Talc (CAS# 14807-96-6) GreenScreen® for Safer Chemicals (GreenScreen®) Assessment

Prepared for:

Washington State Department of Ecology

Prepared by:

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October 16, 2014

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GreenScreen® Executive Summary for Talc (CAS #14807-96-6)

Talc used in cosmetics (and probably referred to by this CAS number) is free from asbestiform fibers, which are a crystallization product of a mineral with thin fibers and enhanced strength, flexibility and durability. In addition, talc and asbestos (including asbestiform materials) are formed naturally under different geological conditions, and separated into adjacent, but disparate strata. Therefore, asbestos contamination can be avoided with proper mining methodologies for talc. In cosmetics, talc has the following functions: abrasive, absorbent, anticaking, bulking, opacifying, skin protection, and slip modification. It has been used widely at concentrations up to 100% in cosmetics, even as baby powder. Medically, talc is used as a sclerosing agent, being administered intrapleurally via chest-tube to decrease the recurrence of malignant pleural effusions in symptomatic patients. Talc is also used as a color additive in drugs. In food, talc is granted the Generally Recognized as Safe (GRAS) status migrating from cotton and cotton fabrics used in dry food packaging and from paper and paperboard products. Talc is used as a dusting powder for medicinal and toilet preparations. Additionally, it functions as a pigment in paints, varnishes, and rubber, a filler for paper, rubber and soap, a lubricant for molds and machinery, and a carrier for insecticides and herbicides.

GreenScreen® Benchmark Score for Relevant Route of Exposure:

Oral: Talc was assigned a GreenScreen® Benchmark Score of 3_{DG} ("Use but Still Opportunity for Improvement Due to Data Gaps"). It has Very High persistence (P), which by itself is not a concern for inorganics. Data gaps (DG) exist for endocrine activity (E), single and repeated dose neurotoxicity (Ns and Nr*), and respiratory sensitization (SnR*). As outlined in CPA (2013) Section 12.2 (Step 8 – Conduct a Data Gap Analysis to assign a final Benchmark score), talc does not meet requirements for a GreenScreen® Benchmark Score of 3. Therefore, a Benchmark score of 3_{DG} was assigned. In a worst-case scenario, if talc were assigned a High score for the data gaps endocrine activity (E), repeated dose neurotoxicity (Nr*), or respiratory sensitization (SnR*), it would be categorized as a Benchmark 1Chemical.

Dermal: Talc was assigned a GreenScreen® Benchmark Score of U ("Unspecified due to Data Gaps"). It has Moderate Group I Human Toxicity (carcinogenicity (C) and Very High persistence (P)). This corresponds to GreenScreen® benchmark classifications 2c and 2e in CPA 2011. Data gaps (DG) exist for endocrine activity (E), acute toxicity (AT), single and repeated dose neurotoxicity (Ns and Nr*), and respiratory sensitization (SnR*). As outlined in CPA (2013) Section 12.2 (Step 8 – Conduct a Data Gap Analysis to assign a final Benchmark score), talc does not meet requirements for a GreenScreen® Benchmark Score of 2. Therefore, a Benchmark score of U was assigned. In a worst-case scenario, if talc were assigned a High score for the data gaps endocrine activity (E), repeated dose neurotoxicity (Nr*), or respiratory sensitization (SnR*), it would be categorized as a Benchmark 1 Chemical.

Inhalation: Talc was assigned a GreenScreen® Benchmark Score of 1 ("Avoid – Chemical of High Concern") as it has Very High persistence (P) and High Group II* Human Toxicity (systemic toxicity repeated exposure (STr*)). This corresponds to GreenScreen® benchmark classification 1c in CPA 2011. Data gaps (DG) exist for acute toxicity (AT), single and repeated dose neurotoxicity (Ns and Nr*), and respiratory sensitization (SnR*). As outlined in CPA (2013) Section 12.2 (Step 8 – Conduct a Data Gap Analysis to assign a final Benchmark score), talc meets requirements for a GreenScreen® Benchmark Score of 1 despite the hazard data gaps. In a worst-case scenario, if talc

were assigned a High score for the data gaps repeated dose neurotoxicity (Nr*) or respiratory sensitization (SnR*), it would still be categorized as a Benchmark 1 Chemical.

GreenScreen® Hazard Ratings for Talc

Route of exposure	Group I Human					Group II and II* Human									Ecotox		Fate		Physical	
	C	M	R	D	E	AT	ST		N		SnS*	SnR*	IrS	IrE	AA	CA	P	B	Rx	F
							single	repeated*	single	repeated*										
Inhalation	**M**	**L**	*L*	**L**	*M*	DG	DG	**H**	DG	DG	**L**	DG	**L**	**L**	**L**	*L*	**vH**	*L*	*L*	*L*
Oral	**L**				DG	**L**	DG	**L**												
Dermal	**M**				DG	DG	DG	**L**												

Note: Hazard levels (Very High (vH), High (H), Moderate (M), Low (L), Very Low (vL)) in *italics* reflect estimated values, authoritative B lists, screening lists, weak analogues, and lower confidence. Hazard levels in **BOLD** font are used with good quality data, authoritative A lists, or strong analogues. Group II Human Health endpoints differ from Group II* Human Health endpoints in that they have four hazard scores (i.e., vH, H, M, and L) instead of three (i.e., H, M, and L), and are based on single exposures instead of repeated exposures. Please see Appendix A for a glossary of hazard acronyms.

GreenScreen® Assessment for Talc (CAS #14807-96-6)

Method Version: GreenScreen® Version 1.2[1]
Assessment Type[2]: Certified

Chemical Name: Talc

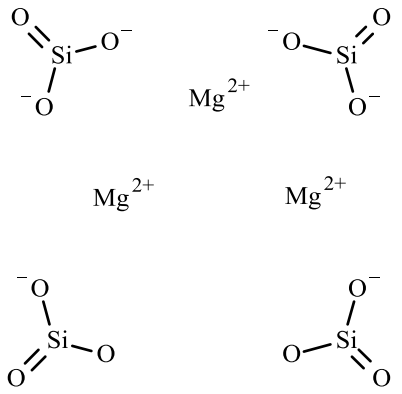
CAS Number: 14807-96-6

GreenScreen® Assessment Prepared By:
Name: Sara M. Ciotti, Ph.D.
Title: Toxicologist
Organization: ToxServices LLC
Date: October 2, 2014
Assessor Type: Licensed GreenScreen® Profiler

Quality Control Performed By:
Name: Bingxuan Wang, Ph.D.
Title: Toxicologist
Organization: ToxServices LLC
Date: October 16, 2014

Confirm application of the *de minimus* rule[3]: N/A

Chemical Structure(s):



Also called: Cosmetic talc; Agalite; Talc (MG3H2(SiO3)4); Talc (powder), containing no asbestos fibers; Silicates (<1% quartz): talc (not containing asbestos) (ChemIDplus 2014)

Chemical Structure(s) of Chemical Surrogates Used in the GreenScreen®:
An adequate dataset was available for talc; therefore, no surrogate was used in this GreenScreen®.

[1] Use GreenScreen® Assessment Procedure (Guidance) V1.2

[2] GreenScreen® reports are either "UNACCREDITED" (by unaccredited person), "AUTHORIZED" (by Authorized GreenScreen® Practitioner), "CERTIFIED" (by Licensed GreenScreen® Profiler or equivalent) or "CERTIFIED WITH VERIFICATION" (Certified or Authorized assessment that has passed GreenScreen® Verification Program)

[3] Every chemical in a material or formulation should be assessed if it is:
1. intentionally added and/or
2. present at greater than or equal to 100 ppm

Identify Applications/Functional Uses:

1. Talc is used as an abrasive, absorbent, anticaking, bulking, opacifying, skin protection, and slip modification agent in cosmetics.
2. Medically, talc is used as a sclerosing agent.
3. Talc is used as a color additive in pharmaceutical drugs.
4. Talc functions as a pigment in paints, varnishes, and rubber.
5. Talc functions as a filler for paper, rubber, and soap.
6. Talc functions as a lubricant for molds and machinery.
7. Talc functions as a carrier for insecticides and herbicides.

(CIR 2010; ChemIDplus 2014)

GreenScreen® Summary Rating for Talc[4]:

Oral: Talc was assigned a GreenScreen® Benchmark Score of 3_{DG} ("Use but Still Opportunity for Improvement Due to Data Gaps"). It has Very High persistence (P), which by itself is not a concern for inorganics. Data gaps (DG) exist for endocrine activity (E), single and repeated dose neurotoxicity (STs and STr*), and respiratory sensitization (SnR*). As outlined in CPA (2013) Section 12.2 (Step 8 – Conduct a Data Gap Analysis to assign a final Benchmark score), talc does not meet requirements for a GreenScreen® Benchmark Score of 3. Therefore, a Benchmark score of 3_{DG} was assigned. In a worst-case scenario, if talc were assigned a High score for the data gaps E, Nr* or SnR*, it would be categorized as a Benchmark 1Chemical.

Dermal: Talc was assigned a GreenScreen® Benchmark Score of U ("Unspecified due to Data Gaps"). It has Moderate Group I Human Toxicity (carcinogenicity (C) and Very High persistence (P)). This corresponds to GreenScreen® benchmark classifications 2c and 2e in CPA 2011. Data gaps (DG) exist for endocrine activity (E), acute toxicity (AT), neurotoxicity single dose (Ns) and repeated dose (Nr*), and respiratory sensitization (SnR*). As outlined in CPA (2013) Section 12.2 (Step 8 – Conduct a Data Gap Analysis to assign a final Benchmark score), talc does not meet requirements for a GreenScreen® Benchmark Score of 2. Therefore, a Benchmark score of U was assigned. In a worst-case scenario, if talc were assigned a High score for the data gaps E, Nr* or SnR*, it would be categorized as a Benchmark 1 Chemical.

Inhalation: Talc was assigned a GreenScreen® Benchmark Score of 1 ("Avoid – Chemical of High Concern") as it has Very High persistence (P) and High Group II* Human Toxicity (systemic toxicity repeated exposure (STr*)). This corresponds to GreenScreen® benchmark classification 1c in CPA 2011. Data gaps (DG) exist for acute toxicity (AT), neurotoxicity single dose (Ns) and repeated dose (Nr*), and respiratory sensitization (SnR*). As outlined in CPA (2013) Section 12.2 (Step 8 – Conduct a Data Gap Analysis to assign a final Benchmark score), talc meets requirements for a GreenScreen® Benchmark Score of 1 despite the hazard data gaps. In a worst-case scenario, if talc were assigned a High score for the data gaps Nr* or SnR*, it would still be categorized as a Benchmark 1 Chemical.

[4] For inorganic chemicals with low human and ecotoxicity across all hazard endpoints and low bioaccumulation potential, persistence alone will not be deemed problematic. Inorganic chemicals that are only persistent will be evaluated under the criteria for Benchmark 4.

Figure 1: GreenScreen® Hazard Ratings for Talc

Route of exposure	Group I Human					Group II and II* Human									Ecotox		Fate		Physical	
	C	M	R	D	E	AT	ST		N		SnS*	SnR*	IrS	IrE	AA	CA	P	B	Rx	F
							single	repeated*	single	repeated*										
Inhalation	M	L	*L*	L	*M*	DG	DG	H	DG	DG	L	DG	L	L	L	*L*	vH	*L*	*L*	*L*
Oral	L				DG	L	DG	L												
Dermal	M				DG	DG	DG	L												

Note: Hazard levels (Very High (vH), High (H), Moderate (M), Low (L), Very Low (vL)) in *italics* reflect estimated values, authoritative B lists, screening lists, weak analogues, and lower confidence. Hazard levels in **BOLD** font are used with good quality data, authoritative A lists, or strong analogues. Group II Human Health endpoints differ from Group II* Human Health endpoints in that they have four hazard scores (i.e., vH, H, M, and L) instead of three (i.e., H, M, and L), and are based on single exposures instead of repeated exposures. Please see Appendix A for a glossary of hazard acronyms.

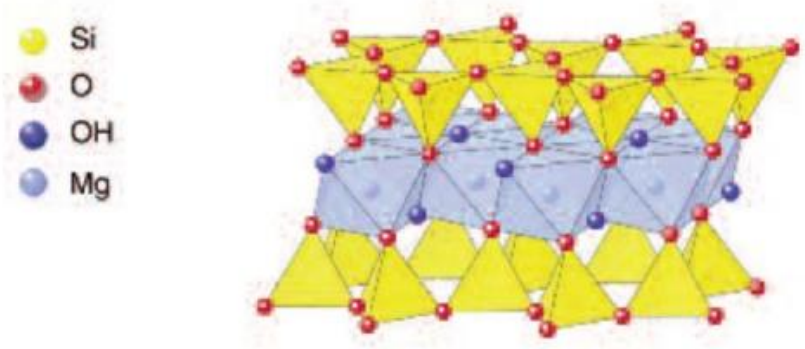
Transformation Products and Ratings:

Identify feasible and relevant fate and transformation products (i.e., dissociation products, transformation products, valence states) **and/or moieties of concern**[5]**:**

No transformation or hydrolysis products were identified for talc (OECD 2013).

Introduction

Talc is a fine powder of native hydrous magnesium silicate. It belongs to the silicate subclass phyllosilicates and is a sheet silicate (i.e., the structural unit consists of three sheets: octahedrally-coordinated magnesium hydroxide groups (brucite) layer sandwiched between two layers of tetrahedrally-linked silica layers, and stacks of triple-sheet crystalline units are held together by van der Walls forces), as shown below (CIR 2013).



Structure of talc (Source: CIR 2013)

Talc used in cosmetics (and probably referred to by this CAS number) is free from asbestiform fibers, which are a crystallization product of a mineral with thin fibers and enhanced strength, flexibility and durability. In addition, talc and asbestos (including asbestiform materials) are formed naturally under different geological conditions, and separated into adjacent, but disparate strata. Therefore, asbestos contamination can be avoided with proper mining methodologies for talc (CIR 2013). In cosmetics, talc

[5] A moiety is a discrete chemical entity that is a constituent part or component of a substance. A moiety of concern is often the parent substance itself for organic compounds. For inorganic compounds, the moiety of concern is typically a dissociated component of the substance or a transformation product.

has the following functions: abrasive, absorbent, anticaking, bulking, opacifying, skin protection, and slip modification. It has been used widely at concentrations up to 100% in cosmetics, even as baby powder. Medically, talc is used as a sclerosing agent, being administered intrapleurally via chest-tube to decrease the recurrence of malignant pleural effusions in symptomatic patients. Talc is also used as a color additive in drugs. In food, talc is granted the Generally Recognized as Safe (GRAS) status migrating from cotton and cotton fabrics used in dry food packaging and from paper and paperboard products. Talc is used as a dusting powder for medicinal and toilet preparations. Additionally, it functions as a pigment in paints, varnishes, and rubber, a filler for paper, rubber and soap, a lubricant for molds and machinery, and a carrier for insecticides and herbicides (CIR 2013, ChemIDplus 2014).

ToxServices assessed talc against GreenScreen® Version 1.2 (CPA 2013) following procedures outlined in ToxServices' SOP 1.69 (GreenScreen® Hazard Assessment) (ToxServices 2013).

GreenScreen® List Translator Screening Results

The GreenScreen® List Translator identifies specific authoritative or screening lists that should be searched to identify GreenScreen® benchmark 1 chemicals (CPA 2012b). Pharos (Pharos 2014) is an online list-searching tool that is used to screen chemicals against the List Translator electronically. It checks all of the lists in the List Translator with the exception of the U.S. Department of Transportation (U.S. DOT) lists (U.S. DOT 2008a,b) and these should be checked separately in conjunction with running the Pharos query. The output indicates benchmark or possible benchmark scores for each human health and environmental endpoint. The output for talc can be found in Appendix C and a summary of the results can be found below:

- Cancer
  - MAK: Carcinogen Group 3B: Evidence of carcinogenic effects but not sufficient for classification
  - IARC: Group 3: Agent is not classifiable as to its carcinogenicity to humans
- Mammalian
  - WHMIS: Class D2A – Very toxic material causing other toxic effects
- PBT
  - DSL: DSL substances that are persistent
- Restricted List
  - CA SCP Candidate Chemicals: Full Candidate Chemical List
  - DSL: Inherently Toxic to Humans: DSL substances that meet human health categorization criteria

PhysicoChemical Properties of Talc

Talc is an inorganic solid that is not volatile or water-soluble. It is available in powder form with varying particle sizes. It appeared to be bioavailable in rats after oral intake.

Table 1: Physical and Chemical Properties of Talc (CAS #14807-96-6)

Property	Value	Reference
Molecular formula	H_2-O_3-Si.3/4Mg	ChemIDplus 2014
SMILES Notation	[Si](O)(=O)[O-].[Si]([O-])(O)=O.[Si](=O)([O-])[O-].[Si](=O)([O-])[O-].[Mg+2].[Mg+2].[Mg+2]	ChemIDplus 2014

Table 1: Physical and Chemical Properties of Talc (CAS #14807-96-6)		
Property	**Value**	**Reference**
Molecular weight	379.263	ChemIDplus 2014
Physical state	Solid	HSDB 2011
Appearance	White; ranges from snow-white to black; greenish-gray and shades of green, pink, and red white, apple-green, gray; pearly or greasy luster	CIR 2013
Melting point	1,652ºF – 1,832ºF	CDC 2011
Vapor pressure	0 mmHg (approx.)	CDC 2011
Water solubility	Insoluble in water	HSDB 2011
Dissociation constant	N/A	
Density/specific gravity	2.58-3.83	HSDB 2011
Partition coefficient	N/A	
Particle size	Dependent on the process used to make the powder Talc in cosmetics = 4 -15 μm	CIR 2013
Structure	Layered hydrated magnesium silicate	HSDB 2011
Bioavailability	Absorbed rapidly through the pleura in rats	CIR 2013

Hazard Classification Summary Section:

Group I Human Health Effects (Group I Human)

Carcinogenicity (C) Score (H, M, or L): M (dermal and inhalation), **L** (oral)
Talc was assigned a score of Moderate for carcinogenicity for the dermal route based on IARC group 2B classification for perineal application, a score of Moderate for inhalation route based on MAK 3B classification, and a score of Low for oral application based on negative data. GreenScreen® criteria classify chemicals as a Moderate hazard for carcinogenicity when associated with the authoritative MAK Group 3B list and/or IARC Group 2B (CPA 2012a).

- Authoritative and Screening Lists
  - *Authoritative:* MAK: Carcinogen Group 3B – Evidence of carcinogenic effects but not sufficient for classification
  - *Authoritative:* IARC: Group 3: Agent is not classifiable as to its carcinogenicity to humans
  - *Screening:* not included on any screening lists
- IARC 2010
  - There is limited evidence in experimental animals for the carcinogenicity of talc not containing asbestos or asbestiform fibers, based on inhalation, intrathoracic, i.p. and subcutaneous injection studies in mice; oral, inhalation, intrathoraci and i.p. injections, intrapleural and ovarian implantation studies in rats; and inhalation and intratracheal injection studies in hamsters.
  - There is inadequate evidence in humans for the carcinogenicity of inhaled talc not containing asbestos or asbestiform fibers, and limited evidence in humans for the carcinogenicity of perineal use of talc-based body powder, based on epidemiological studies.

- Overall, it was concluded that perineal use of talc-based powder is possibly carcinogenic to humans (ovarian cancer in women) (Group 2B), while inhaled talc (not containing asbestos or asbestiform fibers) is not classifiable as to its carcinogenicity to humans (Group 3).
- Studies that were reviewed by IARC are summarized below:
- NTP 1993
  - *Inhalation* – A two-year carcinogenicity study was performed with F344/N rats (49-50/sex/dose group) administered inhalation doses of talc at 0, 6, or 18 mg/m^3 (equivalent to 0, 2.8, and 8.4 mg/kg/day for males and 0, 3.2, and 9.6 mg/kg/day for females, respectively) for 6 hours/day, 5 days/week for up to 113 weeks (males) or 122 weeks (females) depending on when mortality in each group reached 80%. The incidences of alveolar/bronchiolar adenoma, carcinoma, and adenoma or carcinoma (combined) in high dose females were significantly greater than control values. The incidence of pulmonary neoplasms in high dose males was not significantly different from control values. At the high dose, an increased incidence of benign, malignant, or complex (combined) pheochromocytomas in the adrenal gland was observed in both males and females. The NTP researchers concluded that there was some evidence of carcinogenic activity in male F344/N rats based on an increased incidence of pheochromocytomas in the adrenal gland, and clear evidence of carcinogenic activity of talc in female F344/N rats based on the increased pulmonary neoplasms.
  - *Inhalation* – A two-year carcinogenicity study was performed with B6C3F1 mice (47-50/sex/dose group) administered inhalation doses of talc at 0, 6, or 18 mg/m^3 (equivalent to 0, 2, and 6 mg/kg/day for males and 0, 1.3, and 3.9 mg/kg/day for females, respectively) for 6 hours/day, 5 days/week for up to 104 weeks. The incidences of pulmonary neoplasms were similar between the control and treatment groups. The NTP researchers concluded that there was no evidence of carcinogenic activity of talc in male or female B6C3F1 mice at up to 18 mg/m^3.
- Gibel et al. 1976
  - *Oral* – No significant differences in tumor incidence were observed after Wistar rats (25/sex/dose group) were administered oral exposures at 0 or 50 mg/kg/day commercial talc (purity not specified) in the diet for two years.
- Wagner et al. 1977
  - *Oral* – No significant differences in tumor incidence were observed in Wistar-derived rats (16/sex in treatment group, 8/sex in control group) administered oral doses of Italian talc (92% purity) at 0 or 100 mg/day for five months and continued on control diets for the remainder of life.
  - *Inhalation* – No significant differences in lung tumor incidence were observed in Wistar-derived rats (12/sex in treatment group, 24/sex in control group) administered inhalation exposures of Italian talc (92% purity) at 0 or 10.8 mg/m^3 for 7.5 hours/day, 5 days/week for 6 or 12 months.
- Wehner et al. 1977, 1979
  - *Inhalation* – In a carcinogenicity study, Syrian golden hamsters (50/sex in treatment group, 25/sex in control group) were administered aerosol inhalation doses of Vermont talc (95% purity) at 0 or 37.1 mg/m^3 (mean respiratory fraction of 9.8 mg/m^3) 5 days/week for 30 days (exposure duration per day not specified). Another group of animals was administered aerosol inhalation doses of the same talc at 0 or 27.4 mg/m^3 (mean respiratory fraction of 8.1 mg/m^3) for 30 or 150 minutes/day for 300 days. No primary lung tumors were observed in any of the animals.

- The MAK authoritative list classified talc as: Carcinogen Group 3B – Evidence of carcinogenic effects but not sufficient for classification. Association with the MAK Group 3B warrants a Moderate score. However, this classification is applicable to the respirable fraction of talc (MAK 2012). Talc was also evaluated by IARC and it was concluded that perineal use of talc-based powder is possibly carcinogenic to humans (ovarian cancer in women) (Group 2B), while inhaled talc (not containing asbestos or asbestiform fibers) is not classifiable as to its carcinogenicity to humans (Group 3). Therefore, ToxServices defaulted to the more conservative hazard score for the inhalation route (i.e. MAK 3B) and for dermal route (perineal, IARC 2B), which both translate to a Moderate score. Available studies via the oral exposure route do not provide any evidence of carcinogenesis. Therefore, a score of Low was assigned for the oral route.

Mutagenicity/Genotoxicity (M) Score (H, M, or L): L

Talc was assigned a score of Low for mutagenicity/genotoxicity based on negative findings in mutagenicity and clastogenicity studies. GreenScreen® criteria classify chemicals as a Low hazard for mutagenicity/genotoxicity when adequate data are available and negative for both chromosomal aberrations and gene mutations, there are no structural alerts, and they are not GHS classified (CPA 2012a).

- Authoritative and Screening Lists
  - *Authoritative:* not included on any authoritative lists
  - *Screening:* not included on any screening lists
- IARC 2010
  - Talc was not mutagenic to *Salmonella typhimurium* or *Saccharomyces cerevisiae*. It did not induce chromosomal aberrations in cultured human cells or *in vivo* in rats or dominant lethal mutations in rats.
- ECB 2000
  - Negative results for DNA damage and repair were obtained in an unscheduled DNA synthesis and sister chromatid exchange assay. Rat pleural mesothelial cells (unknown strain) were exposed to three talc samples (concentrations not presented). The talc samples did not induce unscheduled DNA synthesis or sister chromatid exchanges.
  - A bacterial reverse mutation assay was performed with *Salmonella typhimurium* test strain TA 1530 and his G46 exposed to talc (concentrations and use of metabolic activating system not specified). No increase in mutation frequency was observed with treatment. No increased mutagenicity was observed when *Saccharomyces cerevisiae* D3 was exposed to talc. No further details were provided.
  - Human W138 cells (human embryonic lung fibroblasts) were exposed to talc at 2-200 µg/mL. No induction of chromosome aberrations was observed with treatment.
  - Rats (strain, sex, and number not specified) administered oral doses of talc at 30-5,000 mg/kg did not exhibit an increase in chromosome aberrations or dominant lethal mutations with treatment. No further details were provided.

Reproductive Toxicity (R) Score (H, M, or L): *L*

Talc was assigned a score of Low for reproductive toxicity based on limited data in rats. GreenScreen® criteria classify chemicals as a Low hazard for reproductive toxicity when adequate data are available and negative, there are no structural alerts, and they are not GHS classified (CPA 2012a).

- Authoritative and Screening Lists
  - *Authoritative:* not included on any authoritative lists
  - *Screening:* not included on any screening lists

- Oral
    - CIR 2013
        - Reproductive parameters were measured in a dominant-lethal study in male rats (strain not specified). Animals (10/group) received talc by gavage at 0, 30, 300, 3,000, or 5,000 mg/kg either as a single dose or daily for 5 days. Each treated male rat was mated with two naïve females, which were sacrificed two weeks after mating to determine fertility and preimplantation loss. A significant dose-related decrease in average corpora lutea and preimplantation losses were found in the single dose study at weeks 4 and 5. Significant increases in average implantations and corpora lutea were reported in the repeated dose study at week 6, as were significant differences in the proportions of females with more than 1 or 2 dead implants. These were only reported at the highest dose and did not vary significantly from the control group. In addition, no dose-response or time-response was observed. CIR concluded that there was no dose response or time-trend pattern observed in this study.
- Dermal
    - No data were identified.
- Inhalation
    - No data were identified.
- Based on the weight of evidence, a score of Low was assigned. No evidence of reproductive toxicity was identified in the dominant lethal assay described above, but there were limited details reported. In addition, the reproductive effects in females were not evaluated. Therefore, the confidence level was adjusted.

Developmental Toxicity incl. Developmental Neurotoxicity (D) Score (H, M, or L): L (Oral), DG (Dermal and Inhalation)

Talc was assigned a score of Low for developmental toxicity through oral exposure based on negative findings in developmental studies in mice, hamsters, and rabbits. GreenScreen® criteria classify chemicals as a Low hazard for developmental toxicity when adequate data are available and negative, there are no structural alerts, and they are not GHS classified (CPA 2012a). It was assigned a score of Data Gap for dermal and inhalation exposure based on a lack of dermal and inhalation developmental toxicity studies.

- Authoritative and Screening Lists
    - *Authoritative:* not included on any authoritative lists
    - *Screening:* not included on any screening lists
- Oral
    - CIR 2013
        - In a developmental toxicity study, gravid albino CD-1 mice (20-22/group) and Wistar rats (20-24/group) received talc by gavage at 0, 16, 74, 350 or 1,600 mg/kg/day on gestational days 6-15. Mice were terminated on gestation day 17 and rats on day 20. Parameters examined included number of implantation sites, resorption sites, live and dead fetuses, and live pup body weights. No effects were observed. Therefore, ToxServices established the NOAEL at 1,600 mg/kg/day for developmental toxicity.
        - In a developmental study, pregnant female golden hamsters (20-23/group) received talc by gavage at 0, 12, 56, 260 or 1,200 mg/kg/day on gestational days 6-10. They were terminated on gestation day 14. Parameters examined in this study are the same as those previously described. No adverse reproductive or developmental

toxicity were observed. ToxServices established the NOAEL at 1,200 mg/kg/day for developmental toxicity.

- In a developmental study, gravid Dutch-belted rabbits (12-15/group) were exposed to talc orally (unspecified) at 0, 9, 42, 195 or 900 mg/kg on gestational days 16-18. Animals were sacrificed on gestation day 29. There were no treatment-related effects on nidation or fetal or maternal survival. Therefore, ToxServices identified the NOAEL at 900 mg/kg/day for this study.

Endocrine Activity (E) Score (H, M, or L): DG (Oral and Dermal), *M* (Inhalation)
Talc was assigned a score of Data Gap for endocrine activity based on a lack of data for this endpoint. It was assigned a score of Moderate for endocrine activity based on findings in a two-year carcinogenicity study in male and female rats. GreenScreen® criteria classify chemicals as a Moderate hazard for endocrine activity when there is evidence of endocrine activity (CPA 2012a).

- Authoritative and Screening Lists
  - *Authoritative:* not included on any authoritative lists
  - *Screening:* not included on any screening lists
- Not listed as a potential endocrine disruptor on the EU Priority List of Suspected Endocrine Disruptors.
- Not listed as a potential endocrine disruptor on the OSPAR List of Chemicals of Possible Concern.
- Oral
  - No data were identified.
- Dermal
  - No data were identified.
- Inhalation
  - NTP 1993
    - In a previously described two-year carcinogenicity study, F344/N rats (49-50/sex/dose group) were administered inhalation doses of talc at 0, 6 or 18 mg/m^3 (equivalent to 0, 2.8, and 8.4 mg/kg/day for males and 0, 3.2, and 9.6 mg/kg/day for females, respectively) for 6 hours/day, 5 days/week for up to 113 weeks (males) or 122 weeks (females) depending on when mortality in each group reached 80%. At the high dose, an increased incidence of benign, malignant, or complex (combined) pheochromocytomas in the adrenal gland was observed in both males and females. The NTP researchers concluded that there was some evidence of carcinogenic activity in male F344/N rats based on an increased incidence of pheochromocytomas in the adrenal gland, and clear evidence of carcinogenic activity of talc in female F344/N rats based on the increased pulmonary neoplasms.
- Based on the weight of evidence, a score of Moderate was assigned for the inhalation route of exposure. In a two-year carcinogenicity study in F344/N rats, male and females had an increased incidence of benign, malignant, or complex (combined) pheochromocytomas in the adrenal gland. It is unclear if endocrine activity was also disrupted; a score of Moderate was assigned and confidence in this endpoint was reduced.

Group II and II* Human Health Effects (Group II and II* Human)

Note: Group II and Group II* endpoints are distinguished in the v 1.2 Benchmark system. For Systemic Toxicity and Neurotoxicity, Group II and II* are considered sub-endpoints and test data for single or repeated exposures may be used. If data exist for single OR repeated exposures, then the endpoint is not considered a data gap. If data are available for both single and repeated exposures, then the more conservative value is used.

Acute Mammalian Toxicity (AT) Group II Score (vH, H, M, or L): L (Oral), DG (Dermal and Inhalation)

Talc was assigned a score of Low for acute toxicity through oral exposure based on evidence from oral studies in rats. GreenScreen® criteria classify chemicals as a Low hazard for acute toxicity when the oral LD_{50} is greater than 2,000 mg/kg (CPA 2012a). It was assigned a Data Gap for acute toxicity through dermal and inhalation exposure based on a lack of dermal and inhalation acute toxicity studies.

- Authoritative and Screening Lists
  - *Authoritative:* not included on any authoritative lists
  - *Screening:* not included on any screening lists
- Oral
  - CIR 2013
    - In an acute oral toxicity study in rats, 10 male rats received 5,000 mg/kg talc suspended in 0.85% saline and all of them died within 24 hours. Subsequently, talc was gavaged to groups of 5 rats at 50, 100, 500, 1,000, 2,000 or 3,000 mg/kg in saline. All animals at 3,000 mg/kg, 4/5 at 2,000 mg/kg, 3/5 at 1,000 mg/kg, and 1/5 at 500 mg/kg died, and therefore the LD_{50} was calculated to be 920 mg/kg. However, the chemical characterization data of talc were not provided.
    - In another oral toxicity study in rats, the LD_{50} was calculated to be > 5,000 mg/kg (in 0.85% saline) with no mortality observed.
    - In a study with 10 male rats, the oral LD_{50} was calculated to be > 5,000 mg/kg (in 18.3% saline). No signs of toxicity were observed.
    - Poorly soluble, nonfibrous talc particles are of low acute toxicity.
- The weight of evidence suggests that the oral LD_{50} of talc in rats is greater than 5,000 mg/kg.

Systemic Toxicity/Organ Effects incl. Immunotoxicity (ST)

***Group II Score (single dose)* (vH, H, M, or L):** DG

Talc was assigned a score of Data Gap for systemic toxicity (single dose) based on a lack of data for this endpoint.

- Authoritative and Screening Lists
  - *Authoritative:* not included on any authoritative lists
  - *Screening:* not included on any screening lists
- Oral
  - No data were identified.
- Dermal
  - No data were identified.
- Inhalation
  - CIR 2013
    - Mice (8 animals, strain and sex not reported) were exposed to baby powder for up to 120 minutes. The composition of baby powder, amount of baby powder, or size of exposure chamber was not reported. Mice were placed in a box with baby powder that was circulating with compressed air. Two mice were removed from the box at

30, 60, 90, and 120 minutes. No adverse effects were reported in mice exposed for up to 60 minutes. Mice exposed for 90 minutes died within 5-6 hours and mice exposed for 120 minutes died immediately. Animal necropsy found the airway mucous membrane was covered in baby powder. Microscopic analysis found hemorrhage, edema, and desquamation of the bronchial epithelium. As no concentrations were reported a NOAEC or LOAEC cannot be established.

- A score of Data Gap was assigned for inhalation exposure because no NOAEC or LOAEC values could be established due to a lack of reported details.

Group II* Score (repeated dose) **(H, M, or L): L** (Oral and Dermal)**, H** (Inhalation)
Talc was assigned a score of Low for systemic toxicity (repeated dose) following oral and dermal exposure based on adequate negative data. GreenScreen® criteria classify chemicals as a Low hazard for systemic toxicity (repeated dose) when adequate data are available and negative, there are no structural alerts, and they are not GHS classified (CPA 2012a). Talc was assigned a score of High for systemic toxicity (repeated dose) following inhalation exposure based on adverse effects reported following occupational exposures and evidence from animal studies. GreenScreen® criteria classify chemicals as a High hazard for systemic toxicity (repeated dose) when they are classified as GHS Category 1.

- Authoritative and Screening Lists
  - *Authoritative:* not included on any authoritative lists
  - *Screening:* not included on any screening lists
- Oral
  - CIR 2013
    - Talc is safe for use in cosmetics at concentrations up to 100%.
    - Oral exposure to talc for 5 days at 5,000 mg/kg/day produced minimal toxicity. No further details were reported.
    - No toxicologically significant effects were reported in a 5-month dietary study in which Italian talc was fed at 100 mg/day to male and female Wistar rats (equivalent to 216 mg/kg/day in males and 337 mg/kg/day in females, respectively[6]). ToxServices identified a NOAEL of 216 mg/kg/day in males and 337 mg/kg/day in females (only dose tested).
- Dermal
  - CIR 2013
    - Talc is safe for use in cosmetics at concentrations up to 100%.
    - Application of talc to wounded skin can lead to scab formation, possible formation, and foreign body granulomas in the dermis.
    - Dermal application of talc powder to shaved rabbit skin for 6 weeks only resulted in local dryness of the skin and skin erosion. It does not indicate if the treatment site was under occlusive conditions or not. No systemic toxicity was reported.
- Inhalation
  - CIR 2013
    - Talc is safe for use in cosmetics at concentrations up to 100%.
    - Chronic occupational exposure to inhaled talc in humans leads to diffuse interstitial fibrosis and progressive massive fibrosis (i.e., complicated pneumoconiosis) of the lung. Depending on the composition and impurities in talc, three categories of talc-

[6] According to U.S. EPA (1988), mean body weights of male and female Wistar rats in a chronic study are 0.462 and 0.297 kg, respectively. Therefore, 100 mg/day is equivalent to 100 mg/day /BW = 100 mg/day /0.462 (or 0.297) kg = 216 and 337 mg/kg/day for males and females, respectively.

related pulmonary effects have been described: pure talcosis (exposure to talc that is free of silica and asbestiform minerals); talco-asbestosis (exposure to talc contaminated with asbestiform fibers) and talco-silicosis (exposure to talc with silica and other non-asbestiform fibers). Pure talcosis presents small nodules usually in the lower pulmonary fields in radiographs. Reticulations (a pattern resembling a net) may also occur with less frequency. Functional test results of pure talcosis are consistent with restrictive pulmonary disease.

- In human case reports, repeated inhalation of talc powder through use/misuse in adults and children has led to consequences ranging from complete recovery to death.
- Inhalation exposure to asbestos-free talc at 0. 2, 6 or 18 mg/m^3 for 6 hours/day, 5 days/week for 4 weeks led to a modest and diffuse increase in macrophages in the alveolar space in B6C3F$_1$ mice and F344/Crl rats. No exposure-related abnormalities were seen at necropsy. ToxServices established the NOAEC at 18 mg/m^3 (0.013 mg/L/6h/day[7]) (highest concentration tested) for this 28-day study. *As the guideline values are tripled from 90-day studies to 28-day studies (i.e. to 0.06 and 0.6 mg/L/6h/day), there is insufficient data to determine if adverse effects would occur at 0.06 or 0.6 mg/L/6h/day.*
- Inhalation exposure to Italian talc dust at 10.8 mg/m^3 in male and female Wistar rats for 7.5 hours/day, 5 days/week for 3, 6, or 12 months. A dose-dependent increase in fibrosis was observed from minimal (3 months) to slight (12 months). ToxServices established the LOAEC at 10.8 mg/m^3 (equivalent to 0.0096 mg/L/6h/day[8]).
- Inhalation exposure to a commercial talc-based baby powder at 3, 30 or 150 min/day for 5 days/week for 30 days at 37.1 µg/L did not cause statistically significant difference in survival in Syrian golden hamsters. However, there was a statistically significant difference in survival between sexes in each group. No dose-related changes were observed regarding the incidence and severity of pulmonary lesions among groups. Due to the non-standardized dosing scheme, no LOAEC or NOAEC could be established.
- Inhalation exposure to talc at 30-383 mg/m^3 for 6h/day, 6 days/week for 9 months did not increase mortality in rats. No LOAEC or NOAEC could be established due to lack of detailed results.
- In the previously described lifetime carcinogenicity study in mice, B6C3F1 mice (47-50/sex/dose group) administered inhalation doses of talc at 0, 6, or 18 mg/m^3 (equivalent to 0, 2, and 6 mg/kg/day for males and 0, 1.3, and 3.9 mg/kg/day for females, respectively) for 6 hours/day, 5 days/week for up to 104 weeks. Analysis of bronchioalveolar lavage fluid suggested chronic pulmonary inflammation, but there was no microscopic evidence of hyperplasia, metaplasia or fibrosis. ToxServices established a LOAEC of 6 mg/m^3 for this study (equivalent to 0.006 mg/L).
- In the previously described lifetime carcinogenicity study in rats, F344/N rats (49-50/sex/dose group) administered inhalation doses of talc at 0, 6 or 18 mg/m^3 (equivalent to 0, 2.8, and 8.4 mg/kg/day for males and 0, 3.2, and 9.6 mg/kg/day for females, respectively) for 6 hours/day, 5 days/week for up to 113 weeks (males) or 122 weeks (females) depending on when mortality in each group reached 80%. Non-neoplastic findings in exposed rats included impaired respiratory function and

[7] Duration adjustment: 18 mg/m^3 x 5 days/7 days x 10^{-3} m^3/L = 0.013 mg/L/day.
[8] Duration adjustment: 10.8 mg/m^3 x 5 days/7 days x 7.5 h/6h x 10^{-3} m^3/L = 0.0096 mg/L/6h/day.

changes in BAL fluid indicative of inflammation; microscopic examination of the respiratory tract showed hyperplasia, metaplasia, and interstitial fibrosis, which can be considered pre-neoplastic lesions. As for mice, the LOAEC for non-neoplastic effects on the rat respiratory system was 6 mg/m^3 (equivalent to 0.006 mg/L).

- Based on the weight of the evidence, a score of Low was assigned for the oral and dermal routes of exposure. A repeated dose toxicity study in rats established oral NOAEL values greater than 200 mg/kg/day and dermal studies reported no adverse systemic effects following exposure. A score of High was assigned for the inhalation route of exposure. Occupational talc exposure can reduce pulmonary function and produce restrictive pulmonary disease; therefore talc was classified as GHS Category 1. Additionally, animal studies reported a dose-dependent increase in lung fibrosis, pulmonary inflammation, and impaired respiratory function; these studies established LOAEC values less than 0.1 mg/L. According to GHS Guidance, a LOAEC value less than 0.02 mg/L/6h/day (dust/mist/fume) classifies a chemical to GHS Category 1. Therefore, talc was classified as GHS Category 1 for the inhalation route of exposure and assigned a High score.

Neurotoxicity (N)
***Group II Score (single dose)* (vH, H, M, or L):** DG
Talc was assigned a score of Data Gap for neurotoxicity (single dose) based on a lack of data for this endpoint.

- Authoritative and Screening Lists
  - *Authoritative:* not included on any authoritative lists
  - *Screening:* not included on any screening lists
- Not classified as a developmental neurotoxicant (Grandjean and Landrigan 2006, 2014).
- No data were identified.

***Group II* Score (repeated dose)* (H, M, or L):** DG
Talc was assigned a score of Data Gap for neurotoxicity (repeated dose) based on a lack of data for this endpoint.

- Authoritative and Screening Lists
  - *Authoritative:* not included on any authoritative lists
  - *Screening:* not included on any screening lists
- Not classified as a developmental neurotoxicant (Grandjean and Landrigan 2006, 2014).
- No data were identified.

Skin Sensitization (SnS) Group II* Score (H, M, or L): L
Talc was assigned a score of Low for skin sensitization based on negative findings in a skin sensitization study in guinea pigs. GreenScreen® criteria classify chemicals as a Low hazard for skin sensitization when adequate data are available and negative, there are no structural alerts, and they are not GHS classified (CPA 2012a).

- Authoritative and Screening Lists
  - *Authoritative:* not included on any authoritative lists
  - *Screening:* not included on any screening lists
- CIR 2013
  - Talc is not dermally sensitizing in female Hartley guinea pigs. Animals were exposed to 10 mg talc via intra-dermal injection and then challenged with talc in one ear and the negative control in the other ear. No changes in response to the treatments were observed between talc and starch.

Respiratory Sensitization (SnR) Group II* Score (H, M, or L): DG
Talc was assigned a score of Data Gap for respiratory sensitization based on a lack of data for this endpoint.

- Authoritative and Screening Lists
  - *Authoritative:* not included on any authoritative lists
  - *Screening:* not included on any screening lists
- No data were identified.

Skin Irritation/Corrosivity (IrS) Group II Score (vH, H, M, or L): L
Talc was assigned a score of Low for skin irritation/corrosivity based on negative findings in dermal irritation studies in humans and rabbits. GreenScreen® criteria classify chemicals as a Low hazard for skin irritation/corrosivity when adequate data are available and negative, there are no structural alerts, and they are not GHS classified (CPA 2012a).

- Authoritative and Screening Lists
  - *Authoritative:* not included on any authoritative lists
  - *Screening:* not included on any screening lists
- ECB 2000
  - When tested for irritant properties on human skin, talc was classified in the "low" class for skin irritation. The possible classifications were low, slight, moderate, or marked. No further details were provided.
  - Primary cutaneous irritation tests performed with rabbits did not produce evidence of dermal irritation. No further details were provided.

Eye Irritation/Corrosivity (IrE) Group II Score (vH, H, M, or L): L
Talc was assigned a score of Low for eye irritation/corrosivity based on negative findings in ocular irritation studies. GreenScreen® criteria classify chemicals as a Low hazard for eye irritation/corrosivity when adequate data are available and negative, there are no structural alerts, and they are not GHS classified (CPA 2012a).

- Authoritative and Screening Lists
  - *Authoritative:* not included on any authoritative lists
  - *Screening:* not included on any screening lists
- ECB 2000
  - When installed into the eyes of rabbits, no signs of irritation were observed after 12 consecutive days. No further details were provided.
  - Slight irritation was observed in rabbit eyes following installation of talc. No further details were provided.

Ecotoxicity (Ecotox)

Acute Aquatic Toxicity (AA) Score (vH, H, M, or L): L
Talc was assigned a score of Low for acute aquatic toxicity based on measured data and expert judgment. GreenScreen® criteria classify chemicals as a Low hazard for acute aquatic toxicity when acute aquatic toxicity values are greater than 100 mg/L (CPA 2012a).

- Authoritative and Screening Lists
  - *Authoritative:* not included on any authoritative lists
  - *Screening:* not included on any screening lists
- HSDB 2011
  - LC_{50} *Brachydanio rerio* (Zebra fish) >100 g/L/24 hr; semistatic

- No further aquatic toxicity data were identified. QSAR modeling cannot be performed as it is an inorganic chemical. As a component of common rocks, talc is not soluble in water and inert. Therefore, it is not expected to cause aquatic toxicity and acute L/EC_{50} values are expected to be greater than 100 mg/L.

Chronic Aquatic Toxicity (CA) Score (vH, H, M, or L): *L*
Talc was assigned a score of Low for chronic aquatic toxicity based on expert judgment. GreenScreen® criteria classify chemicals as a Low hazard for chronic aquatic toxicity when chronic values are greater than 10 mg/L (CPA 2012a). Confidence level is reduced due to lack of measured data.

- Authoritative and Screening Lists
  - *Authoritative:* not included on any authoritative lists
  - *Screening:* not included on any screening lists
- No data were identified. QSAR modeling cannot be performed as it is an inorganic chemical. As a component of common rocks, talc is not soluble in water and inert. Therefore, it is not expected to cause aquatic toxicity and chronic values are expected to be greater than 10 mg/L.

Environmental Fate (Fate)

Persistence (P) Score (vH, H, M, L, or vL): *vH*
Talc was assigned a score of Very High for persistence based on classification by the DSL screening list and expert judgment. GreenScreen® criteria classify chemicals as a Very High hazard for persistence when they are associated with the DSL screening list (CPA 2012a).

- Authoritative and Screening Lists
  - *Authoritative:* not included on any authoritative lists
  - *Screening:* DSL: DSL substances that are persistent
- No biodegradation studies were identified for talc. It is associated with the DSL screening list which warrants a Very High to High score. Talc is an inorganic compound. As such, it is expected to persist in the environment. Therefore, a score of Very High was assigned.

Bioaccumulation (B) Score (vH, H, M, L, or vL): *L*
Talc was assigned a score of Low for bioaccumulation based on expert judgment. Confidence in this endpoint was reduced due to the use of an MSDS. GreenScreen® criteria classify chemicals as a Low hazard for bioaccumulation when they do not bioaccumulate (CPA 2012a).

- Authoritative and Screening Lists
  - *Authoritative:* not included on any authoritative lists
  - *Screening:* not included on any screening lists
- Bayer MaterialScience Undated
  - Does not bioaccumulate
- Talc is an inorganic compound and it is not expected to bioaccumulate. Based on expert judgment and evidence from an MSDS, a score of Low was assigned.

Physical Hazards (Physical)

Reactivity (Rx) Score (vH, H, M, or L): *L*
Talc was assigned a score of Low for reactivity based on its HMIS physical hazard rating. GreenScreen® criteria classify chemicals as a Low hazard for reactivity when they are not explosive, or self-reactive (CPA 2012a).

- Authoritative and Screening Lists

  - *Authoritative:* not included on any authoritative lists
  - *Screening:* not included on any screening lists
- Sigma-Aldrich 2014
  - Talc has an HMIS physical hazard rating of 0. An HMIS physical hazard rating of 0 corresponds to "Materials that are normally stable, even under fire conditions, and will NOT react with water, polymerize, decompose, condense, or self-react. Non-Explosive" (Paint.org 2014).

Flammability (F) Score (vH, H, M, or L): *L*

Talc was assigned a score of Low for flammability based on its HMIS flammability rating. GreenScreen® criteria classify chemicals as a Low hazard for flammability when they are not flammable (CPA 2012a).

- Authoritative and Screening Lists
  - *Authoritative:* not included on any authoritative lists
  - *Screening:* not included on any screening lists
- Sigma-Aldrich 2014
  - Talc has an HMIS flammability rating of 0. An HMIS flammability rating of 0 corresponds to "Materials that will not burn" (Paint.org 2014).

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APPENDIX A: Hazard Benchmark Acronyms
(in alphabetical order)

(AA) Acute Aquatic Toxicity

(AT) Acute Mammalian Toxicity

(B) Bioaccumulation

(C) Carcinogenicity

(CA) Chronic Aquatic Toxicity

(D) Developmental Toxicity

(E) Endocrine Activity

(F) Flammability

(IrE) Eye Irritation/Corrosivity

(IrS) Skin Irritation/Corrosivity

(M) Mutagenicity and Genotoxicity

(N) Neurotoxicity

(P) Persistence

(R) Reproductive Toxicity

(Rx) Reactivity

(SnS) Sensitization- Skin

(SnR) Sensitization- Respiratory

(ST) Systemic/Organ Toxicity

APPENDIX B: Results of Automated GreenScreen® Score Calculation for Talc (CAS #14807-96-6)

TOXSERVICES
TOXICOLOGY RISK ASSESSMENT CONSULTING

GreenScreen® Score Inspector for Inhalation Exposure

Table 1: Hazard Table

			Group I Human					Group II and II* Human								Ecotox		Fate		Physical	
			Carcinogenicity	Mutagenicity/Genotoxicity	Reproductive Toxicity	Developmental Toxicity	Endocrine Activity	Acute Toxicity	Systemic Toxicity		Neurotoxicity		Skin Sensitization*	Respiratory Sensitization*	Skin Irritation	Eye Irritation	Acute Aquatic Toxicity	Chronic Aquatic Toxicity	Persistence	Bioaccumulation	Reactivity	Flammability
Table 2: Chemical Details									S	R *	S	R *	*	*								
Inorganic Chemical?	**Chemical Name**	**CAS#**	**C**	**M**	**R**	**D**	**E**	**AT**	**STs**	**STr**	**Ns**	**Nr**	**SNS***	**SNR***	**IrS**	**IrE**	**AA**	**CA**	**P**	**B**	**Rx**	**F**
Yes	**Talc**	**14807-96-6**	**M**	**L**	*L*	**L**	*M*	DG	DG	**H**	DG	DG	**L**	DG	**L**	**L**	**L**	*L*	*vH*	*L*	*L*	*L*

Table 3: Hazard Summary Table

Benchmark	a	b	c	d	e	f	g
1	No	No	Yes	No	No		
2	STOP						
3	STOP						
4	STOP						

Table 4

Chemical Name	Preliminary GreenScreen® Benchmark Score
Talc	1

Note: Chemical has not undergone a data gap assessment. Not a Final GreenScreen™ Score

Table 6

Chemical Name	Final GreenScreen® Benchmark Score
Talc	1

After Data gap Assessment
Note: No Data gap Assessment Done if Preliminary GS Benchmark Score is 1.

Table 5: Data Gap Assessment Table

Datagap Criteria	a	b	c	d	e	f	g	h	i	j	bm4	End Result
1												1
2												
3												
4												

TOXSERVICES
TOXICOLOGY RISK ASSESSMENT CONSULTING

GREEN SCREEN FOR SAFER CHEMICALS

GreenScreen® Score Inspector for Oral Exposure

Table 1: Hazard Table

			Group I Human					Group II and II* Human								Ecotox		Fate		Physical	
			Carcinogenicity	Mutagenicity/Genotoxicity	Reproductive Toxicity	Developmental Toxicity	Endocrine Activity	Acute Toxicity	Systemic Toxicity		Neurotoxicity		Skin Sensitization*	Respiratory Sensitization*	Skin Irritation	Eye Irritation	Acute Aquatic Toxicity	Chronic Aquatic Toxicity	Persistence	Bioaccumulation	Reactivity	Flammability
Table 2: Chemical Details									S	R *	S	R *	*	*								
Inorganic Chemical?	Chemical Name	CAS#	C	M	R	D	E	AT	STs	STr	Ns	Nr	SNS*	SNR*	IrS	IrE	AA	CA	P	B	Rx	F
Yes	Talc	14807-96-6	L	L	*L*	L	DG	L	DG	L	DG	DG	L	DG	L	L	L	*L*	*vH*	*L*	*L*	*L*

Table 3: Hazard Summary Table

Benchmark	a	b	c	d	e	f	g
1	No	No	No	No	No		
2	No	No	No	No	No	No	No
3	No	No	No	No			
4	STOP						

Table 4

Chemical Name	Preliminary GreenScreen® Benchmark Score
Talc	4

Note: Chemical has not undergone a data gap assessment. Not a Final GreenScreen™ Score

Table 6

Chemical Name	Final GreenScreen® Benchmark Score
Talc	3DG

After Data gap Assessment
Note: No Data gap Assessment Done if Preliminary GS Benchmark Score is 1.

Table 5: Data Gap Assessment Table

Datagap Criteria	a	b	c	d	e	f	g	h	i	j	bm4	End Result
1												
2												
3												
4	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	3DG

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GREEN SCREEN FOR SAFER CHEMICALS

GreenScreen® Score Inspector for Dermal Exposure

Table 1: Hazard Table

			Group I Human					Group II and II* Human								Ecotox		Fate		Physical	
			Carcinogenicity	Mutagenicity/Genotoxicity	Reproductive Toxicity	Developmental Toxicity	Endocrine Activity	Acute Toxicity	Systemic Toxicity		Neurotoxicity		Skin Sensitization*	Respiratory Sensitization*	Skin Irritation	Eye Irritation	Acute Aquatic Toxicity	Chronic Aquatic Toxicity	Persistence	Bioaccumulation	Reactivity	Flammability
Table 2: Chemical Details									S	R *	S	R *	*	*								
Inorganic Chemical?	**Chemical Name**	**CAS#**	**C**	**M**	**R**	**D**	**E**	**AT**	**STs**	**STr**	**Ns**	**Nr**	**SNS***	**SNR***	**IrS**	**IrE**	**AA**	**CA**	**P**	**B**	**Rx**	**F**
Yes	**Talc**	**14807-96-6**	**M**	**L**	*L*	**L**	DG	DG	DG	**L**	DG	DG	**L**	DG	**L**	**L**	**L**	*L*	*vH*	*L*	*L*	*L*

Table 3: Hazard Summary Table

Benchmark	a	b	c	d	e	f	g
1	No	No	No	No	No		
2	No	No	Yes	No	Yes	No	No
3	STOP						
4	STOP						

Table 4

Chemical Name	Preliminary GreenScreen® Benchmark Score
Talc	2

Note: Chemical has not undergone a data gap assessment. Not a Final GreenScreen™ Score

Table 6

Chemical Name	Final GreenScreen® Benchmark Score
Talc	U

After Data gap Assessment
Note: No Data gap Assessment Done if Preliminary GS Benchmark Score is 1.

Table 5: Data Gap Assessment Table

Datagap Criteria	a	b	c	d	e	f	g	h	i	j	bm4	End Result
1												
2	Yes	No	Yes	Yes	Yes							U
3												
4												

APPENDIX C: Pharos Output for Talc (CAS #14807-96-6)

TALC

CAS RN: 14807-96-6

Synonyms: Talc not containing asbestos or asbestiform fibres

Detailed Direct Hazard Listings — Quickscreen

CANCER	German MAK - List of Substances (MAK) Carcinogen Group 3B - Evidence of carcinogenic effects but not sufficient for classification - GreenScreen Benchmark Unspecified (LT-U) - HPD
CANCER	Intnl Agency for Rsrch on Cancer - Cancer Monographs (IARC) Group 3: Agent is not classifiable as to its carcinogenicity to humans - GreenScreen Benchmark Unspecified (LT-U)
MAMMALIAN	Québec CSST - WHMIS Classifications (WHMIS) Class D2A - Very toxic material causing other toxic effects - GreenScreen Benchmark Unspecified (LT-U)
PBT	Environment Canada - Domestic Substances List (DSL) DSL substances that are Persistent - GreenScreen Benchmark Unspecified (LT-U)
RESTRICTED LIST	CA SCP Candidate Chemicals Full Candidate Chemical List - Not included in GreenScreen
RESTRICTED LIST	Environment Canada - Domestic Substances List (DSL) Inherently Toxic to Humans: DSL substances that meet human health categorization criteria - GreenScreen Benchmark Unspecified (LT-U)
EXEMPT	German FEA - Substances Hazardous to Waters (VwVwS) Non-Hazardous to Water (Water Hazard Class 0 NWG) - Not included in GreenScreen

Sources to Check for GreenScreen® Hazard Assessment

Note: For a GreenScreen® Hazard Assessment, data queries should be initially limited to the following references. If data gaps exist after these references have been checked, additional references may be utilized.

U.S. EPA High Production Volume Information System (HPVIS):
http://www.epa.gov/hpvis/index.html

UNEP OECD Screening Information Datasets (SIDS):
http://www.chem.unep.ch/irptc/sids/OECDSIDS/sidspub.html

OECD Existing Chemicals Database: http://webnet.oecd.org/hpv/ui/SponsoredChemicals.aspx

European Chemical Substances Information System IUCLID Chemical Data Sheets:
http://esis.jrc.ec.europa.eu/index.php?PGM=dat

National Toxicology Program: http://ntp.niehs.nih.gov/

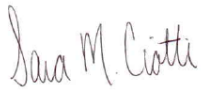
International Agency for the Research on Cancer:
http://monographs.iarc.fr/ENG/Classification/index.php

Human and Environmental Risk Assessment (HERA) on ingredients of household cleaning products:
http://www.heraproject.com/RiskAssessment.cfm

European Chemicals Agency (ECHA) REACH Dossiers: http://echa.europa.eu/

Licensed GreenScreen® Profilers

Talc GreenScreen® Evaluation Prepared by:



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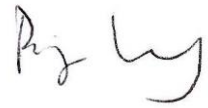
Toxicologist
ToxServices LLC

Talc GreenScreen® Evaluation QC'd by:



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