

SECTION 11. TOXICOLOGICAL INFORMATION

INFORMATION ON LIKELY ROUTES OF EXPOSURE:

INHALATION

SKIN CONTACT

INGESTION

EYE CONTACT

ACUTE TOXICITY: NOT CLASSIFIED BASED ON AVAILABLE INFORMATION.

INGREDIENTS:

AMORPHOUS FUMED SILICA:

ACUTE ORAL TOXICITY:

LD50 (RAT): >20,000 MG/KG

ASSESSMENT: THE SUBSTANCE OR MIXTURE HAS NO ACUTE ORAL TOXICITY

REMARKS: INFORMATION TAKEN FROM REFERENCE WORKS AND THE LITERATURE.

OCTAMETHYLCYCLOTETRASILOXANE:

ACUTE ORAL TOXICITY:

LD50 (RAT): >4,800 MG/KG

ASSESSMENT: THE SUBSTANCE OR MIXTURE HAS NO ACUTE ORAL TOXICITY

REMARKS: BASED ON TEST DATA

ACUTE INHALATION TOXICITY:

LC50 (RAT): 2975 PPM

EXPOSURE TIME: 4 H

TEST ATMOSPHERE: VAPOR

ASSESSMENT: THE SUBSTANCE OR MIXTURE HAS NO ACUTE INHALATION TOXICITY

REMARKS: BASED ON TEST DATA

ACUTE DERMAL TOXICITY:

LD50 (RABBIT): >2.5 ML/KG

ASSESSMENT: THE SUBSTANCE OR MIXTURE HAS NO ACUTE DERMAL TOXICITY

REMARKS: BASED ON TEST DATA

SKIN CORROSION/IRRITATION: NOT CLASSIFIED BASED ON AVAILABLE INFORMATION.

PRODUCT:

RESULT: NO SKIN IRRITATION

REMARKS: BASED ON DATA FROM SIMILAR MATERIALS

INGREDIENTS:

OCTAMETHYLCYCLOTETRASIOXANE:

SPECIES: RABBIT

RESULT: NO SKIN IRRITATION

REMARKS: BASED ON TEST DATA

SERIOUS EYE DAMAGE/EYE IRRITATION:

NOT CLASSIFIED BASED ON AVAILABLE INFORMATION.

PRODUCT:

RESULT: NO EYE IRRITATION

REMARKS: BASED ON DATA FROM SIMILAR MATERIALS

INGREDIENTS:

OCTAMETHYLCYCLOTETRASIOXANE:

SPECIES: RABBIT

RESULT: NO EYE IRRITATION

REMARKS: BASED ON TEST DATA

RESPIRATORY OR SKIN SENSITIZATION:

SKIN SENSITIZATION: NOT CLASSIFIED BASED ON AVAILABLE INFORMATION.

RESPIRATORY SENSITIZATION: NOT CLASSIFIED BASED ON AVAILABLE INFORMATION.

INGREDIENTS:

OCTAMETHYLCYCLOTETRASIOXANE:

ASSESSMENT: DOES NOT CAUSE SKIN SENSITIZATION.

TEST TYPE: MAXIMIZATION TEST (GPMT)

SPECIES: GUINEA PIG

REMARKS: BASED ON TEST DATA

GERM CELL MUTAGENICITY: NOT CLASSIFIED BASED ON AVAILABLE INFORMATION.

INGREDIENTS:

OCTAMETHYLCYCLOTETRASILOXANE:

GENOTOXICITY IN VITRO:

TEST TYPE: BACTERIAL REVERSE MUTATION ASSAY (AMES)

RESULT: NEGATIVE

REMARKS: BASED ON TEST DATA

TEST TYPE: MUTAGENICITY (IN VITRO MAMMALIAN CYTOGENETIC TEST)

RESULT: NEGATIVE

REMARKS: BASED ON TEST DATA

TEST TYPE: CHROMOSOME ABERRATION TEST IN VITRO

RESULT: NEGATIVE

REMARKS: BASED ON TEST DATA

TEST TYPE: IN VITRO SISTER CHROMATID EXCHANGE ASSAY IN MAMMALIAN CELLS

RESULT: NEGATIVE

REMARKS: BASED ON TEST DATA

TEST TYPE:

DNA DAMAGE AND REPAIR, UNSCHEDULED DNA SYNTHESIS IN MAMMALIAN CELLS
(IN VITRO)

RESULT: NEGATIVE

REMARKS: BASED ON TEST DATA

GENOTOXICITY IN VIVO:

TEST TYPE:

MAMMALIAN ERYTHROCYTE MICRONUCLEUS TEST (IN VIVO CYTOGENETIC ASSAY)

SPECIES: RAT

APPLICATION ROUTE: INHALATION (VAPOR)

RESULT: NEGATIVE

REMARKS: BASED ON TEST DATA

TEST TYPE: RODENT DOMINANT LETHAL TEST (GERM CELL) (IN VIVO)

SPECIES: RAT

APPLICATION ROUTE: INGESTION

RESULT: NEGATIVE

REMARKS: BASED ON TEST DATA

GERM CELL MUTAGENICITY - ASSESSMENT:

ANIMAL TESTING DID NOT SHOW ANY MUTAGENIC EFFECTS.

CARCINOGENICITY: NOT CLASSIFIED BASED ON AVAILABLE INFORMATION.

IARC:

NO INGREDIENT OF THIS PRODUCT PRESENT AT LEVELS GREATER THAN OR EQUAL TO 0.1% IS IDENTIFIED AS PROBABLE, POSSIBLE OR CONFIRMED HUMAN CARCINOGEN BY IARC.

OSHA:

NO INGREDIENT OF THIS PRODUCT PRESENT AT LEVELS GREATER THAN OR EQUAL TO 0.1% IS IDENTIFIED AS A CARCINOGEN OR POTENTIAL CARCINOGEN BY OSHA.

NTP:

NO INGREDIENT OF THIS PRODUCT PRESENT AT LEVELS GREATER THAN OR EQUAL TO 0.1% IS IDENTIFIED AS A KNOWN OR ANTICIPATED CARCINOGEN BY NTP.

REPRODUCTIVE TOXICITY: SUSPECTED OF DAMAGING FERTILITY OR THE UNBORN CHILD.

INGREDIENTS:

OCTAMETHYLCYCLOTETRASILOXANE:

EFFECTS ON FERTILITY:

TEST TYPE: TWO-GENERATION REPRODUCTION TOXICITY STUDY

SPECIES: RAT, MALE AND FEMALE

APPLICATION ROUTE: INHALATION (VAPOR)

SYMPTOMS: EFFECTS ON FERTILITY.

REMARKS: BASED ON TEST DATA

EFFECTS ON FETAL DEVELOPMENT:

TEST TYPE: PRENATAL DEVELOPMENT TOXICITY STUDY (TERATOGENICITY)

SPECIES: RABBIT

APPLICATION ROUTE: INHALATION (VAPOR)

SYMPTOMS: NO EFFECTS ON FETAL DEVELOPMENT.

REMARKS: BASED ON TEST DATA

REPRODUCTIVE TOXICITY - ASSESSMENT:

SOME EVIDENCE OF ADVERSE EFFECTS ON SEXUAL FUNCTION AND FERTILITY, BASED ON ANIMAL EXPERIMENTS.

STOT-SINGLE EXPOSURE: NOT CLASSIFIED BASED ON AVAILABLE INFORMATION.

STOT-REPEATED EXPOSURE: NOT CLASSIFIED BASED ON AVAILABLE INFORMATION.

INGREDIENTS:

OCTAMETHYLCYCLOTETRASILOXANE:

ROUTES OF EXPOSURE: INGESTION

ASSESSMENT:

NO SIGNIFICANT HEALTH EFFECTS OBSERVED IN ANIMALS AT CONCENTRATIONS OF 100 MG/KG BW OR LESS.

ROUTES OF EXPOSURE: INHALATION (VAPOR)

ASSESSMENT:

NO SIGNIFICANT HEALTH EFFECTS OBSERVED IN ANIMALS AT CONCENTRATIONS OF 1 MG/L/6H/D OR LESS.

ROUTES OF EXPOSURE: SKIN CONTACT

ASSESSMENT:

NO SIGNIFICANT HEALTH EFFECTS OBSERVED IN ANIMALS AT CONCENTRATIONS OF 200 MG/KG BW OR LESS.

REPEATED DOSE TOXICITY:

INGREDIENTS:

OCTAMETHYLCYCLOTETRASILOXANE:

SPECIES: RAT

APPLICATION ROUTE: INGESTION

REMARKS: BASED ON TEST DATA

SPECIES: RAT

APPLICATION ROUTE: INHALATION (VAPOR)

REMARKS: BASED ON TEST DATA

SPECIES: RABBIT

APPLICATION ROUTE: SKIN CONTACT

REMARKS: BASED ON TEST DATA

ASPIRATION TOXICITY: NOT CLASSIFIED BASED ON AVAILABLE INFORMATION.

PRODUCT: NO ASPIRATION TOXICITY CLASSIFICATION

FURTHER INFORMATION:

INGREDIENTS:

OCTAMETHYLCYCLOTETRASILOXANE:

REMARKS:

RESULTS FROM A 2 YEAR REPEATED VAPOR INHALATION EXPOSURE STUDY TO RATS OF OCTAMETHYLCYCLOTETRASILOXANE (D4) INDICATE EFFECTS (BENIGN UTERINE ADENOMAS) IN THE UTERUS OF FEMALE ANIMALS. THIS FINDING OCCURRED AT THE HIGHEST EXPOSURE DOSE (700 PPM) ONLY. STUDIES TO DATE HAVE NOT DEMONSTRATED IF THESE EFFECTS OCCUR THROUGH PATHWAYS THAT ARE RELEVANT TO HUMANS. BASED ON THE AVAILABLE INFORMATION ON ITS POTENTIAL TO CAUSE HARM TO HUMAN HEALTH, HEALTH CANADA, IN A 2008 SCREENING ASSESSMENT, HAS CONCLUDED THAT OCTAMETHYLCYCLOTETRASILOXANE IS NOT ENTERING THE ENVIRONMENT IN A QUANTITY OR CONCENTRATION OR UNDER CONDITIONS THAT CONSTITUTE OR MAY CONSTITUTE A DANGER IN CANADA TO HUMAN LIFE OR HEALTH ([HTTP://WWW.EC.GC.CA/ESEEEES/DEFAULT.ASP?LANG=EN&N=2481B508-1](http://www.ec.gc.ca/eseees/default.asp?lang=en&n=2481b508-1)). REPEATED EXPOSURE IN RATS TO D4 RESULTED IN PROTOPORPHYRIN ACCUMULATION IN THE LIVER. WITHOUT KNOWLEDGE OF THE SPECIFIC MECHANISM LEADING TO THE PROTOPORPHYRIN ACCUMULATION THE RELEVANCE OF THIS FINDING TO HUMANS IS UNKNOWN.