# Aluminum Hydroxide (CAS# 21645-51-2) GreenScreen® for Safer Chemicals (GreenScreen®) Assessment

**Prepared for:**

**Washington State Department of Ecology**

**Prepared by:**

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**October 14, 2014**

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## GreenScreen® Executive Summary for Aluminum Hydroxide (CAS #21645-51-2)

Aluminum hydroxide is used as an antacid, desiccant powder, in antiperspirants and dentifrices, in packaging materials, as a chemical intermediate, as a filler in plastics, rubber, cosmetics, and paper, as a soft abrasive for brass and plastics, as a glass additive to increase mechanical strength and resistance to thermal shock, weathering, and chemicals, and in ceramics. It is used as a flame-retardant and smoke suppressant in carpet backing, rubber products, fiberglass-reinforced polyesters, cables, and other products. It is also used pharmaceutically to lower plasma phosphorus levels of patients with renal failure.

Aluminum hydroxide was assigned a GreenScreen® Benchmark Score of 1 ("Avoid – Chemical of High Concern") as it has Very High persistence (P), High Group II* Human Toxicity (respiratory sensitization (SnR*)) and Very High Ecotoxicity (chronic aquatic toxicity (CA)). This corresponds to GreenScreen® benchmark classification 1c in CPA 2011. Data gaps (DG) exist for endocrine activity (E). As outlined in CPA (2013) Section 12.2 (Step 8 – Conduct a Data Gap Analysis to assign a final Benchmark score), aluminum hydroxide meets requirements for a GreenScreen® Benchmark Score of 1 despite the hazard data gaps.

**GreenScreen® Benchmark Score for Relevant Route of Exposure:**
As a standard approach for GreenScreen® evaluations, all exposure routes (oral, dermal and inhalation) were evaluated together, so the GreenScreen® Benchmark Score of 1 ("Avoid – Chemical of High Concern") is applicable for all routes of exposure.

**GreenScreen® Hazard Ratings for Aluminum Hydroxide**

| 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* | | | | | | | | | | |
| *L* | **L** | *L* | **L** | DG | **L** | DG | **M** | DG | *M* | L | *H* | **L** | **L** | *L* | *vH* | **vH** | L | *L* | *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 Aluminum Hydroxide (CAS #21645-51-2)

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

**Chemical Name:** Aluminum Hydroxide

**CAS Number:** 21645-51-2

**GreenScreen® Assessment Prepared By:**
Name: Sara M. Ciotti, Ph.D.
Title: Toxicologist
Organization: ToxServices LLC
Date: September 9, 2014
Assessor Type: Licensed GreenScreen® Profiler

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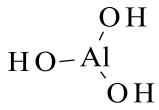
Name: Bingxuan Wang, Ph.D.
Title: Toxicologist
Organization: ToxServices LLC
Date: September 10, 2014

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

**Chemical Structure(s):**



**Also called:** A 3011; AC 450; AC 714KC; AE 107; AF 260; AKP-DA; Alcoa 331; Alcoa 710; Alcoa A 325; Alcoa AS 301; Alcoa C 30BF; Alcoa C 31;l Alcoa C 33; Alcoa C 330; Alcoa C 331; Alcoa C 333; Alcoa C 385; Alcoa H 65; Alhydrogel; Alolt 8; Alolt 80; Alolt 90; ALternaGEL; Alternagel; Alu-Cap; Alugel; Alugelibye; Alumigel; Alumina trihydrate; Aluminic acid (H3AlO3); Aluminum hydroxide gel; Aluminum hydroxide, dried; Aluminum oxide trihydrate; Aluminum trihydroxide; Aluminum(III) hydroxide; Alusal; Amberol ST 140F; Amorphous alumina; Amphogel; Amphojel; Antipollon HT; Apyral; Apyral 120; Apyral 120VAW; Apyral 15; Apyral 2; Apyral 24; Apyral 25; Apyral 4; Apyral 40; Apyral 60; Apyral 8; Apyral 90; Apyral B; BACO AF 260; Boehmite; British aluminum AF 260; C 31; C 31C; C 31F; C 33; C 4D; C-31-F; C.I. 77002; Calmogastrin; CI 77002; Dialume; EINECS 244-492-7; GHA 331; GHA 332; GHA 431; H 46; Higilite; Higilite H 31S; Higilite H 32; Higilite H 42; HSDB 575; Hychol 705; Hydrafil; Hydral 705; Hydral 710; Hydrated alumina; Hydrated aluminum oxide; Liquigel; Martinal; Martinal A; Martinal A/S; Martinal F-A; P 30BF; PGA; Reheis F 1000; Trihydrated alumina; Trihydroxyaluminum; UNII-5QB0T2IUN0; Aluminum hydroxide (Al(OH)3) (ChemIDplus 2014)

**Chemical Structure(s) of Chemical Surrogates Used in the GreenScreen®:**
As aluminum hydroxide had a sufficient dataset, a chemical surrogate was not used for 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:** (U.S. EPA 2008; HCN 2009; HSDB 2013)
1. Antacid
2. Desiccant powder
3. Antiperspirant and dentifrices
4. Chemical intermediate
5. Filler
6. Additive
7. Flame retardant and smoke suppressant
7. Pharmaceutically to lower phosphorus levels of patients with renal failure

**GreenScreen® Summary Rating for Aluminum Hydroxide[4]:** Aluminum hydroxide was assigned a GreenScreen® Benchmark Score of 1 ("Avoid – Chemical of High Concern") as it has Very High persistence (P), High Group II* Human Toxicity (respiratory sensitization (SnR*)) and Very High Ecotoxicity (chronic aquatic toxicity (CA)). This corresponds to GreenScreen® benchmark classification 1c in CPA 2011, 2012a. Data gaps (DG) exist for endocrine activity (E). As outlined in CPA (2013) Section 12.2 (Step 8 – Conduct a Data Gap Analysis to assign a final Benchmark score), aluminum hydroxide meets requirements for a GreenScreen® Benchmark Score of 1 despite the hazard data gaps.

**Figure 1: GreenScreen® Hazard Ratings for Aluminum Hydroxide**

| 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* | | | | | | | | | | |
| *L* | **L** | *L* | **L** | DG | **L** | DG | **M** | DG | *M* | L | *H* | **L** | **L** | *L* | *vH* | **vH** | L | *L* | *L* |

Note: Hazard levels (Very High (vH), High (H), Moderate (M), Low (L), Very Low (vL)) in *italics* reflect estimated (modeled) 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]

In the smelting process, aluminum hydroxide thermally degrades to alumina (aluminum oxide; CAS# 1344-28-1). As alumina is an LT-U chemical the benchmark score of aluminum hydroxide was not adjusted.

[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.
[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.

| Functional Use | Life Cycle Stage | Transformation Pathway | Transformation Products | CAS # | Feasible and Relevant? | List Translator Results[6,7] |
|---|---|---|---|---|---|---|
| N/A | Smelting | Thermal Degradation | Alumina | 1344-28-1 | No | LT-U |

**Introduction**

Aluminum hydroxide is used as an antacid, desiccant powder, in antiperspirants and dentifrices, in packaging materials, as a chemical intermediate, as a filler in plastics, rubber, cosmetics, and paper, as a soft abrasive for brass and plastics, as a glass additive to increase mechanical strength and resistance to thermal shock, weathering, and chemicals, and in ceramics. It is used as a flame-retardant and smoke suppressant in carpet backing, rubber products, fiberglass-reinforced polyesters, cables, and other products. It is also used pharmaceutically to lower plasma phosphorus levels of patients with renal failure (U.S. EPA 2008; HCN 2009; HSDB 2013).

ToxServices assessed aluminum hydroxide 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 aluminum hydroxide can be found in Appendix C and a summary of the results can be found below:

- Developmental
  - MAK: Pregnancy Risk Group D
- PBT
  - DSL: DSL substances that are Persistent
- Restricted List
  - P + W – Precautionary List: Precautionary list of flame retardants
  - DSL: Inherently Toxic to Humans: DSL substances that meet human health categorization criteri
- Exempt
  - VwVwS: Non-Hazardous to Water
- Respiratory
  - AOEC: Asthmagen (ARs) – sensitizer-induced – inhalable forms only – occupational hazard only

[6] The GreenScreen® List Translator identifies specific authoritative or screening lists that should be searched to screen for GreenScreen® benchmark 1 chemicals (CPA 2012b). Pharos (Pharos 2014) is an online list-searching tool that is used to screen chemicals against the lists in the List Translator electronically.
[7] The way you conduct assessments for transformation products depends on the Benchmark Score of the parent chemical (See Guidance).

**PhysicoChemical Properties of Aluminum Hydroxide**

Aluminum hydroxide is an inorganic chemical. It is a solid at room temperature and is practically insoluble in water. Its low vapor pressure indicates it is not likely to form a vapor.

**Table 1: Physical and Chemical Properties of Aluminum Hydroxide (CAS #21645-51-2)**

| Property | Value | Reference |
|---|---|---|
| Molecular formula | Al-H3-O3 | ChemIDplus 2014 |
| SMILES Notation | [Al](O)(O)O | ChemIDplus 2014 |
| Molecular weight | 78.0027 | ChemIDplus 2014 |
| Physical state | Solid | HSDB 2013 |
| Appearance | White powder, balls or granules | HSDB 2013 |
| Melting point | 300 ºC | ECHA 2014 |
| Vapor pressure | < 10 Pa at 20ºC | IPCS 1998 |
| Water solubility | < 0.00009 g/L; 11.7 – 94.7 µg/L $Al(OH)_3$, and 4.06 – 32.75 µg/L Al | ECHA 2014; U.S. EPA 2014 |
| Dissociation constant | N/A | |
| Density/specific gravity | 2.42 $g/cm^3$ | HSDB 2013 |
| Partition coefficient | N/A | |
| Particle size | > 200 µm (0-1% for fine unground hydrate; 2-5% for coarse unground hydrate) < 100 µm (88% for fine unground hydrate; 52-61% for coarse unground hydrate) < 2 µm (1.3-2% for fine unground hydrate; 1% for coarse unground hydrate) | ECHA 2014 |
| Structure | Mono constituent substance | ECHA 2014 |
| Mobility | Not identified | |
| Bioavailability | Mean fractional uptake of Al is 0.025 ± 0.041% after oral gavage in rats; 0.01% absorbed after oral dosing in humans, | U.S. EPA 2014 |

**Hazard Classification Summary Section:**

**Group I Human Health Effects (Group I Human)**

**Carcinogenicity (C) Score (H, M, or L):** *L*

Aluminum hydroxide was assigned a score of Low for carcinogenicity based on the expert judgment of the U.S. EPA and available data in mice and rats. GreenScreen® criteria classify chemicals as a Low hazard for carcinogenicity 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
- U.S. EPA 2008, 2014

  - "Aluminum hydroxide is expected to be a low hazard for carcinogenicity based on expert judgment and comparison to analogous aluminum compounds."
- IPCS 1998
  - Aluminum hydroxide was not carcinogenic after daily intraperitoneal administration to mice (strain not specified) for 4 months at dosages up to 200 mg Al/kg/day. No further details were provided.
- Mahieu 1998
  - In a 6-month study in rats the effects of aluminum on renal function and phosphate handling were studied. Rats (number/strain not reported) were given aluminum hydroxide (80 mg/kg, intraperitoneal administration) 3 times per week. No changes were observed in renal function and no evidence of carcinogenicity was found.
- Based on the weight of evidence, a score of Low was assigned. Based on expert judgment and comparison to analogous aluminum compounds the U.S. EPA concluded aluminum hydroxide is a low hazard for carcinogenicity. No OECD Guideline carcinogenicity studies were identified. One study reported aluminum hydroxide was not carcinogenic to mice following daily intraperitoneal administration for 4 months. An additional study reported aluminum hydroxide was not carcinogenic to rats following intraperitoneal exposure for 6 months. Based on the expert judgment of the U.S. EPA and the available data, a score of Low was assigned. Confidence in this endpoint was reduced due to a lack of available guideline carcinogenicity studies for aluminum hydroxide.

**Mutagenicity/Genotoxicity (M) Score (H, M, or L): L**
Aluminum hydroxide was assigned a score of Low for mutagenicity/genotoxicity based on a negative gene mutation assay and a negative chromosome aberration assay. 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
- ECHA 2014; U.S. EPA 2014
  - Negative in a gene mutation assay in mouse lymphoma L5178Y cells in the presence and absence of metabolic activation at concentrations up to 780 µg/mL (OECD, GLP).
  - Aluminum hydroxide did not induce micronuclei in the bone marrow of Sprague-Dawley rats (OECD, GLP). Rats (6 males) received 500, 1,000, or 2,000 mg/kg/day aluminum hydroxide via oral gavage on two consecutive days. Treatment did not induce micronuclei in the polychromatic erythrocytes of the bone marrow of male rats.

**Reproductive Toxicity (R) Score (H, M, or L):** *L*
Aluminum hydroxide was assigned a score of Low for reproductive toxicity based on the expert opinion of the U.S. EPA. 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
- U.S. EPA 2008, 2014
  - "Aluminum hydroxide is estimated to be of low hazard for reproductive effects based on professional judgment and comparison to analogous aluminum compounds."

- Based on the weight of evidence, a score of Low was assigned. No reproductive toxicity studies were identified for aluminum hydroxide. However, based on professional judgment and comparison to analogous aluminum compounds, the U.S. EPA determined aluminum hydroxide is a low hazard for reproductive effects. Therefore, a score of Low was assigned. Confidence in this endpoint was reduced due to the lack of measured data.

**Developmental Toxicity incl. Developmental Neurotoxicity (D) Score (H, M, or L): L**
Aluminum hydroxide was assigned a score of Low for developmental toxicity based on studies in rats and mice. 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).

- Authoritative and Screening Lists
    - *Authoritative:* MAK – Pregnancy Risk Group D
    - *Screening:* not included on any screening lists
- HCN 2009
    - Female Swiss mice (18-20/group) received 0, 66.5, 133, or 266 mg/kg/day aluminum hydroxide via oral gavage on gestation days 6-15. Mice were sacrificed on gestation day 18. Treatment had no effect on food consumption, body weight, organ weights, appearance, or behavior of the dams. Treatment did not affect the number of implantation sites, resorptions, number of live and dead fetuses, sex ratio, fetal weights and fetal lengths, external soft-tissue, or skeletal abnormalities.
    - Female Wistar rats (18-19/group) received 0, 192, 384, or 768 mg/kg aluminum hydroxide via oral gavage on gestation days 6-15. Rats were sacrificed on gestation day 20. Treatment had no effect on pregnancy rate, implantation sites, resorptions, number of live and dead fetuses, fetal weights, and external, soft-tissue, and skeletal abnormalities.
    - Female Swiss mice (10-13/group) were treated with 166 mg/kg/day aluminum hydroxide, 627 mg/kg/day aluminum lactate, or 570 mg/kg/day aluminum hydroxide concurrent with lactic acid on gestation days 6-15 via oral gavage. Mice were sacrificed on gestation day 18. Treatments had no effect on maternal liver and kidney weights, pregnancy rate, implantations, resorptions, or live and dead fetuses. Treatment with aluminum hydroxide with or without citric acid had no effect on fetal weights or skeletal malformations.
    - Female Swiss mice received 300 mg/kg/day aluminum hydroxide, 85 mg/kg/day ascorbic acid, or aluminum hydroxide and ascorbic acid on gestation days 6-15 via oral gavage. Treatments did not cause maternal toxicity. They had no effect on the number of implantations, resorptions, live fetuses, implantation loss, sex ratio, or fetal body weights. Treatment had no effect on external, soft-tissue, or skeletal abnormalities.

**Endocrine Activity (E) Score (H, M, or L):** DG
Aluminum hydroxide was assigned a score of Data Gap for endocrine disruption 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 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.
- No data were identified.

**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**

Aluminum hydroxide was assigned a score of Low for acute toxicity based on oral $LD_{50}$ values greater than 2,000 mg/kg in rats. GreenScreen® criteria classify chemicals as a Low hazard for acute toxicity when the oral $LD_{50}$ values are greater than 2,000 mg/kg (CPA 2012a).

- Authoritative and Screening Lists
  - *Authoritative:* not included on any authoritative lists
  - *Screening:* not included on any screening lists
- ECHA 2014
  - Oral $LD_{50}$ = > 2,000 mg/kg in rats
- ESIS 2000
  - Oral $LD_{50}$ = > 5,000 mg/kg in rats

**Systemic Toxicity/Organ Effects incl. Immunotoxicity (ST)**

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

Aluminum hydroxide 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
- No data were identified.

***Group II* Score (repeated dose)* (H, M, or L): M**

Aluminum hydroxide was assigned a score of Moderate for systemic toxicity (repeated dose) based on decreased primed cytotoxic T-cells in humans. GreenScreen® criteria classify chemicals as a Moderate hazard for systemic toxicity (repeated dose) when classified as GHS Category 2 (CPA 2012a).

- Authoritative and Screening Lists
  - *Authoritative:* not included on any authoritative lists
  - *Screening:* not included on any screening lists
- HSDB 2013; U.S. EPA 2014
  - Human volunteers between the ages of 28-57 years (mean age 42) were divided into a test group (9 females and 4 males) and a control group (3 females and 2 males). Volunteers ingested 10 mL of antacid (aluminum hydroxide, 59 mg Al/mL or approximately 8.43 mg/kg[8]) three times per day (approximately 25.29 mg/kg/day[9]) for 6 weeks. Ingestion of aluminum hydroxide caused a 10 to 20-fold increase in urinary aluminum compared to the controls. Treatment did not alter lymphocyte subpopulations, lymphocyte proliferation, or *in vitro* Ig and IL production. Treatment caused a slight decrease in the CD8+CD45R0+ population (primed cytotoxic T-cells) in treated individuals.
- U.S. EPA 2014

[8] 59 mg Al/mL * 10 mL = 590 mg Al / 70 kg = 8.43 mg/kg
[9] 8.43 mg/kg * 3 times/day = 25.29 mg/kg/day

  - In a 28-day study, male rats (strain not reported) were orally exposed to aluminum hydroxide in their diet. No adverse effects were reported. The authors identified a NOAEL of 14,470 ppm (302 mg Al/kg/day).
- Based on the weight of evidence, a score of Moderate was assigned. In a 28-day study in rats repeated exposure to 302 mg Al/kg/day produced no adverse effects. However, repeated exposure to approximately 25 mg Al/kg/day in humans caused a decrease in primed cytotoxic T-cells. Therefore, aluminum hydroxide was classified as GHS Category 2 and a score of Moderate was assigned.

**Neurotoxicity (N)**
***Group II Score (single dose)* (vH, H, M, or L):** DG
Aluminum hydroxide 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*: Grandjean and Landrigan 2006: Aluminum compounds are neurotoxic in man.
- No data were identified.

***Group II* Score (repeated dose)* (H, M, or L):** *M*
Aluminum hydroxide was assigned a score of Moderate for neurotoxicity (repeated dose) based on measured data in rats and being listed by Grandjean and Landrigan (2006). GreenScreen® criteria classify chemicals as a Low hazard for neurotoxicity (repeated dose) when classified as GHS Category 2 (CPA 2012a).

- Authoritative and Screening Lists
  - *Authoritative:* not included on any authoritative lists
  - *Screening:* Grandjean and Landrigan 2006: Aluminum compounds are neurotoxic in man
- U.S. EPA 2008, 2014
  - In a 30-day study, rats (number/strain not reported) were fed aluminum hydroxide in their diet with no significant effects noted and a reported NOAEL of 1,252 mg/kg/day.
  - In a 90-day study, rats (number/strain not reported) were given aluminum hydroxide with citric acid by oral gavage and demonstrated impaired learning in a labyrinth maze test. A LOAEL of 35 mg Al/kg/day as aluminum hydroxide was reported. The authors noted that citric acid was added to increase the absorption of aluminum hydroxide and it was proven that the negative effects were not due to citric acid.
  - Aluminum hydroxide is expected to be a moderate hazard for neurotoxicity based on the available data.
- U.S. EPA 2014
  - In a 90-day study, rats (number/strain not reported) received aluminum hydroxide via oral gavage and demonstrated impaired learning in a labyrinth maze test. A LOAEL of 300 mg Al/kg/day as aluminum hydroxide was reported (only dose tested).
- Based on the weight of evidence, a score of Moderate was assigned. Impaired learning was reported in a labyrinth maze test in a 90-day oral study in rats exposed to aluminum hydroxide and citric acid with a LOAEL of 35 mg Al/kg/day (only dose tested, equivalent to 101 mg aluminum hydroxide/kg/day[10]). Citric acid was added to increase the absorption of aluminum hydroxide and it was proven that the negative effects were not due to citric acid. Impaired learning was also reported in a 90-day study in rats orally exposed to aluminum hydroxide with a LOAEL of 300 mg Al/kg/day

[10] MW of Al = 27; MW of aluminum hydroxide = 78. 35 mg Al = 35 mg/27 x 78 (aluminum hydroxide) = 101 mg aluminum hydroxide)

(only dose tested). As 300 mg Al/kg/day was the only dose tested, it is unknown if effects occur at lower doses. Therefore, aluminum hydroxide was conservatively classified as GHS Category 2 and assigned a Moderate score based on the LOAEL of 35 mg Al/kg/day (101 mg aluminum hydroxide/kg/day). Confidence in this endpoint was reduced due to the use of citric acid to increase systemic absorption of aluminum hydroxide in the critical study.

**Skin Sensitization (SnS) Group II* Score (H, M, or L): L**
Aluminum hydroxide was assigned a score of Low for skin sensitization based on a negative guinea pig maximization test. 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
- ECHA 2014
  - Aluminum hydroxide was not sensitizing in a GLP-compliant guinea pig maximization test performed according to OECD 406 in male Dunkin-Hartley guinea pigs (10 animals). Animals were induced with intra-dermal injections of 1% (w/v) aluminum hydroxide and dermal applications of 100% (w/v) aluminum hydroxide and they were epicutaneously challenged with 75% (w/v) aluminum hydroxide and 37.5% (w/v) aluminum hydroxide. Treatment produced no positive skin sensitization reactions.
- ESIS 2000
  - Aluminum hydroxide is not sensitizing.

**Respiratory Sensitization (SnR) Group II* Score (H, M, or L):** *H*
Aluminum hydroxide was assigned a score of High for respiratory sensitization based on being listed as an asthmagen by AOEC, a screening list. GreenScreen® criteria classify chemicals as a Moderate to High hazard for respiratory sensitization when associated with AOEC ARs (CPA 2012a). In the absence of data, ToxServices assigned a High score to be protective of human health. Confidence was reduced due to reliance on screening lists.

- Authoritative and Screening Lists
  - *Authoritative:* not included on any authoritative lists
  - *Screening:* AOEC: ARs – sensitizer-induced – inhalable forms only – occupational hazard only
- No data were identified.

**Skin Irritation/Corrosivity (IrS) Group II Score (vH, H, M, or L): L**
Aluminum hydroxide was assigned a score of Low for skin irritation/corrosivity based on measured data in rabbits, mice, and guinea pigs. 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
- ECHA 2014
  - Aluminum hydroxide did not cause skin irritation in a GLP-compliant skin irritation study performed according to OECD Guideline 404. Aluminum hydroxide was applied to shaved skin of three New Zealand White rabbits for 4 hours under semiocclusive conditions. Skin

irritation was scored 24, 48, and 72 hours after patch removal. No skin irritation was observed at 24, 48, or 72 hours.
    - Repeated exposure to aluminum hydroxide was not irritating to five mice, three rabbits, or two guinea pigs (strains not specified). Animals were exposed to 10% (w/v) aluminum hydroxide once a day for 5 days. No dermal irritation was reported.
- ESIS 2000
    - Aluminum hydroxide did not cause dermal irritation in rabbits (OECD 404).

**Eye Irritation/Corrosivity (IrE) Group II Score (vH, H, M, or L): L**
Aluminum hydroxide was assigned a score of Low for eye irritation/corrosivity based on a GLP-compliant study in rabbits. 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
- ECHA 2014
    - Aluminum hydroxide did not cause eye irritation in a GLP-compliant eye irritation study performed according to OECD Guideline 405. Aluminum hydroxide (0.1 mL) was instilled into one eye of New Zealand White rabbits (3 males) and washed out 1 hour after instillation. Eye irritation was assessed 1, 24, 48, and 72 hours after treatment. Twenty-four hours after treatment two animals showed slight redness of the eye; no redness was observed 48 or 72 hours after treatment.
- ESIS 2000
    - Aluminum hydroxide did not cause eye irritation in rabbits (OECD 405).

**<u>Ecotoxicity (Ecotox)</u>**

**Acute Aquatic Toxicity (AA) Score (vH, H, M, or L):** *L*
Aluminum hydroxide was assigned a score of Low for acute aquatic toxicity based on water solubility of aluminum in aluminum hydroxide being 10 times higher than the measured aquatic toxicity values for soluble aluminum. GreenScreen® criteria classify chemicals as a Low hazard for aquatic toxicity when no effects are expected at saturation in water (CPA 2012a).
- Authoritative and Screening Lists
    - *Authoritative:* not included on any authoritative lists
    - *Screening:* not included on any screening lists
- ESIS 2000
    - 96h NOEC = > 100 mg/L (*Salmo trutta*, fish)
    - 48h NOEC = > 100 mg/L (*Daphnia magna*, daphnia)
    - 72h NOEC = > 100 mg/L (*Selenastrum capricornutum*, algae)
- U.S. EPA 2014
    - Aluminum hydroxide may cause adverse effects in aquatic species (U.S. EPA 2010). Therefore, aluminum hydroxide is a moderate hazard for acute aquatic toxicity.
    - 96h $EC_{50}$ = 0.46 mg/L (*Pseudokirchnerella subcapitata*, algae) (probably listed in terms of mg Al/L)
- U.S. EPA 2010
    - Values listed below are derived from soluble salts of aluminum:
    - Fish 96h $LC_{50}$ (measured) = 3.6-35 mg Al/L

  - Daphnia 48h $LC_{50}$ (measured) = 1.9-38 mg Al/L
  - Green algae 96h $EC_{50}$ (measured) = 0.46-0.57 mg Al/L
- Based on the available data, a score of Low was assigned. The available acute aquatic toxicity studies from ESIS (2000) reported $LC/EC_{50}$ values much greater than the water solubility limit of aluminum hydroxide, indicating the quality of the studies may be inadequate. Measured data from soluble aluminum salts were as low as 0.46 mg Al/L. Reported solubility of aluminum hydroxide is variable. It is known that it is soluble under acidic and basic conditions, and the solubility at neutral conditions is 4.06-32.75 µg/L in terms of aluminum (U.S. EPA 2014). Available data appeared to indicate that the lowest $L/EC_{50}$ values for $Al^{3+}$ in water is more than 10 times higher than the highest reported solubility of aluminum as aluminum hydroxide. Therefore, under neutral conditions, or close to neutral conditions, aluminum hydroxide is not expected to be a concern for acute aquatic toxicity. Confidence level was reduced based on lack of reliable toxicity and solubility data on aluminum hydroxide itself.

**Chronic Aquatic Toxicity (CA) Score (vH, H, M, or L):** *vH*
Aluminum hydroxide was assigned a score of Very High for chronic aquatic toxicity based on NOEC of 0.004 mg Al/L (equivalent to 0.0116 mg $Al(OH)_3$/L) in algae. GreenScreen® criteria classify chemicals as a Very High hazard for chronic aquatic toxicity when chronic NOECs are no greater than 0.1 mg/L (CPA 2012a).

- Authoritative and Screening Lists
  - *Authoritative:* not included on any authoritative lists
  - *Screening:* not included on any screening lists
- U.S. EPA 2014
  - Aluminum hydroxide may cause adverse effects in aquatic species (U.S. EPA 2010). Therefore, aluminum hydroxide is a moderate hazard for chronic aquatic toxicity.
  - 72h NOEC = 0.004-0.052 mg/L (*Pseudokirchnerella subcapitata*, algae) (probably listed in terms of mg Al/L)
- U.S. EPA 2010
  - Values listed below are derived from soluble salts of aluminum:
  - Fish ChV (measured) = 3.3 – 11.0 mg Al/L
  - Daphnia ChV (measured) = 0.320 – 24 mg Al/L
  - Green algae ChV (predicted) = 0.100 mg Al/L
- Based on the weight of evidence, a score of Moderate was assigned. The lowest ChV/NOEC reported is 0.004 mg (presumably Al)/L. Reported solubility of aluminum hydroxide is variable. It is known that it is soluble under acidic and basic conditions, and the solubility at neutral conditions is 4.06-32.75 µg/L in terms of aluminum (U.S. EPA 2014). Therefore, the solubility of aluminum hydroxide may be high enough to measure the chronic aquatic toxicities. Therefore, ToxServices used the value of 0.004 mg Al/L (equivalent to 0.0116 mg $Al(OH)_3$/L) to evaluat this endpoint. Confidence level was reduced based on the lack of reliable toxicity and solubility data on aluminum hydroxide itself.

## Environmental Fate (Fate)

**Persistence (P) Score (vH, H, M, L, or vL): vH**
Aluminum hydroxide was assigned a score of Very High for persistence because it is an inorganic material and is not expected to biodegrade. GreenScreen® criteria classify chemicals as a Very High hazard for persistence when substances are recalcitrant (CPA 2012a).

- Authoritative and Screening Lists

  - *Authoritative:* not included on any authoritative lists
  - *Screening:* DSL: DSL substances that are Persistent
- U.S. EPA 2008
  - Aluminum hydroxide is an inorganic substance; it is not expected to biodegrade, oxidize in air, or undergo hydrolysis. No degradation processes were identified.
  - Aluminum hydroxide is expected to be recalcitrant in water and soil. It has an estimated atmospheric half-life of greater than 1 year.

**Bioaccumulation (B) Score (vH, H, M, L, or vL): L**
Aluminum hydroxide was assigned a score of Low for bioaccumulation based on a measured BCF value of 136 for soluble aluminum salts. GreenScreen® criteria classify chemicals as a Low hazard for bioaccumulation when the BCF is between 100 and 500 (CPA 2012a).

- Authoritative and Screening Lists
  - *Authoritative:* not included on any authoritative lists
  - *Screening:* not included on any screening lists
- U.S. EPA 2008
  - Aluminum hydroxide is not expected to bioaccumulate.
  - BCF < 500 (estimated)
- U.S. EPA 2010
  - Measured 30-BCF in fish for soluble aluminum salts are 50 and 136.

**Physical Hazards (Physical)**

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

- Authoritative and Screening Lists
  - *Authoritative:* not included on any authoritative lists
  - *Screening:* not included on any screening lists
- Sigma-Aldrich 2014
  - Aluminum hydroxide has an HMIS reactivity rating of zero. An HMIS reactivity rating of zero corresponds to "Materials which are normally stable even under fire conditions, and which will not react with water" (Paint.org 2014).

**Flammability (F) Score (vH, H, M, or L):** *L*
Aluminum hydroxide was assigned a score of Low for flammability based on its HMIS flammability score. 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
  - Aluminum hydroxide has an HMIS flammability rating of zero. An HMIS flammability rating of zero 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 Aluminum Hydroxide (CAS #21645-51-2)

TOXSERVICES
TOXICOLOGY RISK ASSESSMENT CONSULTING

## GreenScreen® Score Inspector

**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 | Aluminum hydroxide | 21645-51-2 | *L* | L | *L* | L | DG | L | DG | M | DG | *M* | L | *H* | L | L | *L* | *vH* | 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 |
|---|---|
| Aluminum hydroxide | 1 |

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

**Table 6**

| Chemical Name | Final GreenScreen® Benchmark Score |
|---|---|
| Aluminum hydroxide | 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 | | | | | | | | | | | | |

## APPENDIX C: Pharos Output for Aluminum Hydroxide (CAS #21645-51-2)

### Alumina trihydrate

**CAS RN: 21645-51-2**

**Synonyms: Alumina hydroxide; aluminum hydrate; aluminum hydroxide; ATH**

**Detailed Direct Hazard Listings** — Quickscreen

| | |
|---|---|
| DEVELOPMENTAL | German MAK - List of Substances (MAK)<br>Pregnancy Risk Group D - GreenScreen Benchmark Unspecified (LT-U) |
| PBT | Environment Canada - Domestic Substances List (DSL)<br>DSL substances that are Persistent - GreenScreen Benchmark Unspecified (LT-U) |
| RESTRICTED LIST | P+W - Precautionary List<br>Precautionary list of flame retardants - Not included in GreenScreen |
| RESTRICTED LIST | Environment Canada - Domestic Substances List (DSL)<br>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)<br>Non-Hazardous to Water (Water Hazard Class 0 NWG) - Not included in GreenScreen |

**Compound Group Hazard Listings**

| | |
|---|---|
| RESPIRATORY | AOEC - Asthmagens (AOEC)<br>Asthmagen (ARs) - sensitizer-induced - inhalable forms only - GreenScreen Benchmark Unspecified (LT-U) - occupational hazard only - HPD |

**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/*

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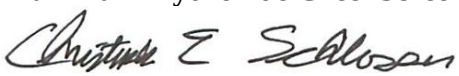
**Aluminum Hydroxide GreenScreen® Evaluation Prepared by:**



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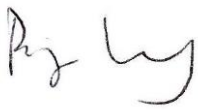

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