JOST CHEMICAL®

*It's in the Details*

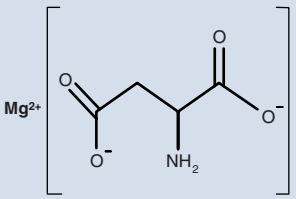
# Fully Reacted Mineral Salts

The emphasis on health and nutrition has focused attention on mineral supplements. As the market for mineral supplements continues to grow and becomes more sophisticated, the need for good chemistry at the point of production becomes more apparent. **The use of mineral salts containing unreacted compounds can lead to formulation stability problems and inaccurate ingredient declarations on the finished product.**

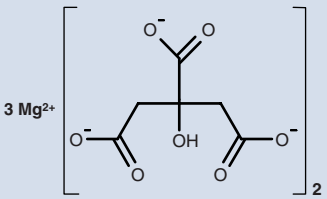
## *Introducing...*Magnesium Salts

Jost Chemical Co. is now manufacturing Magnesium Aspartate Dibasic Anhydrous and Magnesium Citrate Tribasic Anhydrous. Both products are manufactured under systems that comply with cGMPs. These products are typically used in pharmaceutical, nutritional and cosmetic applications. Magnesium Aspartate Dibasic has an As-Is magnesium content of 14.2 – 15.7%. Magnesium Citrate Tribasic offers a slightly higher As-Is magnesium content of 14.5 – 16.4%.

| Jost Code | Chemical Formula | Product Name |
|---|---|---|
| 2520 | $Mg(C_4H_5NO_4)$ | Magnesium Aspartate Dibasic Anhydrous |
| 2549 | $Mg_3(C_6H_5O_7)_2$ | Magnesium Citrate Tribasic Anhydrous USP |




**Magnesium Aspartate Dibasic**




**Magnesium Citrate Tribasic Anhydrous**

In October 1994, the U.S. Congress passed the Dietary Supplement Health and Education Act (DSHEA). DSHEA called for the establishment of current Good Manufacturing Practices (cGMPs) for dietary supplements. The FDA notice of proposed rule making for dietary cGMPs was first published in 1997, and has yet to be finalized. The lack of published monographs on many widely used mineral salts and instances of non-compliance with established monographs reinforces the need for good chemistry and accurate content disclosure. This regulatory ambiguity is a cause of concern for supplement manufacturers leaving them wondering: Are the products I buy safe for their intended use? Are the products fully reacted? Do the chemical manufacturing processes produce the desired product?

The process for manufacturing fully reacted pure salts involves the reaction of an acid and a base in an aqueous solution and the precipitation of a salt compound. Dissolving the reactants provides the opportunity for a complete reaction to occur. This stands in contrast to a dry blend of an acid and a base. In blended or partially reacted products, the mixing of the acid and base might be complete but the reaction might not proceed to completion because of a lack of opportunity. The lack of dissolution inhibits solvation of the reactants and guarantees a slower and ultimately a less complete reaction.

**Most fully reacted salts have a fairly neutral pH.** Blended products might exhibit an acidic or alkaline pH. Infrared spectroscopy, nuclear magnetic resonance spectroscopy, thermal gravimetric analysis and numerous other techniques can be used to differentiate between a fully

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reacted mineral salt and a blend of reactants. Depending upon the mineral salt, the addition of acid to the sample can demonstrate the presence of unreacted mineral base. If carbonate is present, effervescence will occur. In the case of hydrated Magnesium Citrate Tribasic, a material not fully reacted when put in water will cause a reaction and temperature increase.

Negative ramifications of an incomplete reaction abound. Unlike a fully-reacted salt, the blend might be unstable over time because of a slow but on-going reaction, as the alkaline minerals react with any acidic ingredients in the formula. This instability can cause the blend to harden over time or tablets to disintegrate. A blended product might be low or high in pH because of an imbalance in the acid-base stoichiometry. The pH imbalance can lead to problems with the product integrity. Structure and content uniformity can suffer if the product contains a mineral blend and not the fully reacted salt. In compounding operations, blends can separate based on differing physical characteristics.

Another negative ramification occurs when the blend is exposed to water. Processes such as wet granulation or adding the blend into a consumer's drink might allow a reaction to occur at an inopportune time, thereby damaging the integrity of the final product. **These deficiencies are not typically found when using fully reacted mineral salts.**

Besides an end product that may be unstable, formulations that contain blended mineral ingredients may have a misstated ingredient label as well. An example would be a magnesium citrate that lists magnesium content at 20%. This magnesium level is not possible based upon the stoichiometry of a fully reacted salt. Per the USP monograph, Magnesium Citrate Tribasic can only offer 11.2 – 12.0% magnesium on the "As-Is" basis in the hydrated form. Jost Chemical has the drying capability to offer an anhydrous product, whose theoretical magnesium content range is 14.5 – 16.4%. But with the available drying capabilities in today's manufacturing environment, a magnesium content level above 15.5% is rarely achieved. It is apparent that products claiming higher magnesium contents are blends. Appropriate labeling should list the ingredients comprising a "blend" such as magnesium citrate and magnesium oxide, so that the finished product complies with the FDA ingredient declaration mandates.

**Jost Chemical Co. is a manufacturer of fully reacted, pure mineral salts that meet USP/EP/FCC monographs, if applicable. Jost follows the science of manufacturing only pure materials that are the true chemical entity and not a blend or mixture of components.**

## Fully Reacted Mineral Content

| Product "As-Is" | Mineral Percentage | | |
|---|---|---|---|
| **Calcium Citrate Tetrahydrate** | **20.5%** | **–** | **21.2%** |
| **Magnesium Citrate Tribasic Hydrate** | **11.2%** | **–** | **12.0%** |
| **Magnesium Aspartate Dibasic** | **14.2%** | **–** | **15.7%** |
| **Magnesium Ascorbate** | **6.1%** | **–** | **6.6%** |
| **Magnesium Malate Trihydrate** | **11.3%** | **–** | **11.8%** |