

What is NAC?

- N-acetylcysteine (also known as N-Acetyl-L-Cysteine, NAC) is a sulfur-containing amino acid that facilitates the production of glutathione – the master endogenous antioxidant in the body. NAC itself is a powerful antioxidant that promotes healthy immune function and helps provide comprehensive support for many physiological processes within the body including lung, liver, and kidney function, which collectively supports health detoxification pathways.[†]
- While NAC is only available in supplement form, this amino acid is found naturally in high-protein foods – such as chicken, turkey, yogurt, cheese, eggs, sunflower seeds, and legumes- in its cysteine form.
- Chemically, NAC is similar to cysteine. However, the presence of the acetyl group reduces the reactivity of the thiol portion of the molecule. Thus, as compared to cysteine, NAC is less susceptible to oxidation, less toxic, and is more soluble in water, making it a better source of cysteine than ingestion of cysteine itself.

NAC is in the news, but why?

- As you may know, last year the FDA asserted in [warning letters](#) to seven companies that NAC couldn't be lawfully marketed as a dietary supplement because it was first studied and approved as a drug in 1963. It is important to note that several other nutrients (including CoQ10) have previously been approved as drugs, but the FDA has not applied the same rule.
- The warning letters were sent out to companies after the FDA reviewed their websites and determined they were using prohibited language in their marketing claims.
- These claims established that the product was intended to be used as a drug under section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)(B)] because it was intended for use in the cure, mitigation, treatment, or prevention of disease.
- The warning letters caused concerns in the dietary supplement industry because, in part, NAC-containing supplements are widely sold in the U.S.
- The ruling is not final, but these warning letter spurred Amazon in May 2021 to stop selling all products containing NAC and remove remaining inventory from their shipping warehouses. This has created some confusion among users/patients who take NAC-containing products and HCPs who prescribe them - where to purchase and whether NAC-containing products will soon be gone from the market or require a prescription?

How is the supplement industry responding?

- In a letter to FDA in December, the Council for Responsible Nutrition (CRN) [made legal arguments](#) challenging the FDA's position. CRN outlined its reasons for why the agency should "revert to its long-standing policy of allowing manufacturers to market products containing NAC as dietary supplements."
- Dan Fabricant, Ph.D., president, and CEO of the Natural Products Association (NPA) is advising its members to continue selling NAC-containing supplements because the FDA has not taken final agency action.
- So far, FDA has also ruled that it is currently illegal to market CBD by adding it to a food or labeling it as a dietary supplement. However, congress and the supplement industry are challenging this. Eventually, FDA and congress will come up with a legal pathway that will

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allow CBD to be used in supplements. **This can take years.** The outcome of CBD will also impact the outcome of NAC.

What is SFI Health’s home of Klaire Labs response/position?

- On all Klaire Labs brand, private label, and future products we are proceeding business as usual – we will continue to sell and manufacture NAC and NAC-containing products.
- There is no safety concern with NAC. In fact, it is one of the most studied supplements on the market with over 700 randomized clinical studies.
- Some facts on NAC:
 - o NAC has a low molecular weight, is well absorbed via oral administration, and is much safer than cysteine.[†]
 - o It helps to replenish intracellular glutathione, which is vital in cellular antioxidant protection.[†]
 - o Supports natural and healthy liver and kidney detoxification processes.[†]
 - o Acts as a powerful antioxidant.[†]
 - o Promotes immune function.[†]
 - o It has long been used to support healthy mucous production in a subset of patients.[†]

[†]These statements have not been evaluated by the Food and Drug Administration. These products are not intended to diagnose, treat, cure, or prevent any disease.

Klaire Labs products that contain NAC	
PRODUCT	SKU CODE
CLEARITY	CLR
GLUCOTHERA™ FORTÉ	GLF
GLUCOTHERA™	GLC
HAIR AND NAILS FORMULA	CP2130
HEPATOTHERA™	HEP
HEPATOTHERA™ FORTÉ	HEPF
MITOTHERA™	MTO
MITOTHERA™ CAPSULE FORMULA	MTOC
N-ACETYL-L-CYSTEINE	NAC
OCUTHERA™	OCU

PREGNANCY

If pregnant, consult your health professional before using NAC-containing products.

INTERACTIONS/CONTRAINDICATIONS

There are no known adverse interactions or contraindications of NAC at publication date.

References for additional reading:

Lasram MM, Dhoub IB, Annabi A, El Fazaa S, Gharbi N. A review on the possible molecular mechanism of action of N-acetylcysteine against insulin resistance and type-2 diabetes development. *Clin Biochem.* 2015;48(16-17):1200-1208. doi:10.1016/j.clinbiochem.2015.04.017

Elbini Dhoubi I, Jallouli M, Annabi A, Gharbi N, Elfazaa S, Lasram MM. A minireview on N-acetylcysteine: An old drug with new approaches. *Life Sci.* 2016;151:359-363. doi:10.1016/j.lfs.2016.03.003