set out in column 1 of the table to this subsection, the information set out in columns 2 and 3.

TABLE TO SUBSECTION 54(4)

REQUIRED INFORMATION - SUB-CATEGORY "COMBUSTIBLE"

	Column 1	Column 2	Column 3
Item	Type of information	English information	French information
1.	Positive instructions	Keep away from flames or sparks.	Tenir loin des flammes et des étincelles.

CCCR, 2001 Section 54 - PART 3 - FLAMMABLE PRODUCTS
Required Information

DISCUSSION OF CCCR, 2001 SECTION 54

Topics

Definitions:

The following terms are defined in section 1 of the CCCR, 2001:
container, flammable product, fume, fumes, hazard symbol, subcategory, vapour.

Requirements:

The wording for the warnings was developed through a consensus process, with the active collaboration of interested stakeholders, including the medical profession and public health organizations, the chemical industry, consumers' and seniors' groups, academia, technical experts and various federal government departments. During the label development, all sectors involved agreed that the regulations should prescribe mandatory warnings for the various hazard categories and sub-categories. The label statements are generic in terms of the hazard in order to be applicable to all types of consumer chemical products which fall within a particular sub-category. This ensures a constancy in the messages seen by consumers as well as a consistent set of rules for all companies. In addition, the general nature of the statements eliminates the need for ongoing regulatory amendments, but still provides the flexibility to add more specific information that may be appropriate to the chemical product.

Presentation Requirements:

See sections 17 to 32 of the CCCR, 2001 for the presentation format of the required information.

Additional Statements:

The required labelling is the minimum necessary, and is an indication of the minimum standard of care imposed on a person responsible. Manufacturers and importers can add, and are encouraged to add, information considered necessary to fully inform the public of the hazards of using their products (see subsection 15(2)). In composing these statements, use short, simple sentences. Complex conditional sentences, particularly those containing negations, should be avoided. In addition, a person will remember the important product related information better, if fewer dimensions or items are listed.

However, the person responsible is discouraged from deliberately over-stating the hazards posed by a product. If unwarranted warnings are added to products, it may minimize the perception of risk for those products which actually need the warnings, leading to potential injuries from a lack of concern or precaution by the user.

PART 4

QUICK SKIN-BONDING ADHESIVES

Required instructions and first aid statement

55. The container of a quick skin-bonding adhesive must display the instructions and first aid statement set out in section 56 in the manner set out in sections 17 to 20, 24, 25 and 29 to 32.

Required information

56. (1) Subject to subsection (2), the container of a quick skin-bonding adhesive must display, for each type of information set out in column 1 of the table to this subsection, the information set out in columns 2 and 3.

TABLE TO SUBSECTION 56(1)

REQUIRED INFORMATION - QUICK SKIN-BONDING ADHESIVES

	Column 1	Column 2	Column 3
Item	Type of information	English information	French information
1.	Signal word	CAUTION	ATTENTION
2.	Primary hazard statement	BONDS SKIN INSTANTLY	COLLE RAPIDEMENT LA PEAU
3.	Negative instructions	Do not get in eyes or mouth or on skin.	Éviter tout contact avec les yeux, la peau et la bouche.
4.	Positive instructions	Keep out of reach of children.	Tenir hors de la portée des enfants.
5.	First aid statement	FIRST AID TREATMENT	PREMIERS SOINS
		Contains [*name of hazardous ingredients in descending order of proportion*].	Contient [*name of hazardous ingredients in descending order of proportion*].
		Eyelid bonding: see a doctor. Skin bonding: soak skin in water and call a Poison Control Centre. Do not force apart.	Paupières collées : consulter un médecin. Peau collée : tremper dans l'eau et appeler un centre antipoison. Ne pas forcer pour décoller.

Exception - main display panel less than 35 cm^2

(2) The container of a quick skin-bonding adhesive that has a main display panel of less than 35 cm^2 need only display the information set out in columns 2 and 3 of items 2 and 5 of the table to subsection (1) in the height and body size of type set out in subsection 24(3).

DISCUSSION OF CCCR, 2001 SECTIONS 55 AND 56

Topics

Definitions:

The following terms are defined in section 1 of the CCCR, 2001: container, first aid statement, hazardous ingredient, main display panel, quick skin-bonding adhesive.

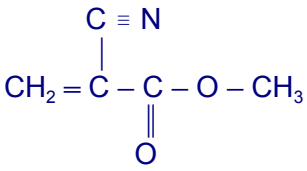
Requirements:

Sections 55 and 56 set out the labelling required for quick skin-bonding adhesives. The criteria for classifying a quick skin-bonding adhesive is in the definition:

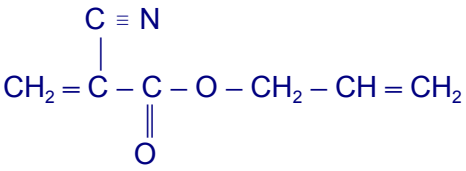
> "quick skin-bonding adhesive" means a Category 4 adhesive set out in Part 4 that has properties similar to an alkyl cyanoacrylate adhesive and that is capable of bonding skin with skin instantly or nearly instantly.

Alkyl cyanoacrylates are monomers with relatively low viscosities. Alkyl cyanoacrylate is a general term, indicating that there is one carbon atom double-bonded to an oxygen atom and two carbon atoms bonded to another oxygen atom somewhere in the molecule (see illustration).

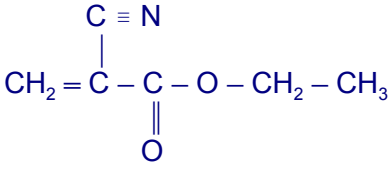
Methyl cyanoacrylate ester:



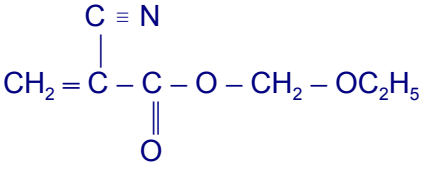
Allyl cyanoacrylate ester:



Ethyl cyanoacrylate ester:



Ethoxymethyl cyanoacrylate ester:



CCCR, 2001 Sections 55 and 56 - PART 4 - QUICK SKIN-BONDING ADHESIVES Required Information

Cyanoacrylate adhesives set in the presence of weak bases, such as water. Moisture is always present in the skin, so cyanoacrylate adhesives tend to set instantly on the skin. Alkyl cyano-acrylates are monomers with relatively low viscosities, so they flow readily from a container and run down the skin or into the eyes, increasing the likelihood of eye or skin exposure. Tissue damage will often result if an attempt is made to force apart the bonded tissues.

Typically, cyanoacrylate glues that are in common household use have been applied to the eye mistakenly as eye drops, causing immediate brief smarting, and firm gluing of the lids together. The glue may cause haze in the cornea and inflammation, but generally without significant permanent injury, except where forceful means were used to separate the bonded tissue.

The ease of separation of bonded skin depends upon the exact chemical composition of the adhesive, the age of the bond and the solvent used. It is easier to break the bonds soon after setting has begun, rather than later. Warm water may be all that is necessary. Acetone may also be used. Other solvents are available but are themselves irritating or toxic. In the absence of tissue-to-tissue bonding, it is best not to attempt to peel off the adhesive. Sweat or other secretions will eventually accumulate under the adhesive film and cause it to lift off.

Presently, alkyl cyanoacrylate adhesives are the only single-component adhesives which pose this hazard. Two component adhesives do not pose such a hazard because the mixing required to activate the adhesive is a deliberate act involving cognition. It is unlikely that a young child would access the two components and mix them prior to being exposed, or that a two-part adhesive would be mistaken for eye drops.

However, the pace of change in the consumer chemical market makes it likely that new types of fast bonding adhesives will appear in the future. The classification criteria are intentionally open, to encompass future products which may pose a similar hazard.

Since there is currently no physical test to quantitatively characterize adhesives that quickly bond the skin, no attempt was made to establish a criteria which might lead to animal testing. There are some promising developments in using “artificial” skin, but no test based on these materials is currently available.

The terms “instantly or nearly instantly” do not specify a set time period because the key words in the definition are “bonding skin with skin”. If the product can bond skin with skin, then the hazard exists and the time it takes for the bonding to occur is less relevant. However, the faster the adhesive bonds, the less time a person has to react to prevent skin bonding from occurring, by washing-off the adhesive.

Exception - Cosmetics:

Cyanoacrylate adhesives sold in artificial fingernail kits are subject to the *Cosmetic Regulations* under the *Food and Drugs Act* and, therefore, are excluded from the jurisdiction of the *Hazardous Products Act*.

CCCR, 2001 Sections 55 and 56 - PART 4 - QUICK SKIN-BONDING ADHESIVES Required Information

Required Information:

The wording for the warnings was developed through a consensus process, with the active collaboration of interested stakeholders, including the medical profession and public health organizations, the chemical industry, consumers' and seniors' groups, academia, technical experts and various federal government departments. During the label development, all sectors involved agreed that the regulations should prescribe mandatory warnings for the various hazard categories and sub-categories. The label statements are generic in terms of the hazard in order to be applicable to all types of consumer chemical products which fall within a particular sub-category. This ensures a constancy in the messages seen by consumers as well as a consistent set of rules for all companies. In addition, the general nature of the statements eliminates the need for ongoing regulatory amendments, but still provides the flexibility to add more specific information that may be appropriate to the chemical product.

Presentation Requirements:

See sections 17 to 32 of the CCCR, 2001 for the presentation format of the required information.

Additional Statements:

The required labelling is the minimum necessary, and is an indication of the minimum standard of care imposed on a person responsible. Manufacturers and importers can add, and are encouraged to add, information considered necessary to fully inform the public of the hazards of using their products (see subsection 15(2)). In composing these statements, use short, simple sentences. Complex conditional sentences, particularly those containing negations, should be avoided. In addition, a person will remember the important product related information better, if fewer dimensions or items are listed.

However, the person responsible is discouraged from deliberately over-stating the hazards posed by a product. If unwarranted warnings are added to products, it may lead to potentially lengthy and unnecessary or inappropriate treatment upon exposure to the product. Furthermore, such a practice minimizes the perception of risk for those products which actually need the warnings, leading to potential injuries from a lack of concern or precaution by the user.

Small Containers:

Inappropriate first aid treatment is the greatest hazard in the case of cyanoacrylate adhesives, which are generally sold to consumers in 1 to 5 mL tubes. Users may tear their skin while pulling apart bonded tissues. For such products, a requirement for the primary hazard statement and first aid statement is appropriate, even when packaged in small containers with a main display panel of less than 35 cm^2. For this reason, and because there is no hazard symbol, quick skin-bonding adhesives are not subject to the small container exemption of subsection 25(2).

CCCR, 2001 Sections 55 and 56 - PART 4 - QUICK SKIN-BONDING ADHESIVES Required Information

Nevertheless, since very small packages of quick skin-bonding adhesives may not have space to print the required information in 6 point and 2 mm type, there is an exemption to be able to use 4.5 point and 1.5 mm type where the main display panel is less than 10 cm^2 (see subsection 24(3)). The minimum size requirements for quick skin-bonding adhesives are summarized below:

Minimum Size Requirements - Quick Skin-Bonding Adhesives

Area of Main Display Panel (cm^2)	Hazard Symbol (mm)	Signal Word (mm)	Hazard Statements, Instructions and First Aid Statement*	
≤ 10.0	not required	1.5	1.5 mm	4.5 point
10.1 - 11.1	not required	1.5	2 mm	6 point
11.2 - 14.8	not required	1.8	2 mm	6 point
14.9 - 19.0	not required	2	2 mm	6 point
19.1 - 23.7	not required	2.3	2 mm	6 point
23.8 - 29.0	not required	2.5	2 mm	6 point
29.1 - 34.9	not required	2.8	2 mm	6 point
35	not required	2.9	2 mm	6 point
35.1 - 41.1	not required	3	2 mm	6 point
41.2 - 47.9	not required	3.3	2 mm	6 point
48.0 - 55.3	not required	3.5	2 mm	6 point
55.4 - 63.2	not required	3.8	2 mm	6 point
63.3 - 71.6	not required	4	2 mm	6 point
71.7 - 80.5	not required	4.3	2 mm	6 point
80.6 - 90.0	not required	4.5	2 mm	6 point
90.1 - < 100	not required	4.8	2 mm	6 point
100	not required	4.9	3 mm	8 point
101 - 110 **	not required	5	3 mm	8 point

* Products with a main display panel area of less than 35 cm^2 need not display negative and positive instructions (see subsection 56(2))
** See section 24 for the requirements for larger sized containers.

CCCR, 2001 Section 57 - PART 4 - QUICK SKIN-BONDING ADHESIVES Child-resistant Packaging

Child-resistant container

57. (1) Subject to subsection (2), a quick skin-bonding adhesive must be in a child-resistant container that complies with sections 9 to 13.

Exception - child-resistant packaging

(2) Subsection (1) does not apply if the packaging that immediately encloses the container and that is displayed to the consumer is child-resistant and complies with sections 9 to 13.

DISCUSSION OF CCCR, 2001 SECTION 57

Topics

Definitions:

The following terms are defined in section 1 of the CCCR, 2001:
container, quick skin-bonding adhesive.

Requirements:

Chemical products that are classified as quick skin-bonding adhesives are required to be packaged in child-resistant containers because of the likelihood of injury should a child come into contact with the product.

See sections 9 to 13 for the design and performance requirements for child-resistant containers. In general, these requirements make it difficult for a child under five years of age to open the container and come into contact with the product within a reasonable time. This requirement means that some children may still be able to open a container if given sufficient time to do so.

Exception:

Outer Packaging

In some cases, the container of quick skin-bonding adhesive is child-resistant. However, very small tubes, usually 2 to 5 mL in volume, that are not child-resistant must be put into a child-resistant package, such as a pill bottle.

The outer child-resistant package may have a hole to allow the tube to protrude as long as the child-resistant requirements are met (for example, it must not be possible to gain access to the glue through the hole).

CCCR, 2001 Section 57 - PART 4 - QUICK SKIN-BONDING ADHESIVES
Child-resistant Packaging

The outer child-resistant package must be appropriately labelled, including the directions for operating the child-resistant container (see sections 11 and 15). However, if the outer packaging is transparent and does not obscure any of the required information on the container within, then this information does not need to be repeated on the outer packaging (see paragraph 16(1)(a)).

More than one tube of cyanoacrylate glue may be placed into the outer child-resistant package, as long as all containers are properly labelled and the outer package meets the chld-resistant container requirements.

CCCR, 2001 Section 58 - PART 5 - PRESSURIZED CONTAINERS Application

PART 5

PRESSURIZED CONTAINERS

Application

58. (1) Subject to subsection (2), this Part applies to a pressurized container that

(*a*) contains or will contain a substance that, when in a liquid state, has an absolute vapour pressure greater than 275 kPa at 37.8˚C as determined using ASTM D 323; or

(*b*) is or will be pressurized to an absolute pressure greater than 275 ± 1 kPa at 21.1˚C or 717 ± 2 kPa at 54.4˚C.

Exceptions

(2) This Part does not apply to a pressurized container that complies with CSA B339.

DISCUSSION OF CCCR, 2001 SECTION 58

Topics

Definitions:

The following terms are defined in section 1 of the CCCR, 2001:
container, vapour, ASTM D 323, CSA B339.

Requirements:

Section 58 classifies a container into the pressurized container hazard category. The criteria describe products that are hazardous because of the internal pressure within the container. If punctured or heated, a pressurized container can rupture, resulting in flying debris or release of hazardous contents. Injuries often include: facial and eye injuries, dental injuries, broken arms and hands, lacerations, bruising, and burns to the hands, arms, face and other parts of the body. In some cases, the container itself can be forcefully propelled and cause injury, especially to the head and face.

CCCR, 2001 Section 58 - PART 5 - PRESSURIZED CONTAINERS Application

Classification:

Conventional pressurized containers currently on the market for consumer use, such as aerosol containers, have internal pressures greater than those specified in the criteria. However, the criteria would not encompass containers that are only slightly pressurized, such as pop bottles or other carbonated beverage containers.

The classification criteria in non-metric units is the following:

1. The pressurized container contains a substance that, when in a liquid state, has an vapour pressure greater than 40 pounds per square inch absolute (psia) at 100 ˚F; or
2. The container is pressurized to greater than 40 psia at 70˚F or 104 psia at 130˚F.

Note that gauge pressure is measured above atmospheric (14.7 psi), hence 40 psia = 25 psig; and 104 psia = 89 psig.

“Vapour pressure” means: the pressure of the vapour given off by a liquid or solid. The vapour pressure increases with temperature. If the liquid or solid is in an enclosed space the number of molecules leaving it eventually reaches an equilibrium with the number of molecules returning to it. At this point, the vapour is saturated and the pressure is the “saturated vapour pressure”.

Aerosol Containers

A typical aerosol container is a metallic container, usually tin-plated steel or aluminum. Tin-plate cans usually consist of three pieces: a base, a seamed cylinder and a top which contains the valve mechanism. Such containers are able to withstand more than 1750 kPa (240 psi). Some two-piece plated steel cans are available. Aluminum cans are usually one piece.

The valve mechanism is typically made up of an actuator, a valve stem, a spring, gaskets and a dipper tube. The dipper tube extends to the bottom of the container and draws the liquid contents up to the valve. When the actuator is pressed-down, it pushes the valve stem through the gasket and opens the valve’s hole, allowing the liquid product to pass through the valve and actuator. The valve and actuator contain small holes and channels, which control the flow-rate through the valve and the spray’s characteristics. Adjustments to these components can affect the droplet size and dispersion of the spray, and hence also influence the flame projection of a flammable product.

Inside the container are the product and propellant under pressure. If a compressed gas is used, it will usually only be in the head-space above the liquid product in the can. If a liquified gas propellant is used, it will exist as both a liquid and as a vapour in the head-space. The liquid and gaseous phases of the propellant are at equilibrium at constant temperature. A temperature increase will cause the equilibrium to shift and increase the pressure within the container. For example, dichlorodifluoromethane has a vapour pressure of 580 kPa at 52˚C and 3100 kPa at 99˚C. Such drastic increases in pressure means that putting an aerosol

container in a fire or on a stove (or even leaving it in the trunk of a car on a hot day) may cause the pressure in the container to exceed the bursting pressure, resulting in a leak or explosion.

Propellants

Most aerosol containers today use liquefied petroleum gas (LPG) as a propellant. LPG is a mixture of propane, isobutane and n-butane, which are all flammable gases. Chlorofluoro-carbons (CFC's) are liquefied propellant gases which were commonly used in consumer chemical products in the past, until they were prohibited under the *Canadian Environmental Protection Act* (*CEPA*). Dimethyl ether, an alternative to liquefied propellant, is sometimes used (eg. in air fresheners); it is also flammable. Non-soluble compressed gases such as compressed air or nitrogen are sometimes seen in consumer products. Carbon dioxide is a soluble compressed gas that is occasionally used for specialized applications.

With liquefied propellants, the propellant is an essential part of the formulation. When the liquid propellant emerges from the actuator, it will vaporise immediately. Thus, if the propellant is intimately mixed with the product, the emerging droplets will burst into smaller droplets as the propellant vaporises. In this way, the ultimate size of the droplets is also controlled by adjusting the amount of propellant and its pressure in the aerosol container.

With compressed gas propellants, the propellant occupies the head-space within the can and usually does not mix with the product. The propellant pushes the liquid out of the can, and only the product is sprayed-out. As the product is used-up, the pressure will drop as the propellant gas has more and more space within the can. For these products, the only means to control the spray is through the valve and actuator design.

Other Pressurized Containers

Refillable and non-metallic pressurized containers are now marketed, as well as products which release the contents through the operation of a valve in the product rather than on the pressurized container itself (for example, butane-fuelled curling irons). The hazard posed by these products are the same as that for the conventional disposable aerosol dispenser: rupture of the container and violent release of the contents when punctured or heated, especially if placed in a fire or trash compactor.

The pressurized container hazard category includes all products that pose a bursting hazard, whatever the means of construction. The criteria also apply to products designed for and intended to be used as pressurized containers which are sold empty but filled and pressurized by the user.

CCCR, 2001 Section 58 - PART 5 - PRESSURIZED CONTAINERS Application

Harmonization With the WHMIS Controlled Products Regulations:

The CCCR, 2001 classification criteria for pressurized containers in section 58 are harmonized with those for workplace chemicals under the requirements of *WHMIS* for compressed gases. The pressurized container hazard category is equivalent to *WHMIS* Class A (compressed gas) in paragraphs 34(c) and (d) of the *Controlled Products Regulations*. Note that the CCCR, 2001 do not include criteria for critical temperature and absolute vapour pressure at 50˚C

Harmonization With the Transportation of Dangerous Goods (TDG) Regulations:

The classification criteria for pressurized containers are the same as that adopted in the *Transportation of Dangerous Goods (TDG) Regulations*. For typical aerosol containers, the risk may be reduced by the requirements of the *TDG Regulations*, which require the testing of pressurized containers in a water bath at 50˚C to ensure container integrity during shipment. However, this testing requirement is strictly for transport and does not eliminate the hazard once a consumer uses or stores the product at home.

Exception - Barbecue Cylinders:

Subsection 58(2) exempts containers that meet the requirements of CSA B339 (entitled *Cylinders, Spheres and Tubes for the Transportation of Dangerous Goods*), which sets out performance requirements for pressurized containers such as barbecue cylinders. When the product is in compliance with the standard, the hazard should be minimized and therefore pressurized container labelling is not required.

CCCR, 2001 Section 59 - PART 5 - PRESSURIZED CONTAINERS Required Information

Required information

59. A pressurized container must display, for each type of information set out in column 1 of the table to this section, the information set out in columns 2 and 3.

TABLE TO SUBSECTION 59

REQUIRED INFORMATION - PRESSURIZED CONTAINERS

	Column 1	Column 2	Column 3
Item	Type of information	English information	French information
1.	Hazard symbol		
2.	Signal word	CAUTION	ATTENTION
3.	Primary hazard statement	CONTENTS UNDER PRESSURE	CONTENU SOUS PRESSION
4.	Specific hazard statement	CONTAINER MAY EXPLODE IF HEATED	CE CONTENANT PEUT EXPLOSER S'IL EST CHAUFFÉ
5.	Negative instructions	Do not puncture. Do not burn.	Ne pas perforer. Ne pas brûler.
6.	Positive instructions	Store away from heat.	Conserver loin des sources de chaleur.

DISCUSSION OF CCCR, 2001 SECTION 59

Topics

Definitions:

The following terms are defined in section 1 of the CCCR, 2001:
container, hazard symbol.

Requirements:

The wording for the warnings was developed through a consensus process, with the active collaboration of interested stakeholders, including the medical profession and public health organizations, the chemical industry, consumers' and seniors' groups, academia, technical experts and various federal government departments. During the label development, all sectors involved agreed that the regulations should prescribe mandatory warnings for the various hazard categories and sub-categories. The label statements are generic in terms of the hazard in order to be

applicable to all types of consumer chemical products which fall within a particular sub-category. This ensures a constancy in the messages seen by consumers as well as a consistent set of rules for all companies. In addition, the general nature of the statements eliminates the need for ongoing regulatory amendments, but still provides the flexibility to add more specific information that may be appropriate to the chemical product.

Presentation Requirements:

See sections 17 to 32 of the CCCR, 2001 for the presentation format of the required information.

Additional Information:

The required labelling is the minimum necessary, and is an indication of the minimum standard of care imposed on a person responsible. Manufacturers and importers can add, and are encouraged to add, information considered necessary to fully inform the public of the hazards of using their products (see subsection 15(2)). In composing these statements, use short, simple sentences. Complex conditional sentences, particularly those containing negations, should be avoided. In addition, a person will remember the important product related information better, if fewer dimensions or items are listed.

However, the person responsible is discouraged from deliberately over-stating the hazards posed by a product. If unwarranted warnings are added to products, it may lead to potentially lengthy and unnecessary or inappropriate treatment upon exposure to the product. Furthermore, such a practice minimizes the perception of risk for those products which actually need the warnings, leading to potential injuries from a lack of concern or precaution by the user.

CCCR, 2001 Sections 60 to 62 - COMING INTO FORCE

TRANSITIONAL PROVISION

Transition period - excluding a retailer

60. (1) A person, other than a retailer, who on October 1, 2001 is in the business of producing, selling or importing a chemical product or a container that complies with the *Consumer Chemicals and Containers Regulations* as they read on September 30, 2001, or who incidentally, as part of their business, is producing, selling or importing such a chemical product or container, may continue the activity with respect to that product or container for a period of two years commencing on October 1, 2001.

Transition period - retailer

(2) A retailer may sell to a consumer a chemical product or a container that complies with the *Consumer Chemicals and Containers Regulations*, as they read on September 30, 2001,

(*a*) for a period of four years commencing on October 1, 2001, in the case of a product or container that is classified only in any or all of the hazard category "Category 5, Pressurized Container" or the sub-categories "harmful", "irritant" or "combustible"; and

(*b*) for a period of three years commencing on October 1, 2001, in any other case.

Definition of "producing"

(3) In subsection (1), "producing" a chemical product or container means that the plating-up stage of production, necessary for printing the label for the chemical product or container, has been completed.

REPEAL

Repeal - *Consumer Chemicals and Containers Regulations*

61. The *Consumer Chemicals and Containers Regulations* (SOR/88-556) are repealed.

COMING INTO FORCE

Coming into force

62. These Regulations come into force on October 1, 2001.

DISCUSSION OF CCCR, 2001 SECTIONS 60 to 62

Definitions:

The following terms are defined in section 1 of the CCCR, 2001:
chemical product, container, hazard category, subcategory.

Topics

Transition Between Regulations:

The *CCCR, 2001* came into effect on October 1, 2001, with a transition period for existing consumer chemical products and containers that complied with the previous *Consumer Chemicals and Containers Regulations* (CCCR). There is a two-year transition period for upper-level suppliers of consumer chemical products and containers, with an additional one- or two-year transition period at retail, depending on the hazard posed by the product.

The transition period applied to consumer chemical products and containers that were being produced, sold or imported prior to October 1, 2001. A product must have reached the stage of production at which the plating-up of its label was completed and the plated-up label complied with the CCCR. Manufacturers, distributors and importers have until September 30, 2003 to meet the requirements of the CCCR, 2001. During the two-year transition period, products that comply with either the CCCR or the CCCR, 2001 are legal. After October 1, 2003, all consumer chemical products and containers must be in full compliance with the CCCR, 2001 when they are imported or sold above the retail level of trade.

Products that were being sold in Canada before October 1, 2001 that were not subject to the CCCR but are now covered under the CCCR, 2001 qualify for the transition period. But the transition period does not apply in the following circumstances:

New Products: the product was not produced, sold or imported into Canada prior to October 1, 2001;

Modified Products: the product was produced before October 1, 2001 in compliance with the CCCR, but there has been a subsequent change to the product's formulation, labelling or packaging;

Noncompliant: the product was produced before October 1, 2001, but it did not comply with the CCCR.

Hence, new or modified products, or products that did not comply to the previous CCCR as of October 1, 2001, do not qualify for the transition period and must meet the CCCR, 2001 immediately.

Examples:

The following examples may help to clarify the transitional provision:

1. Product A is available at retail prior to October 1st, 2001 and is regulated by and complies with the former CCCR.

   Since Product A already complies with the former CCCR, it can legally comply with either the CCCR or the CCCR, 2001 during the transition period. Product A, with its existing packaging and labelling, can be manufactured or imported until September 30, 2003 and sold at retail until either September 30, 2004 or 2005 depending on the level of risk.

2. Product B is a new product that would have been regulated by the former CCCR if it had been sold at retail prior to October 1st, 2001. It was in production on September 30, 2001 and reached the stage where the printing plates that comply with the former CCCR were completed.

   Product B is equivalent to Product A. Product B can legally comply with either the former CCCR or the CCCR, 2001 during the transition period. It is not practical for the producer of Product B to incur the immediate cost of re-plating to comply with the CCCR, 2001. Instead, the transition provision recognizes the producer as a person "in the business of producing" the product in accordance with the former CCCR. Such producers will not be penalized for failing to introduce the product to retail before October 1, 2001.

3. Product C is available at retail on October 1st , 2001, and was not regulated by the former CCCR but is regulated by the CCCR, 2001.

   Since Product C was not subject to the former CCCR, it can either continue to use its current labelling and packaging or be labelled and packaged in accordance with the CCCR, 2001 during the transition period. Product C in its old form can be manufactured or imported until September 30, 2003 and sold at retail with its existing labelling until either September 30, 2004 or 2005, depending on the level of risk. However, Health Canada strongly urges that such products be brought into compliance with the CCCR, 2001 as soon as possible.

4. Product D is a new product that would not have been regulated by the former CCCR but will be regulated by the CCCR, 2001. It was in production on September 30, 2001 and reached the stage where the printing plates were completed.

   Product D is equivalent to Product C. Product D can legally use its existing labelling and packaging or can comply with the CCCR, 2001. It is not practical to force the producer of Product D to incur the immediate cost of re-plating to comply with the CCCR, 2001. Instead, the provision recognizes the producer of this product as a person "in the business of producing" the product in accordance with the former CCCR. While such producers will not be penalized for failing to introduce the product to retail before October 1, 2001, Health Canada strongly urges that such products be brought into compliance with the CCCR, 2001 as soon as possible.

5. Product E is a new product that would have been regulated by the former CCCR. It was in production on September 30, 2001, but had not reached the stage where the printing plates that comply with the former CCCR were completed.

   Product E must comply with the CCCR, 2001 as of October 1, 2001. The producer of Product E had not developed plates to produce the label in compliance with the former CCCR in time to qualify for the transition provision. The producer must create a label and use packaging that complies with the CCCR, 2001 before the product is put on the market.

6. Product F is a new product that would not have been regulated by the former CCCR. It is in production on September 30, 2001, but had not reached the stage where the printing plates that comply with the former CCCR were completed.

   Product F must comply with the CCCR, 2001 as of October 1, 2001. The producer of Product F had not developed plates to produce the label for the product in time to qualify for the transition provision. The producer must create a label and to use packaging that complies with the CCCR, 2001 before the product is put on the market.