Magnesium Carbonate

Handling/Processing

Identification of Petitioned Substance

Chemical Names:
basic magnesium carbonate; magnesium carbonate; magnesium carbonate anhydrate; magnesium carbonate hydrate; magnesium carbonate hydroxide.

Other Name:
basic hydrated or normal hydrated magnesium carbonate or mixture of the two; carbonic acid, magnesium salt; carbonic acid, magnesium salt (1:1) hydrate; carbonic acid, magnesium salt (1:1), mixt. with magnesium hydroxide, hydrated; magnesite; magnesium carbonate (light or heavy); magnesium carbonate basic; magnesium hydrogen carbonate; magnesium hydroxide carbonate; magnesium subcarbonate (light or heavy).

Trade Names:
magnesium carbonate; magnesium carbonate hydroxide; Companies use generic names in the marketplace.

CAS Numbers:
magnesium carbonate, anhydrous: 546-93-0
magnesium carbonate, basic: 39409-82-0
magnesium carbonate monohydrate: 23389-33-5
magnesium carbonate hydroxide: 12125-28-9

Other Codes:
E Numbers 504, 504(i), and 504(ii)
EC Numbers 208-915-9 and 235-192-7

Summary of Petitioned Use

This full scope technical report supports the National Organic Standards Board (NOSB) review of magnesium carbonates, including E numbers E504(i) and magnesium carbonate hydroxide E504(ii), handling materials petitioned by Leroux SA in December of 2022 (Leroux SA, 2022a, 2022b). "E numbers" are created by the European Food Safety Authority (EFSA) and describe different food additives (EFSA, 2023). The exact chemical identity of magnesium carbonates is ambiguous at times, and magnesium carbonates appear under a few CAS Registry Numbers and names.

This technical report focuses on uses of magnesium carbonates as processing aids in the production of organic chicory extract. The petitioner would like to use magnesium carbonates (both E504(i) and E504(ii)) as an anti-caking agent in order to prevent chicory root powder from sticking to the walls of equipment, which causes production disruptions (Leroux SA, 2022a).

Magnesium carbonate was initially reviewed by the NOSB in 1996 (NOSB, 1996). It was included on the National List of Allowed and Prohibited Substances (hereafter referred to as the "National List") with the first publication of the National Organic Program (NOP) Final Rule (65 FR 80548). It was classified as a synthetic substance only for use in "made with organic" products at 7 CFR 205.605(b). The annotation did not otherwise prescribe a specific use of the material.

In 2005, magnesium carbonate was again included in a petition (Flavorchem International Inc., 2005). Flavorchem requested that the NOSB consider its use as a filtering aid. While not entirely clear from available documents, the petitioner requested that magnesium carbonate be allowed for use in organic products, as well as "made with organic" products. The NOSB voted to relist magnesium carbonate without changes to its annotation in 2005 and 2010 (NOP, 2010b; NOSB, 2009).

In 2015, the NOSB recommended that magnesium carbonate be removed from the National List, because it was not essential to organic handling (NOSB, 2015). The NOP removed it from the National List in 2017 (82 FR 31241).

For the remainder of this report, magnesium carbonate will be referred to as "MC" (singular) or "MCs" (when referring to multiple magnesium carbonates). We will refer to specific substances and CAS Registry Numbers (as possible) when necessary to describe more specific materials.

Characterization of Petitioned Substance

Composition of the Substance:
MC is a salt comprised of magnesium and carbonate ions, sometimes also including hydroxide ions and/or water. Its simplest molecular formula is $MgCO_3$, as illustrated in Figure 1. However, magnesium, with a common oxidation state of 2^+, forms numerous stable hydrated and basic (containing hydroxide ions) carbonates (Patnaik, 2003). Its hydrated forms, especially the di-, tri-, and tetrahydrates, occur naturally as minerals (National Center for Biotechnology Information, 2023).

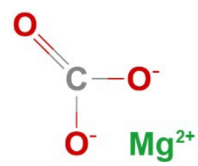

Figure 1. Chemical structure of $MgCO_3$

The term "magnesium carbonate" may refer to any number of different MCs, including hydrated magnesium carbonate (Rowe et al., 2009), basic hydrated magnesium carbonate, or a mixture of the two (JECFA, 2006; Leroux SA, 2022a). The scientific literature and market data use nomenclature somewhat interchangeably.

Table **1** lists names, chemical formulas, and identifying numbers for various MCs. Rowe et al. (2009) note that basic MC is likely the most common form.

Untangling chemical identities, CAS RNs, and other identifiers for magnesium carbonates
The current petition for magnesium carbonate E 504(i) (Leroux SA, 2022a) describes it as a "basic hydrated or normal hydrated magnesium carbonate or mixture of the two." This description is consistent with other sources (JECFA, 2006) and the European Commission (2012) definition for magnesium carbonate, E 504(i).

Magnesium carbonate E 504(i) is sometimes referred to by EINECS number, 208-915-9 (European Commission, 2012), which corresponds to CAS Registry Number (CAS RN) 546-93-0 (European Chemicals Agency, n.d.a). This is the CAS RN for the anhydrous form, $MgCO_3$. However, the European Commission (2012) definition for E 504(i) identifies a hydrated MC chemical formula ($MgCO_3 \cdot H_2O$), in addition to the possibility of a basic hydrated MC in the description. Magnesium carbonate monohydrate has the CAS RN 23389-33-5. It is therefore possible that this and potentially other hydrated MCs fall under E 504(i) along with anhydrous MC. Basic (containing hydroxyl group(s)) hydrated MCs may also be included, but this poses some overlap with E 504(ii).

The current petition for magnesium carbonate hydroxide E 504(ii) (Leroux SA, 2022b) describes it as "magnesium carbonate hydroxide hydrated." This is consistent with the description in the JECFA (2002) monograph and European Commission (2012) regulation for E 504(ii). The EINECS number identified in the European Commission regulation, 235-192-7, corresponds to CAS RN 12125-28-9 (European Chemicals Agency, n.d.b). The petition also references CAS RN 12125-28-9.

The European Commission regulation for E 504(ii) uses the chemical formula $4MgCO_3 \cdot Mg(OH)_2 \cdot 5H_2O$, as does the FDA GRAS listing for magnesium carbonate[1] at 21 CFR 184.1425. The GRAS listing, however, identifies the CAS RN as 39409-82-0. Thus, both CAS Registry Numbers appear to be applicable under E 504(ii). The number of hydroxyl groups or level of hydration state may not be specifically limited. This understanding is supported by description of magnesium carbonate hydroxide by the National Institute of Health as a mixture of magnesium hydroxide and magnesium carbonate rather than a specific chemical compound (National Center for Biotechnology Information, 2023). It is not a homogenous material (Rowe et al., 2009).

Table 1. Forms of magnesium carbonate and identifying information from various sources

Names	Chemical Formulas	E No.	EC No. (EINECS)	CAS RN
Magnesium carbonate	$MgCO_3$	504(i)	208-915-9	546-93-0
Magnesium carbonate anhydrate	$MgCO_3$	504(i)	208-915-9	546-93-0
Magnesium carbonate hydrates	$MgCO_3 \cdot xH_2O$; $MgCO_3 \cdot H_2O$	504(i)	208-915-9	23389-33-5
Carbonic acid, magnesium salt (1:1) hydrate	$MgCO_3 \cdot H_2O$	504(i)	208-915-9	23389-33-5
A basic hydrated or normal hydrated magnesium carbonate or a mixture of the two	$MgCO_3 \cdot xH_2O$	504(i)	208-915-9	546-93-0
Magnesium carbonate basic	$(MgCO_3)_4 \cdot Mg(OH)_2 \cdot 5H_2O$; $4MgCO_3 \cdot Mg(OH)_2 \cdot 5H_2O$	504(i)	---	39409-82-0
Carbonic acid, magnesium salt (1:1)	$MgCO_3 \cdot H_2O$	504(i)	208-915-9	546-93-0
Magnesium carbonate hydroxide	$(MgCO_3)_4 \cdot Mg(OH)_2 \cdot 5H_2O$; $4MgCO_3 \cdot Mg(OH)_2 \cdot 5H_2O$	504(ii)	235-192-7	39409-82-0
Carbonic acid, magnesium salt (1:1), mixt. with magnesium hydroxide, hydrate	---	504(ii)	235-192-7	12125-28-9
Magnesium hydroxide carbonate	$(MgCO_3)_4 \cdot Mg(OH)_2 \cdot 5H_2O$; $4MgCO_3 \cdot Mg(OH)_2 \cdot 5H_2O$	504(ii)	235-192-7	12125-28-9
Magnesium carbonate hydroxide hydrated	$(MgCO_3)_4 \cdot Mg(OH)_2 \cdot 5H_2O$; $4MgCO_3 \cdot Mg(OH)_2 \cdot 5H_2O$	504(ii)	235-192-7	12125-28-9
Hydrated basic magnesium carbonate	$(MgCO_3)_4 \cdot Mg(OH)_2 \cdot 5H_2O$; $4MgCO_3 \cdot Mg(OH)_2 \cdot 5H_2O$	504(ii)	235-192-7	---
Magnesium subcarbonate (light or heavy)	$(MgCO_3)_4 \cdot Mg(OH)_2 \cdot 5H_2O$; $4MgCO_3 \cdot Mg(OH)_2 \cdot 5H_2O$	504(ii)	235-192-7	---
Magnesium hydrogen carbonate	$(MgCO_3)_4 \cdot Mg(OH)_2 \cdot 5H_2O$; $4MgCO_3 \cdot Mg(OH)_2 \cdot 5H_2O$	504(ii)	235-192-7	---

Sources: (European Chemicals Agency, n.d.a, n.d.b; European Commission, 2012; Institute of Medicine, 2003; JECFA, 2002, 2006; Kuhnert, 2016; Leroux SA, 2022a, 2022b; National Center for Biotechnology Information, 2023; National Research Council, 1981; U.S. FDA, 2018, 2023; US Pharmacopoeia, 2006)

Specifications for conforming to standards of identity

The GRAS listing for magnesium carbonate references the specifications outlined in the Food Chemicals Codex (FCC) 3rd edition: for MC an assay of 40.0% - 43.5% MgO (National Research Council, 1981), whereas the assay requirement for E 504(ii) in the European Commission regulation is 40.0% - 45.0% MgO. The assay requirement for E 504(i) is 24% - 26.4%, reported as Mg rather than MgO (European Commission, 2012). Later editions of the FCC differentiate between magnesium carbonate and magnesium carbonate hydroxide (see Table 1). The FCC 5th edition requires, for magnesium carbonate hydroxide, 40% – 42% MgO and for magnesium carbonate, 40.0% - 43.5% MgO. The JECFA specifications match those for E 504(i) and (ii).

[1] The FDA GRAS listing at 21 CFR 184.1425 presents the molecular formula as "approximately" $4MgCO_3 \cdot Mg(OH)_2 \cdot 5H_2O$ and notes that it is also known as magnesium carbonate hydroxide.

The FCC 5th Ed. (2003) lists specifications for MC and identifies formulas for anhydrous MC, monohydrate, and hydroxide hydrated. Its assay is the equivalent of not less than 40.0% and not more than 43.5% MgO. This matches US Pharmacopoeia specifications (US Pharmacopoeia, 2006). The FCC monograph for MCH also lists 40% – 42% MgO, further supporting that the terms are used somewhat interchangeably.

EU Pharmacopoeia differentiates between "light" and "heavy" MC (Rowe et al., 2009). These are both basic hydrated MCs (Ropp, 2013), light MC generally being the trihydrate, $3MgCO_3{\cdot}Mg(OH)_2{\cdot}3H_2O$, and heavy MC generally the tetrahydrate, $3MgCO_3{\cdot}Mg(OH)_2{\cdot}4H_2O$ (Rowe et al., 2009).

MC also forms several double salts with other alkaline earth metals and alkali metal salts, such as (Ropp, 2013):

- $MgCO_3{\cdot}Na_2CO_3$
- $MgCO_3{\cdot}K_2CO_3{\cdot}8H_2O$
- $MgCO_3{\cdot}KHCO_3{\cdot}4H_2O$
- $MgCO_3{\cdot}(NH_4)_2CO_3{\cdot}4H_2O$
- $MgCO_3{\cdot}MgCl_2{\cdot}7H_2O$
- $MgCO_3{\cdot}MgBr_2{\cdot}7H_2O$

These double salts of MC are not included in the scope of this technical report.

Source or Origin of the Substance:

Natural occurrence of magnesium carbonates

MCs occur in numerous different forms in a variety of different minerals, and the composition of naturally occurring MC minerals is not homogenous (Hemmati et al., 2014). These different minerals are abundant in the earth's crust. Magnesite, for example, occurs in a wide variety of geologic environments, such as near ultramafic (iron- and magnesium-rich igneous) complexes, and in sedimentary deposits across the globe (González et al., 2021). Dolomite (a double salt of calcium and magnesium carbonate) occurs in sedimentary and metamorphic rock deposits, the largest being in Sumatra (González et al., 2021). Minerals containing magnesium carbonate are the most common magnesium ore minerals (González et al., 2021), and are summarized in Table 2. Although different industries extract these minerals for a variety of commercial uses, food-grade MC generally originates from separate sources of magnesium and carbonates.

Table 2. Naturally **occurring magnesium carbonate minerals**

Mineral name	Formula
Magnesite	$MgCO_3$
Barringtonite	$MgCO_3{\cdot}2H_2O$
Nesquehonite	$MgCO_3{\cdot}3H_2O$
Lansfordite	$MgCO_3{\cdot}5H_2O$
Artinite	$MgCO_3{\cdot}Mg(OH)_2{\cdot}3H_2O$
Hydromagnesite	$4MgCO_3{\cdot}Mg(OH)_2{\cdot}4H_2O$
Dypingite	$4MgCO_3{\cdot}Mg(OH)_2{\cdot}5\text{-}8H_2O$
Dolomite	$CaCO_3{\cdot}MgCO_3$
Huntite	$CaCO_3{\cdot}3MgCO_3$

Sources: (González et al., 2021; Hemmati et al., 2014; Moore et al., 2015; Seeger et al., 2000)

Natural occurrence and extraction of magnesium

As an alkali earth metal, magnesium itself makes up 2.1% of the earth's crust, and is the eighth most abundant element in the earth's crust and the third most abundant in seawater (González et al., 2021). In the U.S., magnesium is primarily extracted from brines (González et al., 2021). Seawater and natural brines accounted for approximately 67% of magnesium compound production in the U.S. in 2022 (USGS, 2023). Magnesium can also be extracted from the minerals noted above and from other, non-carbonate minerals such as brucite ($Mg(OH)_2$), carnallite ($MgCl_2 \cdot KCl \cdot 6H_2O$), bischofite ($MgCl_2 \cdot 6H_2O$), olivine ($(Mg,Fe)_2SiO_4$), serpentinite ($Mg_3Si_2O_5(OH)_4$), and serpentinite ferromagnesian minerals ($(Mg,Fe)_3Si_2O_5(OH)_4$) (González et al., 2021).

Natural occurrence and extraction of carbonates

Carbonates are also ubiquitous in the environment and occur in common mineral salts such as limestone ($CaCO_3$) and sodium carbonates, in addition to other minerals (see Table 2). Carbonate ions also originate from atmospheric carbon dioxide as part of the carbonic acid system, which the *Carbon Dioxide* technical report describes in detail (NOP, 2023). Carbon dioxide and sodium carbonate or bicarbonate are the principal sources of carbon in manufacturing processes used to produce MCs (see *Evaluation Question #1*).

<u>Properties of the Substance:</u>

MC comes in numerous different forms, and properties such as molecular weight vary depending on the form. Other properties, such as reactivity with acids (Ropp, 2013), are characteristic of all MCs. Another property common to all MCs is high absorptive ability. MC is hygroscopic (Ropp, 2013), meaning it tends to absorb moisture from the air. Like some other magnesium salts, MC is able to form crystals with high water content (Seeger et al., 2000).

MC occurs as trigonal crystals that may be colorless to white or light gray, depending on hydration state (Seeger et al., 2000; see Table 3, below). MC generally appears as a light, friable mass or bulky, white powder (Institute of Medicine, 2003). MC may also be in granular form (JECFA, 2006; Rowe et al., 2009). It is odorless, but can absorb odors and has a slightly earthy taste (Rowe et al., 2009). MC is practically insoluble in water, ethanol, acetone, and ammonia (National Center for Biotechnology Information, 2023; Ropp, 2013; Rowe et al., 2009). It is soluble in aqueous carbon dioxide and in dilute mineral acids (National Center for Biotechnology Information, 2023; Rowe et al., 2009). When MC dissolves in acids, it releases CO_2 (Institute of Medicine, 2003; Rowe et al., 2009).

The solubility of MCs increases with the level of hydration (González et al., 2021). The least hydrated MC, $MgCO_3$, is the most stable (González et al., 2021). Moore et al. (2015) describe it as "the energetically favored magnesium carbonate," and other forms that are hydrated and/or contain hydroxyl groups as "themodynamically metastable phases." The authors explain that the metastable minerals form when the kinetic energy required to remove water molecules from the crystal structure is unavailable even on geologic time scales, leaving less thermodynamically stable forms remaining (Moore et al., 2015).

Table 3. Physical and chemical properties of magnesium carbonate

Property	Value
Physical State and Appearance	White powder, friable mass, or granular
Odor	Odorless
Taste	Slight earthy taste
Molecular Weight (g/mol)	Varies depending on form, starting at 84.33 for $MgCO_3$
Bulk Density (g/cm^3)	Varies depending on form: 2.96 for $MgCO_3$, 2.83 for $MgCO_3 \cdot 2H_2O$, 1.84 for $MgCO_3 \cdot 3H_2O$; 0.21-0.56 for Heavy MC; approximately 0.12 for Light MC
Solubility in water (g/L)	Varies depending on form; 0.1 for $MgCO_3$; Basic MC also practically insoluble in water
Stability	Stable in air
Reactivity	Reactive with acids

Sources: (Institute of Medicine, 2003; National Center for Biotechnology Information, 2023; Ropp, 2013; Rowe et al., 2009; Seeger et al., 2000)

Upon heating under normal pressure, MC begins to decompose at around 360-400 degrees C, releasing CO_2 and forming some magnesium oxide, MgO (Ropp, 2013). Decomposition proceeds rapidly above 550 degrees C (Seeger et al., 2000), and is complete at approximately 700 degrees C, having entirely converted to MgO (Institute of Medicine, 2003).

Specific Uses of the Substance:

Use as an anti-caking agent

The petition refers to the use of MCs as anti-caking agents during the spray-drying of chicory root powder (Leroux SA, 2022a, 2022b). MCs are some of the most commonly used anti-caking agents (Martins et al., 2019). Anti-caking agents are regularly added to dried powdered foods including table salt, flours, coffee, milk powders, and sugar to enable a free-flowing physical state (Martins et al., 2019; Msagati, 2012).

Other uses

Magnesium carbonate and magnesium hydroxide carbonate also serve as acidity regulators in food processing (Martins et al., 2019). For example, MCs are used for the alkalinization (Dutching) process of cocoa (Puchol-Miquel et al., 2021).

Magnesium carbonate and magnesium hydroxide carbonate serve as color retention agents in food processing (Koop et al., 2022; Martins et al., 2019). Processors use MC in a blanching pre-treatment to improve sensory perception for color of dehydrated green vegetables (Maharaj & Sankat, 1996; Singh et al., 2000). MC effectively inhibits the conversion of green chlorophyll to brown pheophytin responsible for the color loss (Maharaj & Sankat, 1996).

MC can serve as a carrier, being a relatively inert material (Martins et al., 2019). Encapsulation of sodium bicarbonate with MC can prevent the premature leavening reaction of alkaline sodium bicarbonate (Gélinas, 2022).

Approved Legal Uses of the Substance:

When food producers use MC as a processing aid, it falls under the jurisdiction of U.S. Food and Drug Administration (FDA) regulations. There are numerous references to MC in FDA regulations. FDA regulations only include CAS RN 39409-82-0 for MC. The FDA regulations include uses that are consistent with what is described by the petitioner; the material could be legally used as petitioned.

Identity under FDA

The FDA describes the identity and use of MC at 21 CFR 184.1425. Important details include the following:

- CAS RN 39409-82-0, also known as magnesium carbonate hydroxide or $(MgCO_3)_4Mg(OH)_2 \cdot 5H2O$
- The ingredient needs to meet the specifications of the Food Chemicals Codex, 3rd Ed., p. 177 (National Research Council, 1981):

  "…a basic hydrated magnesium carbonate or a normal hydrated magnesium carbonate."

  "The equivalent of not less than 40.0% and not more than 43.5% of MgO."

The FDA's generic chemical description aligns most closely with the description of E 504(ii) (see Table 1). The European Food Safety Authority (EFSA) identifies E 504(ii) with the EINECS number 235-192-7 (European Commission, 2012). According to the European Chemicals Agency (ECHA), this EINECS number corresponds to CAS RN 12125-28-9 (European Chemicals Agency, n.d.b); however, the FDA notes CAS RN 39409-82-0. The assay requirements (in terms of MgO equivalent) for E 504(ii) and the FCC's description for MC are similar, but not identical (see *Composition of the Substance*, above).

Separately, the FDA lists MC as a general-purpose food additive that is Generally Recognized as Safe (GRAS) at 21 CFR 582.1425. The Select Committee on GRAS Substances database (SCOGS) uses the same CAS RN (39409-82-0) for the material under this GRAS listing as at 21 CFR 184.1425 (US FDA, 2020). The only conditions of use are that it is used in accordance with good manufacturing or feeding practice.

Use under FDA

The FDA also describes the use of MC at 21 CFR 184.1425, as follows. See footnotes for citations and definitions for these uses:

- an anticaking agent and free-flow agent[2]
- a flour treating agent[3]
- a lubricant and release agent[4]
- a nutrient supplement[5]
- a pH control agent[6]
- a processing aid[7]
- a synergist[8]

Beyond the scope of the petitioned use, the FDA includes MC as an optional ingredient that is "safe and suitable" for:

- a variety of cheeses (21 CFR 133.102-195)
- canned peas (21 CFR 155.170)
- cacao nibs (21 CFR 163.110)
- chocolate liquor (21 CFR 163.111)
- breakfast cocoa (21 CFR 163.112)

The FDA also permits flour to be bleached with a combination of benzoyl peroxide and magnesium carbonate (21 CFR 137.105).

Action of the Substance:

MC functions as an anti-caking agent in flowable dry foods by absorbing moisture. Magnesium ions tend to polarize their environment (Aufort et al., 2022), making one side more positive and the other more negative. This affects and bonds with carbonate ions and various combinations of hydroxide ions and water molecules in crystalline structures. This ability to form crystals with high water content (Seeger et al., 2000) leads to its hygroscopic properties. Martins et al. (2019) note that anti-caking agents such as MCs selectively bind water and thereby prevent caking without interfering with the final appearance of the food. Lipasek et al. (2012) report this as one of several anti-caking mechanisms, in which the anti-caking agent competes for moisture with the food to which it is added.

In a recent study, researchers found that carbonate plays an important role in the hygroscopic nature of MC (Aufort et al., 2022). The authors examined the dynamics of water exchange around a magnesium ion paired with carbonate vs. a free magnesium ion in an aqueous solution. The authors found that water associated with the magnesium-carbonate complex exchanged more easily than water in the presence of free magnesium. The carbonate ion appeared to accelerate water exchange around the aqueous magnesium ion, suggesting a role in ion adsorption (Aufort et al., 2022). This function of the carbonate group in facilitating ion exchange points to its importance in the anti-caking action of MC.

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[2] 21 CFR 170.3(o)(1) Anticaking agents and free-flow agents: Substances added to finely powdered or crystalline food products to prevent caking, lumping, or agglomeration.

[3] § 170.3(o)(13) Flour treating agents: Substances added to milled flour, at the mill, to improve its color and/or baking qualities, including bleaching and maturing agents.

[4] § 170.3(o)(18) Lubricants and release agents: Substances added to food contact surfaces to prevent ingredients and finished products from sticking to them.

[5] § 170.3(o)(20) Nutrient supplements: Substances which are necessary for the body's nutritional and metabolic processes.

[6] § 170.3(o)(23) pH control agents: Substances added to change or maintain active acidity or basicity, including buffers, acids, alkalis, and neutralizing agents.

[7] § 170.3(o)(24) Processing aids: Substances used as manufacturing aids to enhance the appeal or utility of a food or food component, including clarifying agents, clouding agents, catalysts, flocculants, filter aids, and crystallization inhibitors, etc.

[8] § 170.3(o)(31) Synergists: Substances used to act or react with another food ingredient to produce a total effect different or greater than the sum of the effects produced by the individual ingredients.

Combinations of the Substance:

MCs are generally available as single-substance products, without carriers or other additives, based on a web search for commercially available products.

See *Evaluation Question #8* for additional details on impurities found in MC.

Status

Historic Use:

Historically, MC has been referred to by various names, including magnesia alba (Multhaup, 1976), magnesite, and talcum carbonatum (Kramer, 2001).

As an anti-caking agent, Morton Salt started adding MC in 1911 to create the first free-flowing salt (Cross, 2002). In 1955, the anti-caking blend of neutral fillers included MC, hydrated calcium silicate, and tricalcium phosphate in amounts of 0.5-2.0% depending on conditions of use (Hester & Diamond, 1955). Calcium silicate has since replaced MC as the singular anti-caking agent in Morton Salt products (USDA, 2018).

Throughout the 1600's, a combination of MC and acid was used in experiments (along with other substances) in attempts to produce sufficient rise in a variety of bakery goods (Gélinas, 2022).As early as 1816, bakers used MC as an additive to bread dough to aid its expansion.

MC was used as a color retention agent for heat processed vegetables as early as 1931 (Sharma, 1931).

Organic Foods Production Act, USDA Final Rule:

OFPA does not include any reference to MCs (Organic Foods Production Act of 1990, 1990).

Magnesium carbonate was previously allowed for use only in agricultural products labeled "made with organic (specified ingredients or food group(s))" but was removed from the National List in 2017 as part of its sunset review. The NOSB had determined that it was no longer necessary, and alternative substances were available (82 FR 31241).

International:

Canada, Canadian General Standards Board – CAN/CGSB-32.311-2020, Organic Production Systems Permitted Substances List

Canadian organic regulations allow producers to use MC (no forms/CAS RNs specified) as a food additive per CAN/CGSB 32.311-2020, PSL Table 6.3: "as an anti-caking agent in non-standardized dry mixes (e.g., seasonings) used in meat products with 70-95% organic content."

CODEX Alimentarius Commission – Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)

CODEX organic guidelines allow producers to use MCs (E 504(i) and E 504(ii)) as ingredients in food of plant origin, per GL 32-1999, Table 3. The CODEX organic guidelines do not allow their use in food of animal origin.

European Economic Community (EEC) Council Regulation – EC No. 2018/848 and 2021/1165

European organic regulations allow producers to use MCs (as E504, without further specification) as food additives and processing aids in products of plant origin, per Regulation (EU) 2021/1165 Annex V Part A, Section A1. Similar to CODEX guidelines, the European organic regulations do not include an allowance for their use in food of animal origin.

Japan Agricultural Standard (JAS) for Organic Production
Japanese organic regulations allow producers to use MC (E 504(i) only) as a food additive per the Japanese Agricultural Standard for Organic Processed Foods, Article 5, Appended Table 1-1: "limited to the use in processed products of plant origin." Under Appended Table 1-2, MC (E 504(i) only) is also allowed for use as an additive in organic alcohol beverages.

IFOAM-Organics International
IFOAM Norms allow producers to use MCs (INS 504, equivalent to E 504, with no further specifications) as food additives per the 2014 IFOAM Standard for Organic Production and Processing, Appendix 4-Table 1.

Evaluation Questions for Substances to be used in Organic Handling

<u>Evaluation Question #1:</u> Describe the most prevalent processes used to manufacture or formulate the petitioned substance. Further, describe any chemical change that may occur during manufacture or formulation of the petitioned substance when this substance is extracted from naturally occurring plant, animal, or mineral sources (7 U.S.C. § 6502 (21)).
Manufacturers use different starting materials and vary reaction conditions to affect hydration state, alkalinity, and composition of MCs (Rowe et al., 2009).

Production of magnesium carbonate
The primary manufacturing processes for MC can be generally summarized as follows (González et al., 2021; National Center for Biotechnology Information, 2023; NOSB, 1996; Royal Society of Chemistry, 2023; Seeger et al., 2000; U.S. FDA, 2018):

Carbonation of magnesium hydroxide

$$Mg(OH)_2(aq) + CO_2(aq) \rightarrow MgCO_3(s) + H_2O$$

magnesium hydroxide + carbon dioxide → magnesium carbonate + water

and

Reaction of magnesium salt with alkaline carbonate

$$Mg_2SO_4(aq) + Na_2CO_3\,(aq) \rightarrow MgCO_3\,(s) + Na_2SO_4\,(aq)$$

magnesium sulfate + sodium carbonate → magnesium carbonate + sodium sulfate

Soluble magnesium salts that could be used in the reaction noted above include but are not limited to magnesium sulfate, magnesium chloride, and magnesium nitrate. The literature widely reports the use of magnesium chloride from brines in the U.S. (González et al., 2021; Kramer, 2001; Ropp, 2013). The alkaline carbonate used is commonly sodium carbonate or sodium bicarbonate. MC precipitates as a solid from both of these aqueous reactions. Manufacturing processes also include steps such as filtering, washing, and drying at various stages (Royal Society of Chemistry, 2023).

Other manufacturing processes exist, and largely entail the manipulation of MC-containing ores. For example, in one process, the manufacturer subjects an aqueous suspension of dolomite to carbon dioxide under pressure. Upon heating, calcium carbonate precipitates out of the solution, leaving magnesium bicarbonate. After boiling, carbon dioxide and water evaporate from the solution, yielding light MC (Rowe et al., 2009).

Liang et al. (2017) reported an experimental process for modifying an MC-containing mineral. They obtained a pure anhydrous $MgCO_3$ through the dehydration of the trihydrate, nesquehonite

($MgCO_3{\cdot}3H_2O$), under high heat and pressure. In their experiment, $MgCO_3$ decomposed under elevated temperature, converting entirely to MgO after prolonged heating to 1000 degrees C. But, since $MgCO_3$ is stable under high pressure, even at high temperatures, the authors reported that conditions of 800 degrees C and 3 GPa for one hour suppressed the decomposition of $MgCO_3$ to MgO (Liang et al., 2017).

Reaction variables

Reaction conditions that affect MC crystal formation include (Prigiobbe & Mazzotti, 2013):

- temperature
- pressure
- initial concentration of magnesium in the solution
- supersaturation ratio
- pH

The scientific literature contains numerous examples of this. Moore et al. (2015) reported that solutions with Mg^{2+} and CO_3^{2-} ions form $MgCO_3$ directly at temperatures over 120 degrees C. Below 120 degrees C, the same solution forms hydromagnesite ($4MgCO_3{\cdot}Mg(OH)_2{\cdot}4H_2O$) (Moore et al., 2015). In the study, hydromagnesite eventually converted to $MgCO_3$ over time (Moore et al., 2015).

Prigiobbe and Mazzotti (2013) documented similar processes. They looked at the precipitation kinetics of MC under various temperatures and atmospheric carbon dioxide pressures, with different concentrations of reacting components. Sodium carbonate (Na_2CO_3) and magnesium chloride hexahydrate ($MgCl_2$-$6H_2O$), reacted under varying conditions, generated super-saturated solutions of three MC phases: artinite ($MgCO_3{\cdot}Mg(OH)_2\ {\cdot}3H_2O$), hydromagnesite ($(MgCO_3)_4\ Mg(OH)_2\ 4H_2O$), and magnesite ($MgCO_3$). Similar to Moore et al. (2015), Prigiobbe and Mazzotti (2013) reported a direct precipitation of magnesite, or of hydromagnesite that then completely transformed into magnesite, under the supersaturated conditions at 120 and 150 degrees C and partial CO_2 pressure. Seeger et al. (2000) and Ropp (2013) noted that the carbonation of magnesium hydroxide does require high-pressure conditions to produce MC.

Manufacturing processes for magnesium precursors used in MC manufacturing

Several production facilities in the U.S. utilize magnesium oxide from imported mined minerals to generate magnesium hydroxide via pressure hydration (Kramer, 2001). Magnesium hydroxide is a precursor in the production of MC. Other MC manufacturers use magnesium sourced from underground brines in their production processes (Kramer, 2001). However, we did not find further information documenting which sources of magnesium are most commonly used to manufacture MC. Kramer (2001) noted that trade data for MC was grouped together with other carbonates and so could not be individually identified.

Industries can obtain magnesium through a number of different extraction routes and from an array of different magnesium-containing brines and mineral ores.

- *Underground brines* pumped into solar evaporation ponds are a natural source of concentrated magnesium chloride (U.S. EPA, n.d.) that may be used in the production of MC (Kramer, 2001).
- *Surface brines* from the Great Salt Lake diverted to evaporation ponds are concentrated and treated with calcium chloride ($CaCl_2$). The precipitated salts calcium sulfate, potassium chloride, and sodium chloride are removed in a thickener and the remaining brine is further concentrated and spray dried as dry magnesium chloride powder ($MgCl_2$) (U.S. EPA, n.d.).
- *Seawater* contains hydrous magnesium chloride (U.S. EPA, n.d.). The addition of lime (CaOH) or another caustic to seawater causes magnesium hydroxide to precipitate in agitated flocculators. The magnesium hydroxide settles and is pumped to rotary filters where it is dewatered, washed, and put back into solution with the wash water from the magnesium chloride purification step. Subsequent addition of hydrochloric acid and sulfuric acid precipitates excess calcium as calcium sulfate. Filtering removes the calcium sulfate and other solids like clay and silica from the brine. Drying this purified brine in a fluid-bed dryer produces magnesium chloride granules (U.S. EPA, n.d.).

- *Mineral ores* provide another source for magnesium extraction, often using hydrometallurgical processes, which are those that use aqueous chemistry to extract various mineral components.

As an example of magnesium extraction from ores, Tier et al. (2007) and Hematti et al. (2014) both used hydrochloric acid to dissolve magnesium silicates from the mineral serpentinite ($Mg_3Si_2O_5(OH)_4$), resulting in a solution containing magnesium chloride ($MgCl_2$). However, the authors reported other intended uses for these solutions that are not as food additives.

González (2021) notes that the aqueous solution used to leach minerals and extract magnesium depends in part on the starting mineral ore. Dilute inorganic acids extract minerals from ores that dissolve slowly. However, these acids can be more corrosive to processing equipment and less selective in what they extract than organic acids, making subsequent purification more difficult. Organic acids are effective at extracting magnesium from faster dissolving minerals, but are less stable at higher temperatures. Ammonium salt solutions can also extract magnesium from certain magnesium-bearing ores (González et al., 2021).

Magnesium carbonates from natural sources

MC is naturally occurring in the rock known as magnesite (González et al., 2021; Ropp, 2013). We did not identify any commercial sources of food-grade MC produced directly from magnesite. Naturally occurring magnesite can contain impurities (P. Li et al., 2021). However, magnesite ore is used to produce magnesium oxide (MgO), which is used in the chemical synthesis of magnesium hydroxide and other magnesium compounds, including MCs (Kramer, 2001).

<u>Evaluation Question #2:</u> Discuss whether the petitioned substance is formulated or manufactured by a chemical process, or created by naturally occurring biological processes (7 U.S.C. § 6502 (21)). Discuss whether the petitioned substance is derived from an agricultural source.

MCs form naturally through geological processes and occur abundantly in nature. However, as described in *Evaluation Question #1*, commercial sources of food grade MCs are produced through chemical processes. These processes use material sources for magnesium and carbon that have been modified from their original form through extraction and purification processes. Furthermore, MC is not derived from an agricultural source.

Evaluation of MCs against Guidance NOP 5033-1 *Decision Tree for Classification of Materials as Synthetic or Nonsynthetic* (NOP, 2016a) is discussed below.

1. *Is the substance manufactured, produced, or extracted from a natural source?*

MC, produced from the carbonation of magnesium hydroxide

The substance, MC, is manufactured by chemical reaction of precursors, which themselves may be nonsynthetic, as is the case with some magnesium salts and sodium carbonates, or else synthetic, such as magnesium hydroxide and carbon dioxide. Carbonation of magnesium hydroxide involves the reaction of two synthetic substances. Thus, the answer to whether MC (produced from the carbonation of magnesium hydroxide) is manufactured from a natural source in this case would be no, and the end product is considered synthetic.

MC, produced from the reaction of magnesium salt with alkaline carbonate

The determination for MC manufactured by the reaction of a magnesium salt with an alkaline carbonate is more complex. Assuming a magnesium chloride or magnesium sulfate is from a nonsynthetic source, and the sodium carbonate with which it is reacted is also nonsynthetic, gives the following result when evaluated using the decision tree:

1. *Is the substance manufactured, produced, or extracted from a natural source?*

One could answer yes, because the magnesium and carbonate sources are natural.

2. *Has the substance undergone a chemical change so that it is chemically or structurally different than how it naturally occurs in the source material?*

The answer to this question would be yes if we consider the source materials to be the reactants, because their ions exchange during the process: in solution magnesium is in ionic form (Mg^{2+}), separate from the salt ions (Cl^- or SO_4^{2-}), but combines with carbonate ions (CO_3^{2-}) from a different source in a crystalline structure, yielding the final MC. The next question is:

3. *Is the chemical change created by a naturally occurring biological process, such as composting, fermentation, or enzymatic digestion; or by heating or burning biological matter?*

The answer to this question is no. The chemical change is the result of a chemical reaction. No biological processes are involved, and while temperature can affect the form of the final MC, the reaction is not driven by heating. Thus, the material is synthetic according to the decision tree.

Evaluation Question #3: If the substance is a synthetic substance, provide a list of nonsynthetic or natural source(s) of the petitioned substance (7 CFR 205.600(b)(1)).
We found no indication that nonsynthetic MC is commercially available for applications in food processing. Up until the 1980s, people had identified few deposits of pure, easily accessible magnesite (Seeger et al., 2000). Since that time, natural deposits of magnesite have been identified and mined (P. Li et al., 2021), though primarily to obtain magnesium oxide (MgO) for use as refractory lining in the steel industry (P. Li et al., 2021; Seeger et al., 2000). Primary magnesium production in the U.S. is from brines (González et al., 2021), which must undergo chemical reactions to obtain food grade MC.

Evaluation Question #4: Specify whether the petitioned substance is categorized as generally recognized as safe (GRAS) when used according to FDA's good manufacturing practices (7 CFR 205.600(b)(5)). If not categorized as GRAS, describe the regulatory status.
As described in *Approved Legal Uses of the Substance*, above, MC (CAS RN 39409-82-0) is categorized by the FDA as GRAS at 21 CFR 582.1425. The conditions of use are that it be used in accordance with good manufacturing or feeding practice.

Evaluation Question #5: Describe whether the primary technical function or purpose of the petitioned substance is a preservative. If so, provide a detailed description of its mechanism as a preservative (7 CFR 205.600(b)(4)).
The U.S. FDA defines "chemical preservative" as "any chemical that, when added to food, tends to prevent or retard deterioration thereof, but does not include common salt, sugars, vinegars, spices, or oils extracted from spices, substances added to food by direct exposure thereof to wood smoke, or chemicals applied for their insecticidal or herbicidal properties" at 21 CFR 101.22(a)(1)(5). MC used as petitioned does not fit the FDA's definition of "chemical preservative." MC used as a drying /anti-caking agent food additive may contribute to shelf life, quality, and storage of the processed product, however (Krishnaiah et al., 2014; Qadri et al., 2022; Toneli et al., 2010). For more information on the anti-caking properties of MC, refer to the *Action of the Substance* section of this TR.

Other uses of MC within the food and pharmaceutical industry are as: a carrier (Alvebratt et al., 2020), an acidity regulator (FAO & WHO, 2023) and a stabilizer (Tabatar et al., 2008; J. Yang et al., 2018).

Evaluation Question #6: Describe whether the petitioned substance will be used primarily to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law) and how the substance recreates or improves any of these food/feed characteristics (7 CFR 205.600(b)(4)).
When used as petitioned, MC can improve the texture of chicory extract during the production, packaging, and storage of the product (European Commission Directorate-General for Agriculture and Rural Development, 2022; Kramer, 2001). As for flavors, colors, or nutritive value, we did not find any

studies suggesting that the addition of MC would contribute to improving such qualities to any appreciable degree.

Texture improvement

Dry chicory root extract contains mostly inulin (Nwafor et al., 2017), a polysaccharide. Toneli et al. (2010) found that spray-drying materials that contain a high content of polysaccharides frequently results in amorphous powders that do not flow as well as crystalline powders. Scanning electron microscope photos taken by Takenata et al. (1971) showed that products containing MC (such as gum Arabic, gelatin, poly-vinyl alcohol, etc.) were fairly uniform spherical particles. When researchers added MC to spray-dried powders, they found that MC improved the fluidity and free-flowing properties (Takenaka et al., 1971).

MC improves the texture of the powder by improving the flowability (European Commission Directorate-General for Agriculture and Rural Development, 2022). Increasing the flowability of chicory root powder reduces fouling in production and packaging facilities. Consequently, production becomes compatible with industrial requirements (reducing material losses and water usage)(European Commission Directorate-General for Agriculture and Rural Development, 2022).

Storage improvement

Dry chicory root extract contains, by weight, approximately 98% inulin and 2% other compounds (Nwafor et al., 2017). Inulin powder is highly hygroscopic (Toneli et al., 2008). Toneli et al. (2008) found that when stored, chicory powder turns into a solid mass as it absorbs moisture. Use of MC improves flowability and preserves the texture of stored instant chicory extract for the long term.

Flavor retention

While not a primary function, the fine texture of MC makes it an excellent carrier and retainer of perfumes (Kramer, 2001) and therefore its addition to the chicory extract powder could improve flavor by retaining some of the volatile compounds that characterize the beverage. Chicory "coffee" contains volatile compounds that confer a spicy/peppery, sweet/caramel aroma (Wu & Cadwallader, 2019).

<u>Evaluation Question #7</u>: Describe any effect or potential effect on the nutritional quality of the food or feed when the petitioned substance is used (7 CFR 205.600(b)(3)).

Magnesium is an essential mineral that is needed for a broad variety of physiological functions. The recommended intake of magnesium for adults is between 300 and 420 mg/day (Vormann, 2003).

Oliveira et al. (2012) studied the contribution to mineral intake of commercial instant coffee and coffee substitutes, among them instant chicory coffee substitute. During this research, they found that consuming 4 g of instant chicory daily would provide about 1 mg of elemental magnesium per day.

The addition of MC into instant chicory would slightly increase the amount of elemental magnesium of the powder. However, this increment is unlikely to significantly boost the nutritional profile of the product in terms of the elemental magnesium content.

As described in the petition, the maximum quantity of MC used during the instant chicory extract spray drying would be 0.05% (Leroux SA, 2022a). Assuming that a serving of instant chicory (approximately three teaspoons) weighs about 5 g, each serving of chicory beverage would contain about 2.5 mg of MC. Considering that MC contains only around 25% of elemental magnesium (Leroux SA, 2022a), the standard cup of instant chicory beverage would provide about 0.6 mg of elemental magnesium coming from the MC which, when compared to the recommended magnesium daily intake, would be a negligible amount.

<u>Evaluation Question #8:</u> List any reported residues of heavy metals or other contaminants in excess of FDA tolerances that are present or have been reported in the petitioned substance (7 CFR 205.600(b)(5)).

We found no reports of heavy metal or other contaminants in excess of FDA tolerances in MC. The requirements for food grade MC are (National Research Council, 1981):

- not more than 0.05% acid-insoluble substances
- not more than 3 ppm arsenic
- not more than 30 ppm of heavy metals (as lead)[9]
- not more than 0.6% calcium oxide
- not more than 10 ppm of lead and
- not more than 1% soluble salts

<u>Evaluation Question #9:</u> Discuss and summarize findings on whether the manufacture and use of the petitioned substance may be harmful to the environment or biodiversity (7 U.S.C. § 6517(c)(1)(A)(i) and 7 U.S.C. § 6517(c)(2)(A)(i)).

The MC present in the chicory extract is unlikely to harm the environment or biodiversity, after it is ingested. When ingested, it is metabolized by the consumer and if disposed in the environment it would easily dissolve in water becoming readily available to organisms (Jahnen-Dechent & Ketteler, 2012). MC naturally occurs in deposits, mostly in the form of magnesite and dolomite. Magnesium is the eighth most abundant element in the earth's crust, the third most plentiful element dissolved in seawater (Cherubini et al., 2008) and it is an essential mineral within organisms (Vormann, 2003).

The environmental impacts occur during the production process of MC, before it is consumed. At the same time, the amount of MC used specifically for chicory production we expect to be small. However, the subsequent discussion will focus on the impacts of the processes to produce MC, regardless of the small amount that is likely to be used for this purpose.

Magnesium oxide can be used as a reactant in the production of MC; therefore, this response focuses on the mining of magnesium ores (such as magnesite and dolomite) from which magnesium oxide and magnesium hydroxide are obtained.

Magnesium chloride is a salt that is used to produce magnesium carbonate by making it react with a carbonate source (For more information, refer to Evaluation Question #1). Magnesium chloride is produced from natural sources such as brines (Kramer, 2001), and the environmental impact of this process is also described below.

Mining

The worldwide primary magnesium market has been dominated by Chinese producers for the last twenty years (Ehrenberger, 2020). Approximately 77% of the world demand for magnesium is currently supplied by China (Cherubini et al., 2008). China holds the world's largest reserves of magnesite and 85% of the total of its deposits are found in the Liaoning province (An & Xue, 2017). Evaluating the environmental impact of Liaoning's magnesium oxide industry provides a clear picture of its harm to the environment.

Carbon emissions

To obtain magnesium oxide and other magnesium products, the Liaoning magnesite industry uses reverberatory kilns, shaft kilns and electric furnaces, and significant quantities of coal, heavy oil, and electricity are consumed during the production process, resulting in carbon emissions (An & Xue, 2017). Global warming potential resulting from carbon emissions is considered to be the most important environmental impact during the production of magnesium oxide (An & Xue, 2017; J. Li et al., 2015).

[9] As it appears in the third edition of the FCC book, this information seems to be a discrepancy with "not more than 10 ppm of lead."

An & Xue (2017) estimated that the carbon footprint resulting from the production of all kinds of magnesium oxide in 2014 was greater than 1.66 x 10^7 t CO_2-eq. These carbon emissions have had significant environmental impact within the Liaoning region (An & Xue, 2017).

Studies have been performed to quantify the global warming potential at the Dead Sea Magnesium plant, which produces magnesium from the Dead Sea evaporite deposits in Israel using electrolysis and natural gas as an energy supply. The global warming potential of this process accounts for 14.0–17.8 kg CO_2 eq/kg magnesium (D'Errico et al., 2022).

Compared to the global warming potential of gold (Au) and platinum (Pt) production, which display some of the highest environmental burdens (Nuss & Eckelman, 2014) at 12,500 kg CO_2-eq/kg, magnesium and its complexes possess a relatively low global warming potential (see Table 4, below).

Table 4. Greenhouse gas emissions of potential MC precursors

Precursor	Type of production	Greenhouse gas emissions per kg of Mg compounds	References
Mined ore (dolomite)	Mining	~0.3 kg CO_2-eq/kg Mg	(Ehrenberger et al., 2013)
Magnesium Hydroxide	Seawater and brines; Dead Sea evaporates	~1.6-3.3 kg CO_2-eq/kg $Mg(OH)_2$; 14.0-17.8 kg CO_2-eq/kg Mg	(Luong et al., 2018; D'Errico et al., 2022)
Magnesium Hydroxide	Magnesium-containing ores and further purification	~2.6-5.2 Kg CO_2-eq/kg $Mg(OH)_2$	(Luong et al., 2018)
Magnesium Sulfate	Langbeinite ore extraction and further purification	~0.3 Kg CO_2-eq/kg $MgSO_4$	(City of Winnipeg, 2012; Kim & Overcash, 2003)
Calcined dolomite	Mining and calcination	~8.0 to 8.6 kg CO_2-eq/kg Mg	(Ehrenberger et al., 2013)

Soil contamination by magnesite dust

Aside from carbon emissions, the magnesium oxide industry impacts soil and groundwater.

Magnesite ore air pollutants are a mixture of magnesium oxide and MC, and their powder form is the major component of environmental pollution (Fazekaš et al., 2018). Soil contamination in magnesite mine regions of the province of Liaoning are characterized by high pH, high magnesium concentration, low microbial activity, and decreased nitrogen and phosphorus availability (D. Yang et al., 2012). Mining regions can develop a magnesium-enriched crust that affects ecologically important soil functions, particularly reducing water penetration rate (Wang et al., 2015). The main component of the dust that forms the crusts in this regions is magnesium oxide, which can react with carbon dioxide and water in air and soil, changing into MC and magnesium hydroxide, and in turn causing soil pH to increase above 8 (Fazekaš et al., 2018; Wang et al., 2015).

Fazekaš et al. (2018) studied the contamination of soil and vegetation at a magnesite mining area in Slovakia. The studies concluded that the spray particles of free magnesium oxide strongly influence soil pH, diversity and vegetation cover. The median concentrations of magnesium found in this mining region (26150.00 ± 59039.25 mg/kg) exceeded what is considered a high content of this element (200-400 mg/kg) by 492.5 times. At this concentration, magnesium content induced toxicity to plants resulting in a gradual necrosis and loss of soil vegetation cover, and causing an extremely low vegetation diversity (Fazekaš et al., 2018).

Magnesium chloride brines (used as a source of magnesium) and electrolysis

U.S. Magnesium (USM) (Formerly MagCorp) is the single producer of primary magnesium in the United States, and it does it entirely through the electrolysis of brines (González et al., 2021). The source of raw materials for the manufacture of magnesium is the magnesium chloride that occurs naturally in the Great Salt Lake (Tripp, 2009). To achieve the required brine magnesium concentration (greater than 8.4%), USM employs the world's most extensive industrial use of solar energy (Tripp, 2009). Under a mineral lease, USM uses 300 km^2 (7.5 x 10^4 acres) of State land and water resources for what is known as the Stansbury Basin ponds (Tripp, 2009). USM brings between 75 and 135 billion liters of lake water into the "wet area" of these ponds (Tripp, 2009). The brine advances like a slow-moving river that becomes shallower as it approaches the plant (Tripp, 2009). As a result of evaporation, less than one percent of the original Great Salt Lake brine reaches the plant, and in concentrating the brine, about five million metric tons of salts are deposited in the ponds each year (Tripp, 2009). The precipitation of the magnesium chloride contained in the concentrated lake brine entails the removal of unwanted impurities through chemical means, further concentrating the brine and eliminating water (Tripp, 2009). Mineral extraction from the Great Salt Lake represents about 9% of the water use in the watershed (Abbot et al., 2023). Unsustainable use of saline lake water can desiccate the habitat and expose toxic dust (Abbot et al., 2023; Ekrami et al., 2021).

Brines can have a strong negative impact on the environment due to their high concentration of salts and other pollutants, and they are commonly discharged without any further treatment (Ariono et al., 2016). In January 2001, USM was sued by the EPA for discharging toxic waste into unlined ditches and a 400-acre pond on the western edge of Great Salt Lake (Trentelman, 2009). As of 2008, USM was considered one of the top five polluters in Utah (Fahys, 2008). In September of 2008, the EPA proposed adding USM to its Superfund National Priorities List, arguing that chemical waste at a 4,500 acre site is endangering workers, their families, waterfowl, and the environment (Trentelman, 2009). In 2009, the USM facility included a sewage pond, a solid waste landfill, and waste piles for barium sulfate, gypsum, and other mineral wastes that were mixed with other hazardous constituents (U.S. EPA, 2022). USM's waste disposal practices contaminated soil, air, surface water, and groundwater (US EPA, 2022). Since then, EPA has taken action to assure that cleanup activities occur on the affected site (US EPA, 2022).

Despite USM's investment to modernize the electrolytic process and try to capture essentially all (99.9%) of the chlorine (a co-product of the electrolysis) (Tripp, 2009), toxic plumes are still produced. Through aircraft observations, Womack et al. (2023) found that USM produces plumes that contain extreme levels of hydrogen chloride and dihalogens (chlorine, bromine, and bromine monochloride) emissions. During the nighttime flights performed for this study, the largest concentrations observed during the transects were 600 parts per billion (ppb) of chlorine, 3 ppb of bromine, and 100 ppb of bromine monochloride (Womack et al., 2023). These are the highest levels of these halogens ever measured in ambient air, outside of chlorine in volcanic plumes (Womack et al., 2023). The halogen fluxes deplete ozone in the adjacent areas and increase oxidants and particulate matter, affecting the air quality in populated regions of the Great Salt Lake Basin (Womack et al., 2023).

Evaluation Question #10: Describe and summarize any reported effects upon human health from use of the petitioned substance (7 U.S.C. § 6517(c)(1)(A)(i), 7 U.S.C. §6517(c)(2)(A)(i)) and 7 U.S.C. § 6518(m)(4)).

Magnesium and MC are not toxic to humans at doses that fall close to the maximum daily intake (NIH, 2023). However, high doses of magnesium from dietary supplements or medications often result in diarrhea that can be accompanied by nausea and abdominal cramping (ECHA, 2023; Harvard School of Public Health, 2019; NIH, 2023). Magnesium-containing laxatives and antacids at a concentration of more than 5,000 mg/day magnesium have been associated with magnesium toxicity, including fatal hypermagnesemia in a 28-month-old boy and an elderly man (NIH, 2023). Symptoms of magnesium toxicity can include (NIH, 2023):

- hypotension (low blood pressure)
- nausea
- vomiting
- facial flushing
- retention of urine
- ileus (improper bowel function)
- depression
- lethargy

With high enough dosage (producing serum concentrations of 1.74-2.61 mmol Mg/L), magnesium toxicity can progress to (NIH, 2023):

- muscle weakness
- difficulty breathing
- extreme hypotension
- irregular heartbeat
- cardiac arrest

Too much magnesium from food does not pose a health risk in healthy individuals because the kidneys eliminate excess amounts in the urine (NIH, 2023). However, the risk of magnesium toxicity increases with impaired renal function or kidney failure because the ability to remove excess magnesium is reduced or lost (NIH, 2023).

Evaluation Question #11: Describe any alternative practices that would make the use of the petitioned substance unnecessary (7 U.S.C. § 6518(m)(6)).

We did not find literature that indicated any clear alternative practices to using MCs as an anti-caking agent for the manufacture of spray-dried chicory root powder. A variety of dehydrated powdered foods contain MCs (see *Specific Uses of the Substance*, above) as an anti-caking agent. Spray-drying is a popular but complex method for producing many dehydrated powdered foods, particularly sticky foods (Amrutha et al., 2014; Bhatkar et al., 2021). Braga et al. (2020) demonstrated optimization of the spray drying process and the associated machinery can improve yields without the introduction of additives. Process and machinery modifications that can improve production yield without the use of additives appear in Table 5 below. Cooling the chamber wall may help minimize particle stickiness, but does not resolve the caking problem entirely as it can cause an increase in relative humidity (Krishnaiah et al., 2014). Processors can scrape the dryer surfaces to improve yield, but this is laborious and debatably not suitable as a viable alternative for spray-drying bulk powders with the use of flow conditioners (Krishnaiah et al., 2014; Leroux SA, 2022a). There are also alternative anti-caking agents currently on the National List that can supplement the additional process and machinery modifications. Further detail of these appear in *Evaluation Question #12* and *#13*.

Sun drying is also a method for producing dehydrated powdered foods, including chicory. This process requires no additives, but is limited to certain processing locations with favorable climates (Indzere et al., 2018).

Table 5. Spray dryer process and machinery modification alternatives to optimize product yield

Primary Modification	Food Product	Effect	Reference
Optimize inlet temperature	Chicory root inulin	Increased drying temperature paired with reduced rotation speed produced more spherical particles and smoother surfaces	(Toneli et al., 2010)
Optimize inlet temperature	Kiwiberry pulp powder	Decreased drying temperature produced lower moisture content, lower water activity, and larger particle sizes that should increase flowability	(Jedlińska et al., 2022)
Optimize inlet temperature	Rice starch	Decreased drying temperature compared to common starch manufacturing for better energy savings, improved thermal efficiency, lower costs and higher productivity	(Tay et al., 2021)
Dehumidify air	Kiwiberry pulp powder	Reduced air humidity to allow for reduced drying temperature and avoid material stickiness and adhesion	(Jedlińska et al., 2022)
Dehumidify air	Tomato pulp powder	The lower humidity of drying air paired with lower outlet drying temperatures resulted in a solid particle surface and decreased the residue accumulation minimizing the thermoplastic particles from sticking	(Goula & Adamopoulos, 2005)

<u>Evaluation Question #12:</u> Describe all natural (non-synthetic) substances or products which may be used in place of a petitioned substance (7 U.S.C. § 6517(c)(1)(A)(ii)). Provide a list of allowed substances that may be used in place of the petitioned substance (7 U.S.C. § 6518(m)(6)).
The characteristics that make MCs desirable anti-caking agents include their traits as materials that selectively bind water and their lack of interference with the final appearance and taste of powdered foods (see *Properties of the Substance*, above). We did not find literature that indicated that the alternative materials listed below have been studied for use in chicory root powder production. These may or may not be suitable alternatives to MC.

Chicory root powder is a "deliquescent substance," or one that absorbs moisture from the air until it dissolves into the absorbed water (Mauer & Taylor, 2010). Salt and sugar are both deliquescent materials (Lipasek et al., 2012). Lipasek et al. (2012) studied the effects of various anti-caking agents on the deliquescence of different food powders and found that different agents had differing effects on the individual food powders. Blends of anti-caking agents also had unique effects on food powders. The authors suggest that the time it takes for a powder to absorb moisture and dissolve into it, will vary based on the following:

- Nature of the powder's components
- Sorption kinetics of the material
- Relative humidity
- Relative temperature

For these reasons, some anti-caking agents or a combination of several that function through different mechanisms may be more effective at preventing clumping and improving flowability for certain deliquescent powders (Lipasek et al., 2012).

The following materials are common anti-caking agents for dried, powdered foods that are theoretical alternatives to MCs for the petitioned use (discussed in detail, below):

- Calcium carbonate
- Tricalcium phosphate (calcium phosphate, tribasic)

Silicon dioxide is also an allowed synthetic for this use when organic rice hulls are not commercially available (Martins et al., 2019). However, the use of silicon dioxide as an anti-caking agent is under increasing scrutiny. This is in part related to the presence of nanoparticles in some forms (Anastasi et al., 2019; European Commission Directorate-General for Agriculture and Rural Development, 2022) and in part due to the consumer demand for non-synthetic food additives (Larsson, 2016; Zhong et al., 2018). The French government in recent years implemented more rigorous evaluation and restrictions of nanomaterials and in collaboration with ANSES. ANSES is working on risk assessments for food additives and ingredients that it has identified as high risk for containing nanoparticles, including the silicon dioxide form synthetic amorphous silica (E551) (ANSES, 2020). Further information on organic rice hull powder as a viable commercial alterative is included in *Evaluation Question #13*.

Calcium carbonate (nonsynthetic)
Calcium carbonate is a common anti-caking agent (European Commission Directorate-General for Agriculture and Rural Development, 2022; Martins et al., 2019). It is readily available commercially, both domestically and globally (EPA, 2022). Processors add calcium carbonate at rates of 0.6-1% as an anti-caking agent in a variety of products including the following (EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS), 2011):

- baking powder
- salt and salt substitutes

Potential risks to human health with calcium carbonate include hypercalcemia, the formation of kidney stones, alkalosis, and increased risk of myocardial infarction (EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS), 2011; NOP, 2018). Similar to silicon dioxide, the use of calcium carbonate as a food additive is under increasing scrutiny in France as a source of nanoparticles (ANSES, 2020).

Environmental concerns related to the mining of calcium carbonate include potential for contamination of aquifers and surface water sources, and consequent negative effects on biodiversity (NOP, 2018).

Tricalcium phosphate (allowed synthetic)
Tricalcium phosphate is also a common anti-caking agent with a high water-binding capacity (Martins et al., 2019). It is chemically inert except in acidic environments (NOP, 2016b). It is readily available commercially, both domestically and globally (ChemAnalyst, 2023). Tricalcium phosphate is an effective anti-caking agent at rates $<2\%$ in a variety of products including:

- salt, spices (Adhikari et al., 2001)
- sugar (Hollenbach et al., 1982)
- honey powder (Umesh Hebbar et al., 2008)

Elevated serum phosphate is a potential human health concern. High phosphate consumption is a risk factor for end-stage renal disease and mortality, abnormally high arterial stiffness, and increased risk of cardiovascular disease (NOP, 2016b; Ritz et al., 2012). Additionally, high phosphate consumption is a risk factor for abnormally low blood circulation (NOP, 2016b). The phosphate in tricalcium phosphate is highly bioavailable compared to natural phosphate from food and more effective at increasing blood phosphate levels. Calcium phosphates contribute calcium, with Ca:P ratios of 1.9:1 for tricalcium phosphate. A sufficiently high intake of calcium appears to counteract some of the effects of excess dietary phosphorus, but leads to an increased requirement for magnesium (NOP, 2016b). Similar to silicon dioxide and calcium carbonate, the use of tricalcium phosphate as a food additive is under increasing scrutiny in France as a source of nanoparticles (ANSES, 2020).

<u>Evaluation Information #13:</u> Provide a list of organic agricultural products that could be alternatives for the petitioned substance (7 CFR 205.600(b)(1)).
The MCs addressed in this report are purified inorganic chemicals. They are not agricultural products and cannot be made available as organic agricultural products.

Alternative anti-caking agents available as organic agricultural products include corn starch, potato starch, rice hulls, and cane sugar (USDA, 2023). We did not find literature that indicated that these have been studied for use in chicory root powder production. These may or may not be suitable alternatives to MC.

Corn Starch
Corn starch is a common anti-caking agent (Lipasek et al., 2011; Meals et al., 2021). It is readily available commercially, both domestically and globally (OTA, 2023; USDA, 2023). Corn starch is an effective anti-caking agent at a rate of 2% inclusion for vitamin C powder, a deliquescent material (Lipasek et al., 2011).

The source material, corn, is a crop susceptible to heavy metal uptake at rates that may have adverse effects on human health (Rai et al., 2019).

Rice Hulls
Rice hulls contain a high concentration of amorphous silica and may demonstrate a similar functionality to silicon dioxide (Alshatwi et al., 2015; NOP, 2010a, 2016b). They are readily available, both domestically and globally (OTA, 2023; USDA, 2023).

Rice is known to be a crop susceptible to heavy metal uptake at rates that may have adverse effects on human health (T. Li et al., 2018; Senarathne et al., 2023). However, there is also limited data to support that rice hulls may contain bioactive compounds with limited antioxidative and anticancer properties (Friedman, 2013; Peanparkdee & Iwamoto, 2019).

Rice is a staple food worldwide and rice hulls are an inevitable by-product of the industry. The application of rice hulls as an anti-caking agent could offer a way to curb the negative environmental impacts of commercial agriculture (Alshatwi et al., 2015).

Report Authorship

The following individuals were involved in research, data collection, writing, editing, and/or final approval of this report:

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All individuals are in compliance with Federal Acquisition Regulations (FAR) Subpart 3.11—Preventing Personal Conflicts of Interest for Contractor Employees Performing Acquisition Functions.

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