Phenolphthalein disulfate tripotassium salt hydrate

sc-272017

Material Safety Data Sheet

Hazard Alert Code Key:	EXTREME	HIGH	MODERATE	LOW

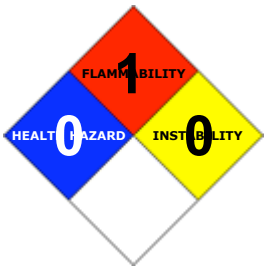
Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME
Phenolphthalein disulfate tripotassium salt hydrate

STATEMENT OF HAZARDOUS NATURE

CONSIDERED A HAZARDOUS SUBSTANCE ACCORDING TO OSHA 29 CFR 1910.1200.

NFPA



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EMERGENCY
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SYNONYMS
C20H13K3O11S2·xH2O

Section 2 - HAZARDS IDENTIFICATION

CHEMWATCH HAZARD RATINGS

		Min	Max
Flammability:	1		
Toxicity:	2		
Body Contact:	0		
Reactivity:	1		
Chronic:	3		

Min/Nil=0
Low=1
Moderate=2
High=3
Extreme=4

CANADIAN WHMIS SYMBOLS

EMERGENCY OVERVIEW

RISK

Possible risk of impaired fertility.
Possible risk of irreversible effects.

POTENTIAL HEALTH EFFECTS

ACUTE HEALTH EFFECTS

SWALLOWED

■ Accidental ingestion of the material may be damaging to the health of the individual.
■ Phenolphthalein is used as a laxative.
Large doses phenolphthalein and related substances cause nausea, vomiting and diarrhoea.
■ Constant use of purgatives/laxatives may decrease the sensitivity of the intestinal mucosa causing a diminished response to normal stimuli.
The redevelopment of a normal habit is thus prevented.

EYE

■ Although the material is not thought to be an irritant, direct contact with the eye may cause transient discomfort characterized by tearing or conjunctival redness (as with windburn).
Slight abrasive damage may also result.

SKIN

■ The material is not thought to produce adverse health effects or skin irritation following contact (as classified using animal models).
Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable gloves be used in an occupational setting.
■ Open cuts, abraded or irritated skin should not be exposed to this material.
■ Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects.
Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.

INHALED

■ The material is not thought to produce either adverse health effects or irritation of the respiratory tract following inhalation (as classified using animal models).
Nevertheless, adverse effects have been produced following exposure of animals by at least one other route and good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting.
■ Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled.

CHRONIC HEALTH EFFECTS

■ Strong evidence exists that the substance may cause irreversible but non-lethal mutagenic effects following a single exposure.
There is ample evidence that this material can be regarded as being able to cause cancer in humans based on experiments and other information.
Ample evidence from experiments exists that there is a suspicionthis material directly reduces fertility.
Exposure to the material may result in a possible risk of irreversible effects. The material may produce mutagenic effects in man. This concern is raised, generally, on the basis of
appropriate studies using mammalian somatic cells in vivo. Such findings are often supported by positive results from in vitro mutagenicity studies.
Limited evidence suggests that repeated or long-term occupational exposure may produce cumulative health effects involving organs or biochemical systems.
There is some evidence that inhaling this product is more likely to cause a sensitization reaction in some persons compared to the general population.
There is limited evidence that, skin contact with this product is more likely to cause a sensitization reaction in some persons compared to the general population.
Very rarely, allergic reactions occur with phenolphthalein and its analogues.
In one study over fifteen per cent of the patients (177) in a gastroenterologic clinic employed phenolphthalein as a habitual laxative. In a large percentage (152) a diagnosis of catarrhal colitis was made. A small percentage (22) had established a tolerance for the drug and exhibited no signs of toxicity. Chronic stomatitis was present in three patients addicted to the drug.
In industrial situations, long-term, repeated exposure to high levels of dust will lead to chronic non-specific lung disease (ILO Encyclopaedia). Indiscriminate use of phenolphthalein results in chronic constipation and laxative dependence, loss of normal bowel function, and bowel irritation.
Habitual use over several years may cause a "cathartic colon", i.e., a poorly functioning, atonic dilation of the colon, especially of the right side, resulting in extensive bowel retention. This condition resembles chronic ulcerative colitis both radiologically and pathologically, involves thinning of the intestinal wall and loss of the normal mucosal pattern of the terminal ileum. Long term use or overdose have been associated, anecdotally, with abdominal pain, diarrhoea, electrolyte imbalance (hypokalaemia, hypocalcaemia, and/ or metabolic acidosis or alkalosis), dehydration, malabsorption, protein-losing gastroenteropathy, steatorrhea, anorexia, weight loss, polydipsia, polyuria, cardiac arrhythmias, muscle weakness, prostration and histopathologic lesions.
Kidney, muscle, and central nervous system disturbances may be due to electrolyte imbalance. Hypokalaemia contributes to kidney dysfunction associated with rhabdomyolysis (muscle wasting).
Phenolphthalein allergy is often manifested by inflammatory reactions of the skin. In extreme cases recurrences involve progressively more severe lesions characterised by bullous erythema multiforme, with focal haemorrhage and necrosis. Cross-sensitivity reactions in individuals previously sensitised by phthalic anhydride and its congeners, might be the subject of speculation.
Phenolphthalein has weak oestrogen activity, in fashion similar to that said to be exerted by other phthalates. Phenolphthalein competes with oestrogen for binding sites on cultured MCF-7 human breast cancer cells.
In a study conducted in Melbourne, Australia, with 1408 subjects, there was no statistically significant increased risk of colorectal cancer in phenolphthalein laxative users (Kune, 1993).
Under the conditions of a 2-year feed study using male rats, there was clear evidence of carcinogenic activity based on a marked increased in the incidence of benign pheochromocytomas of the adrenal medulla, and of renal tubule adenomas, and adenomas or carcinomas

(combined). There was some evidence of carcinogenic activity of phenolphthalein in female rats. There was clear evidence in male mice of carcinogenic activity based on increased incidences of histiocytic sarcomas an of malignant lymphomas of thymic origin. In female mice there was also clear evidence of carcinogenic activity based on increased incidences of histiocytic sarcomas, malignant tumours of all types, lymphomas of thymic origin, and benign sex-cord stromal tumours of the ovary.
National Toxicological Program, Technical Reports Series, No. 465, 1996
Phenolphthalein causes enhanced oxygen radical production in in vitro systems. In vivo, reduction of phenoxy radicals could allow reformation of phenolphthalein, establishing a futile cycle of oxidation and reduction, thereby generating more free radical species. Thus, phenolphthalein may be a significant source of oxidative stress in physiological systems.
Abnormal sperm were induced in male mice, but not male rats, treated with phenolphthalein via dosed feed for 13 weeks.
In a mouse carcinogenicity bioassay phenolphthalein produced evidence of carcinogenic effects with significant increases in histiocytic sarcoma and malignant lymphoma. Benign ovary tumours were significantly increased in all treatment groups.
Phenolphthalein induces a significant increase in the frequency of chromosome aberrations in human cells. The lowest dose level at which the clastogenic effect is evident is 23 ug/ml. Similar positive results were obtained in a Chinese hamster liver cell line, which is metabolically competent to activate different classes of promutagens and procarcinogens into biologically active metabolites. Instead, parallel experiments in Chinese hamster ovary cells did not show any clastogenic effect due to phenolphthalein. These latter data suggested that phenolphthalein acts as a promutagen and must be metabolically activated to exert its clastogenic effect. Teratogenesis Carcinog. Mutagen. 20:209-217, 2000.
Extended use of purgatives and laxatives can cause a profuse, watery diarrhea with severe dehydration, mineral losses, weakness and weight loss. Absorption from the bowel may become impaired and damage to the heart and kidneys can also occur.

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

NAME	CAS RN	%
phenolphthalein disulfate, tripotassium salt	62625-16-5	>98

Section 4 - FIRST AID MEASURES

SWALLOWED
· If swallowed do NOT induce vomiting. · If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.

EYE
■ If this product comes in contact with the eyes: · Wash out immediately with fresh running water. · Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.

SKIN
■ If skin contact occurs: · Immediately remove all contaminated clothing, including footwear · Flush skin and hair with running water (and soap if available).

INHALED
· If dust is inhaled, remove from contaminated area. · Encourage patient to blow nose to ensure clear passage of breathing. · If irritation or discomfort persists seek medical attention.

NOTES TO PHYSICIAN
■ Treat symptomatically.

Section 5 - FIRE FIGHTING MEASURES

Vapour Pressure (mmHG):	Negligible
Upper Explosive Limit (%):	Not available.
Specific Gravity (water=1):	Not available
Lower Explosive Limit (%):	Not available

EXTINGUISHING MEDIA
· Water spray or fog.
· Foam.

FIRE FIGHTING
· Alert Emergency Responders and tell them location and nature of hazard.
· Wear breathing apparatus plus protective gloves.

GENERAL FIRE HAZARDS/HAZARDOUS COMBUSTIBLE PRODUCTS
· Combustible solid which burns but propagates flame with difficulty.
· Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion. Dust clouds generated by the fine grinding of the solid are a particular hazard; accumulations of fine dust may burn rapidly and fiercely if ignited.
Combustion products include: carbon monoxide (CO), carbon dioxide (CO_2), sulfur oxides (SOx), metal oxides, other pyrolysis products typical of burning organic material.
May emit poisonous fumes.
May emit corrosive fumes.

FIRE INCOMPATIBILITY
■ Avoid contamination with oxidizing agents i.e. nitrates, oxidizing acids,chlorine bleaches, pool chlorine etc. as ignition may result.

PERSONAL PROTECTION

Glasses:
Chemical goggles.
Gloves:
Respirator:
Particulate

Section 6 - ACCIDENTAL RELEASE MEASURES

MINOR SPILLS
· Clean up waste regularly and abnormal spills immediately.
· Avoid breathing dust and contact with skin and eyes.
· Wear protective clothing, gloves, safety glasses and dust respirator.
· Use dry clean up procedures and avoid generating dust.
· Vacuum up or sweep up. NOTE: Vacuum cleaner must be fitted with an exhaust micro filter (HEPA type) (consider explosion-proof machines designed to be grounded during storage and use).
· Dampen with water to prevent dusting before sweeping.
· Place in suitable containers for disposal.
MAJOR SPILLS
· Clear area of personnel and move upwind.
· Alert Emergency Responders and tell them location and nature of hazard.

Section 7 - HANDLING AND STORAGE

PROCEDURE FOR HANDLING

· Avoid all personal contact, including inhalation.
· Wear protective clothing when risk of exposure occurs.
Empty containers may contain residual dust which has the potential to accumulate following settling. Such dusts may explode in the presence of an appropriate ignition source.
· Do NOT cut, drill, grind or weld such containers.
· In addition ensure such activity is not performed near full, partially empty or empty containers without appropriate workplace safety authorisation or permit.

RECOMMENDED STORAGE METHODS

· Polyethylene or polypropylene container.
· Check all containers are clearly labelled and free from leaks.

STORAGE REQUIREMENTS

· Store in original containers.
· Keep containers securely sealed.

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS

Source	Material	TWA ppm	TWA mg/m³	STEL ppm	STEL mg/m³	Peak ppm	Peak mg/m³	TWA F/CC	Notes
Canada - British Columbia Occupational Exposure Limits	phenolphthalein disulfate, tripotassium salt (Particles (Insoluble or Poorly Soluble) Not Otherwise Classified (PNOC))		10 (N)						
US - Wyoming Toxic and Hazardous Substances Table Z1 Limits for Air Contaminants	phenolphthalein disulfate, tripotassium salt (Particulates not otherwise regulated (PNOR)(f)-Respirable fraction)		5						
US - Tennessee Occupational Exposure Limits - Limits For Air Contaminants	phenolphthalein disulfate, tripotassium salt (Particulates not otherwise		5						

	regulated Respirable fraction)					
US - California Permissible Exposure Limits for Chemical Contaminants	phenolphthalein disulfate, tripotassium salt (Particulates not otherwise regulated Respirable fraction)		5			(n)
US - Oregon Permissible Exposure Limits (Z-1)	phenolphthalein disulfate, tripotassium salt (Particulates not otherwise regulated (PNOR) (f) Total Dust)	-	10			Bold print identifies substances for which the Oregon Permissible Exposure Limits (PELs) are different than the federal Limits. PNOR means “particles not otherwise regulated.”
US - Michigan Exposure Limits for Air Contaminants	phenolphthalein disulfate, tripotassium salt (Particulates not otherwise regulated, Respirable dust)		5			
Canada - Prince Edward Island Occupational Exposure Limits	phenolphthalein disulfate, tripotassium salt (Particles (Insoluble or Poorly Soluble) [NOS] Inhalable particles)		10			See Appendix B current TLV/BEI Book
US - Oregon Permissible Exposure Limits (Z-1)	phenolphthalein disulfate, tripotassium salt (Particulates not otherwise regulated (PNOR) (f) Respirable Fraction)	-	5			Bold print identifies substances for which the Oregon Permissible Exposure Limits (PELs) are different than the federal Limits. PNOR means “particles not otherwise regulated.”

ENDOELTABLE

PERSONAL PROTECTION



RESPIRATOR

Particulate

EYE

· Safety glasses with side shields.
· Chemical goggles.

HANDS/FEET

■ NOTE: The material may produce skin sensitization in predisposed individuals. Care must be taken, when removing gloves and other protective equipment, to avoid all possible skin contact.
Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include: such as:
· frequency and duration of contact,
· chemical resistance of glove material,
· glove thickness and
· dexterity
Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739).
· When prolonged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 240 minutes according to EN 374) is recommended.
· When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374) is recommended.
· Contaminated gloves should be replaced.
Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.
Experience indicates that the following polymers are suitable as glove materials for protection against undissolved, dry solids, where abrasive particles are not present.
· polychloroprene
· nitrile rubber
· butyl rubber
· fluorocaoutchouc
· polyvinyl chloride
Gloves should be examined for wear and/ or degradation constantly.

OTHER

· Employees working with confirmed human carcinogens should be provided with, and be required to wear, clean, full body protective clothing (smocks, coveralls, or long-sleeved shirt and pants), shoe covers and gloves prior to entering the regulated area.
· Employees engaged in handling operations involving carcinogens should be provided with, and required to wear and use half-face filter-type respirators with filters for dusts, mists and fumes, or air purifying canisters or cartridges. A respirator affording higher levels of protection may be substituted.
· Emergency deluge showers and eyewash fountains, supplied with potable water, should be located near, within sight of, and on the same level with locations where direct exposure is likely.
· Prior to each exit from an area containing confirmed human carcinogens, employees should be required to remove and leave protective clothing and equipment at the point of exit and at the last exit of the day, to place used clothing and equipment in impervious containers at the point of exit for purposes of decontamination or disposal. The contents of such impervious containers must be identified with suitable labels. For maintenance and decontamination activities, authorized employees entering the area should be provided with and required to wear clean, impervious garments, including gloves, boots and continuous-air supplied hood.
· Prior to removing protective garments the employee should undergo decontamination and be required to shower upon removal of the garments and hood.
· Overalls.
· P.V.C. apron.
· Barrier cream.
· Skin cleansing cream.
· Eye wash unit.

ENGINEERING CONTROLS

· Employees exposed to confirmed human carcinogens should be authorized to do so by the employer, and work in a regulated area.
· Work should be undertaken in an isolated system such as a "glove-box" . Employees should wash their hands and arms upon completion of the assigned task and before engaging in other activities not associated with the isolated system.
· Within regulated areas, the carcinogen should be stored in sealed containers, or enclosed in a closed system, including piping systems, with any sample ports or openings closed while the carcinogens are contained within.
· Open-vessel systems are prohibited.
· Each operation should be provided with continuous local exhaust ventilation so that air movement is always from ordinary work areas to the operation.
· Exhaust air should not be discharged to regulated areas, non-regulated areas or the external environment unless decontaminated. Clean make-up air should be introduced in sufficient volume to maintain correct operation of the local exhaust system.
· For maintenance and decontamination activities, authorized employees entering the area should be provided with and required to wear clean, impervious garments, including gloves, boots and continuous-air supplied hood. Prior to removing protective garments the employee should undergo decontamination and be required to shower upon removal of the garments and hood.
· Except for outdoor systems, regulated areas should be maintained under negative pressure (with respect to non-regulated areas).
· Local exhaust ventilation requires make-up air be supplied in equal volumes to replaced air.
· Laboratory hoods must be designed and maintained so as to draw air inward at an average linear face velocity of 150 feet/ min. with a minimum of 125 feet/ min. Design and construction of the fume hood requires that insertion of any portion of the employees body, other than hands and arms, be disallowed.

Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL PROPERTIES

Solid.
Mixes with water.

State	Divided solid	Molecular Weight	610.75(anhy)
Melting Range (°F)	Not available	Viscosity	Not Applicable
Boiling Range (°F)	Not available	Solubility in water (g/L)	Miscible
Flash Point (°F)	Not available	pH (1% solution)	Not applicable
Decomposition Temp (°F)	Not available	pH (as supplied)	Not applicable
Autoignition Temp (°F)	Not available	Vapour Pressure (mmHG)	Negligible
Upper Explosive Limit (%)	Not available.	Specific Gravity (water=1)	Not available
Lower Explosive Limit (%)	Not available	Relative Vapor Density (air=1)	Not Applicable
Volatile Component (%vol)	Negligible	Evaporation Rate	Not applicable

APPEARANCE
Off-white powder; mixes with water.

Section 10 - CHEMICAL STABILITY

CONDITIONS CONTRIBUTING TO INSTABILITY
· Presence of incompatible materials.
· Product is considered stable.

STORAGE INCOMPATIBILITY
■ Avoid reaction with oxidizing agents.

For incompatible materials - refer to Section 7 - Handling and Storage.

Section 11 - TOXICOLOGICAL INFORMATION

phenolphthalein disulfate, tripotassium salt

TOXICITY AND IRRITATION
PHENOLPHTHALEIN DISULFATE, TRIPOTASSIUM SALT:
■ unless otherwise specified data extracted from RTECS - Register of Toxic Effects of Chemical Substances.
■ For phenolphthalein
Phenolphthalein is absorbed in the small bowel and is conjugated in the liver to form phenolphthalein glucuronide, which is eliminated in the bile. As it passes through the small intestine, it is partially deconjugated and reabsorbed. Phenolphthalein and its glucuronide enhance oxygen radical production and cause oxidative damage in vitro. Phenolphthalein has also been shown to have low oestrogenic activity in some model systems. Phenolphthalein induced micronucleated erythrocytes in mice given multiple but not single treatments by gavage or in feed. Abnormal spermatozoa were induced in male mice but not male rats treated with phenolphthalein in the feed for 13 weeks. The malignant thymic lymphomas induced by phenolphthalein in female heterozygous p53-deficient mice showed loss of the normal p53 allele.
Phenolphthalein induced chromosomal aberrations, Hprt gene mutations and morphological transformation but not aneuploidy or ouabain-resistant mutations or sister chromatid exchange in cultured mammalian cells. It did not induce gene mutations in bacteria.
The main target organ for the toxic effects of phenolphthalein is reported to be the intestine. Indiscriminate use of phenolphthalein results in chronic constipation and laxative dependence, loss of normal bowel function and bowel irritation. Habitual use for several years may cause a "cathartic colon", i.e. a poorly functioning colon with atonic dilatation, especially on the right side, resulting in extensive retention of the bowel contents. The clinical condition, which resembles chronic ulcerative colitis both radiologically and pathologically, involves thinning of the intestinal wall and loss of the normal mucosal pattern of the terminal ileum .
Anecdotal cases of long-term use or overdose of phenolphthalein have been associated with abdominal pain, diarrhoea, vomiting, electrolyte imbalance (hypokalaemia, hypocalcaemia and/or metabolic acidosis or alkalosis), dehydration, malabsorption, protein-losing gastroenteropathy, steatorrhoea, anorexia, weight loss, polydipsia, polyuria, cardiac arrhythmia, muscle weakness, prostration and histopathological lesions . Kidney, muscle and central nervous system disturbances are thought to be due to electrolyte imbalance. Loss of intestinal sodium and water stimulates compensatory renin production and secondary aldosteronism, leading to sodium conservation and potassium loss by the kidney. The hypokalaemia contributes to renal insufficiency and is sometimes associated with rhabdomyolysis.
Abuse of phenolphthalein-containing laxatives has been associated with gastrointestinal bleeding, iron-deficient anaemia, acute pancreatitis and multiple organ damage in cases of massive overdose, including fulminant hepatic failure and disseminated intravascular coagulation
Allergy to phenolphthalein is often manifested as cutaneous inflammatory reactions or fixed drug eruptions, i.e. solitary or multiple, well-defined, erythematous macules that may progress to vesicles and/or bullae. These lesions characteristically recur in the same location with each subsequent dose of phenolphthalein and generally leave residual hyperpigmentation that increases in intensity with each exposure; numerous melanin-containing dermal macrophages have been found in pigmented areas In extreme cases, recurrences have involved progressively more severe lesions characterised as bullous erythema multiforme, with focal haemorrhage and necrosis and perivascular lymphocytic infiltration and, in one case report, toxic epidermal necrolysis
A review of 204 cases of phenolphthalein ingestion in children aged five years and younger reported to the Pittsburgh Poison Center (USA) over a 30-month period indicated that ingestion of < 1 g was associated with a minimal risk of developing dehydration due to excessive diarrhoea and resulting fluid loss
Despite the profile of low acute toxicity documented in this study, cases of fatal poisoning of children have been reported; symptoms of pulmonary and cerebral oedema, multiple organ effects and encephalitis were attributed to hypersensitivity reactions. Repeated administration of phenolphthalein-containing laxatives to children has led to serious illness and multiple hospitalisations
Analogy with related biphenolic compounds suggests that phenolphthalein has oestrogenic activity; however, studies with MCF-7 human breast cancer cells in tissue culture and in rat uterus in vivo suggested only a weak oestrogenic response.
Phenolphthalein is a partial oestrogen in immature rat uteri. Doses of 1-10 mg given subcutaneously twice daily for two days to female Wistar rats weighing 35-40 g induced a dose-related increase in uterine weight, but the maximum increase was only about half of that

induced by oestradiol. Phenolphthalein was shown to bind to the oestrogen receptor and was a competitive antagonist to oestradiol.
In a study reported in an abstract, exposure of female B6C3F1 mice to 1895 mg/kg bw phenolphthalein orally [method not stated] daily for 30 or 60 days caused no changes in weight gain, oestrous cycles or the numbers of oocyte-containing follicles of any class (primordial, primary, growing or antral), or any detectable pathological
change in ovarian cells. In a 1997 study there was no evidence of reproductive toxicity in female B6C3F1 mice or male or female Fischer 344/N rats. Lower epididymal weights and lower sperm density (number of sperm/g of crude epididymal tissue) were observed in male mice at 12 000, 25 000 and 50 000 mg/kg
Studies have shown that phenolphthalein, at high dose levels, is carcinogenic in mice and has a weak genotoxic (clastogenic) activity in vivo. With respect to the carcinogenicity study, the US FDA has stated that " the systemic exposures in rodents were approximately 40 to 70 fold and 60 to 100 fold the human exposure for rats and mice, respectively
Phenolphthalein is reasonably anticipated to be a human carcinogen based on sufficient evidence of increased incidence of malignant and/or combination of malignant and benign tumors in multiple tissue sites and in multiple species (IARC 2000). In a two-year B6C3F1 mouse carcinogenicity study, NTP (1996) concluded that phenolphthalein, administered in feed, induced significant increases in the incidence of histiocytic sarcoma and lymphomas of thymic origin in males and females and malignant lymphoma (all types) and benign ovarian sex cord stromal tumors in females. In the corresponding Fischer 344 rat dietary carcinogenicity study, phenolphthalein induced significant increases in the incidence of benign pheochromocytoma of the adrenal medulla in males and females and renal tubule adenoma in males (NTP 1996). In a 6-month dietary study with female heterozygous p53-deficient transgenic mice, phenolphthalein induced a significant increase in the incidence of malignant lymphoma of thymic origin .
A few epidemiological studies have investigated the association between the use of phenolphthalein-containing laxatives and colon cancer or adenomatous colorectal polyps. No consistent association was found.
Phenolphthalein has been identified as a multisite carcinogen in rodents, but the molecular species responsible for the carcinogenicity is not known. A catechol metabolite hydroxyphenolphthalein , was recently identified and may be the molecular species responsible for at least part of the toxicity/carcinogenicity The metabolite is an extremely potent mixed-type inhibitor of the O-methylation of the catechol estrogens. It has been suggested that chronic administration of phenolphthalein may enhance metabolic redox cycling of both the metabolite and the catechol estrogens and this, in turn, may contribute to hydroxyphenolphthalein-induced tumourigenesis.
Toxicol Appl. Pharmacol Vol 162(2) pp 124-131 2000
Although negative for mutagenicity and DNA damage in bacteria, phenolphthalein exhibits genetic activity in several in vitro and in vivo mammalian assays. Phenolphthalein was positive for the induction of chromosomal aberrations in cultured Chinese hamster ovary cells in the presence of metabolic activation and induced hprt gene mutations, chromosomal aberrations, and morphological transformation in Syrian hamster embryo cells. Phenolphthalein was also positive for the
induction of micronucleated erythrocytes in mice following multiple, but not single, treatments administered by gavage or dosed feed.
Phenolphthalein also induced micronuclei in female heterozygous p53-deficient transgenic mice exposed via dosed feed for 26 weeks.
Phenolphthalein was negative for Na/K ATPase gene mutations and aneuploidy in Syrian hamster embryo cells.
No significant acute toxicological data identified in literature search.

Section 12 - ECOLOGICAL INFORMATION

No data

Section 13 - DISPOSAL CONSIDERATIONS

Disposal Instructions

All waste must be handled in accordance with local, state and federal regulations.
¦ Puncture containers to prevent re-use and bury at an authorized landfill.
Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked.
A Hierarchy of Controls seems to be common - the user should investigate:
· Reduction
· Reuse
· Recycling
· Disposal (if all else fails)
This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate.
DO NOT allow wash water from cleaning equipment to enter drains. Collect all wash water for treatment before disposal.
· Recycle wherever possible.
· Consult manufacturer for recycling options or consult Waste Management Authority for disposal if no suitable treatment or disposal facility can be identified.

Section 14 - TRANSPORTATION INFORMATION

NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS: DOT, IATA, IMDG

Section 15 - REGULATORY INFORMATION

phenolphthalein disulfate, tripotassium salt (CAS: 62625-16-5) is found on the following regulatory lists;
"Canada Domestic Substances List (DSL)","US Toxic Substances Control Act (TSCA) - Inventory"

Section 16 - OTHER INFORMATION

Reasonable care has been taken in the preparation of this information, but the author makes no warranty of merchantability or any other warranty, expressed or implied, with respect to this information. The author makes no representations and assumes no liability for any direct, incidental or consequential damages resulting from its use. For additional technical information please call our toxicology department on +800 CHEMCALL.

■ Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.
A list of reference resources used to assist the committee may be found at:
www.chemwatch.net/references.

■ The (M)SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

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