

UNITED STATES COURT OF INTERNATIONAL TRADE

BEFORE: LISA W. WANG, JUDGE

	:	
BASF CORPORATION,	:	
	:	
Plaintiff,	:	
	:	
v.	:	Consol. Court No. 12-00422
	:	
UNITED STATES,	:	
	:	
Defendant.	:	
	:	

**DEFENDANT’S REPLY IN SUPPORT OF ITS  
CROSS-MOTION FOR SUMMARY JUDGMENT**

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**TABLE OF CONTENTS**

ARGUMENT .....2

I. Note 1 To Chapter 29, As Informed By The Explanatory Note, Requires That The Additives Such As Gelatin And Sucrose In Betatene Be Necessary For Beta-Carotene’s Preservation Or Transport And Not Render Betatene Suitable For Specific Rather Than General Use.....2

II. Betatene Is Suitable For Use Only In Dietary Supplements, And BASF Produced No Evidence To The Contrary .....3

III. Betatene Contains More Gelatin And Sucrose Than Necessary For Beta-Carotene’s Stabilization For Preservation Or Transport.....8

IV. Betatene’s Gelatin And Sucrose Do More Than Just Stabilize Beta-Carotene For Preservation Or Transport.....9

CONCLUSION.....11

**TABLE OF AUTHORITIES**

**Cases**

*Al-Site Corp. v. VSI Int’l, Inc.*,  
174 F.3d 1308 (Fed. Cir. 1999) ..... 4

*Applikon Biotech., Inc. v. United States*,  
807 F. Supp. 2d 1323 (Ct. Int’l Trade 2011) ..... 6

*Degussa Corp. v. United States*,  
508 F.3d 1044 (Fed. Cir. 2007) ..... 3

*Grimes v. Dist. of Columbia*,  
794 F.3d 83 (D.C. Cir. 2015)..... 7

*Keer, Maurer Co. v. United States*,  
41 Cust. Ct. 38 (1958)..... 7

*Keer, Maurer Co. v. United States*,  
46 C.C.P.A. 110 (1959) ..... 6

*Roche Vitamins, Inc. v. United States*,  
772 F.3d 728 (Fed. Cir. 2014) ..... 3, 5, 8, 10

*W.R. Filbin & Co. v. United States*,  
744 F. Supp. 289 (Ct. Int’l Trade 1990) ..... 6, 7

*Wasco v. T Corp.*,  
2008 WL 53707 (D.D.C. Jan. 3, 2008)..... 5

*Watson v. Allstate Texas Lloyd’s*,  
224 F. App’x 335 (5th Cir. 2007) ..... 5

**Harmonized Tariff Schedule of the United States**

Chapter 21:

Heading 2106 ..... 2, 7, 9, 10

Chapter 29:

Heading 2936 ..... *passim*

Note 1 ..... *passim*

**Rules**

USCIT Rule 56(c)(1)(B) ..... 7

**Other Authorities**

Chester K. Wentworth,  
*A Scale of Grade and Class Terms for Clastic Sediments*, 30 *J. Geology* 377 (1922)..... 4

Explanatory Note 29.36 ..... *passim*

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**DEFENDANT’S REPLY IN SUPPORT OF ITS  
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Beta-carotene is an organic colorant and a source of provitamin A activity, and its commercial uses include serving as a colorant in foods, beverages, and cosmetics; as a food and beverage fortifier; and as an ingredient in dietary supplements. To be classifiable under heading 2936, Harmonized Tariff Schedule of the United States (HTSUS), a beta-carotene preparation must meet the conditions of note 1 to chapter 29. Among other things, the preparation’s additives must be “necessary” for beta-carotene’s “preservation or transport,” and must not render the preparation suitable for specific rather than general use. Note 1 to chapter 29. But BASF has never heard of its Betatene 7.5% N (“Betatene”) formulation being used as a colorant or as anything other than a dietary supplement. That is not surprising. BASF tests and markets Betatene solely for that use, and Betatene’s oily gelatin-sucrose beadlets in fact make the product unsuitable (albeit not physically impossible) to be used otherwise. Furthermore, BASF has marketed other stable beta-carotene formulations that contain more beta-carotene and less additives, such as gelatin and sucrose, than Betatene. The additives in Betatene’s formulation are thus not necessary for beta-carotene’s preservation or transport; rather, they undisputedly

render beta-carotene suitable for use only in dietary supplements. Betatene is thus properly classified as a “food preparation” of heading 2106, not an all-purpose “provitamin” of heading 2936.

BASF’s counterarguments are unavailing. ECF No. 78 (BASF Resp.). The law, contrary to what BASF suggests, requires BASF to demonstrate that Betatene’s additives do not do more than stabilize beta-carotene for preservation or transport, are not in quantities greater than necessary for those purposes, and do not prepare beta-carotene for specific rather than general use. BASF has failed to demonstrate each of these three requirements, as it must. And BASF’s speculation that some commercially illiterate manufacturer somewhere might use Betatene as something other than a dietary-supplement ingredient is insufficient to show that Betatene is *suitable* for general use—particularly given uncontradicted expert testimony to the contrary.

Accordingly, the Court should deny BASF’s motion for summary judgment and grant the Government’s cross-motion for summary judgment.

### **ARGUMENT**

#### **I. Note 1 To Chapter 29, As Informed By The Explanatory Note, Requires That The Additives Such As Gelatin And Sucrose In Betatene Be Necessary For Beta-Carotene’s Preservation Or Transport And Not Render Betatene Suitable For Specific Rather Than General Use**

As explained in the Government’s cross-motion for summary judgment, for a beta-carotene formulation to be classified under heading 2936, note 1 to chapter 29 mandates that any “added stabilizer” be “necessary for [beta-carotene’s] preservation or transport.” ECF No. 74 (Gov’t Br.) at 13–14. Explanatory Note 29.36 informs that language, providing that a stabilizer is “necessary” only if three conditions are met: (1) the stabilizer must be added for the purposes of “preservation or transport”; (2) “the amount of stabilizer added” must not be “more than necessary” for those purposes; and (3) “the addition of stabilizer ingredients” must not “render

the basic product, beta-carotene, particularly suitable for specific use rather than for general use.” *Roche Vitamins, Inc. v. United States*, 772 F.3d 728, 732 (Fed. Cir. 2014) (citing Explanatory Note 29.36 (3d ed. 2002)). Betatene fails each condition, as the Government’s cross-motion demonstrates. Gov’t Br. at 14–23.

BASF complains that the Government is reading “additional restrictions” into the text of note 1 to chapter 29, BASF Resp. at 18, but BASF’s true grievance is with binding precedent. The U.S. Court of Appeals for the Federal Circuit has already held that Explanatory Note 29.36’s standard “provide[s] further insight as to the proper classification of merchandise under heading 2936,” and applied that standard to the classification of a beta-carotene preparation. *Roche Vitamins*, 772 F.3d at 731. And contrary to BASF’s contention, BASF Resp. at 16–17, the Federal Circuit has never held “that an explanatory note cannot define a term in a way that might narrow the plausible interpretation of a chapter note or heading.” *Degussa Corp. v. United States*, 508 F.3d 1044, 1048 (Fed. Cir. 2007). It is appropriate to use an Explanatory Note to define or clarify language used in the tariff—even if that definition or clarification creates a reticulated standard—just as *Degussa* and *Roche Vitamins* did. *Id.* at 1048; *Roche Vitamins*, 772 F.3d at 731. As such, BASF’s quibble over the substantive legal standard is both foreclosed by binding precedent and unpersuasive.

## **II. Betatene Is Suitable For Use Only In Dietary Supplements, And BASF Produced No Evidence To The Contrary**

Although beta-carotene has multiple commercial applications (including as a colorant or additive for foods, beverages, and cosmetics), Betatene—the formulation—is “not suitable for general uses,” Gov’t Ex. 8 (Cantor Report) at 9, but rather is suitable for specific use in dietary supplements. Gov’t Br. at 18–23. It is unsuitable for use as a colorant or food-fortifier because of its expensive gelatin-sucrose matrix, which must be dissolved to color or chewed to fortify,

along with its use of oil, which prevents the preparation from being water-dispersible and causes a funny taste when chewed as the oil oozes out.<sup>1</sup> Gov't Br. at 19–21; *see* Gov't Ex. 6 (Meyers Dep.) at 104:6–8 (“As soon as you crack [the beadlet] you have lost the benefit of why you are forming a beadlet.”). But Betatene is particularly suitable for its intended use—as a tableting ingredient—because that same gelatin-sucrose matrix protects the beta-carotene during the tableting process and need not be dissolved or chewed to be useful. Gov't Br. at 19–21. Accordingly, note 1 to chapter 29, as informed by Explanatory Note 29.36, excludes Betatene from heading 2936.

BASF first claims that Betatene’s formulation must have “alter[ed] the inherent nature of beta-carotene to be provitamin A” to be excluded from chapter 29 by note 1, BASF Resp. at 37–40, but that is not an accurate description of the legal standard. Explanatory Note 29.36’s “criteria” are “written in the conjunctive,” as BASF itself notes, BASF Resp. at 40, which means that Betatene must satisfy *all* of them—not that it need only satisfy one of them. *Al-Site Corp. v. VSI Int’l, Inc.*, 174 F.3d 1308, 1326 (Fed. Cir. 1999) (“Because this is a conjunctive test, failure to prove even one of these elements precludes a showing of [liability]. Therefore, the defendant can secure a summary judgment ... by demonstrating that the plaintiff cannot show any element[.]”).

Furthermore, the test is not whether the additives alter the beta-carotene in the formulation at the molecular level or otherwise alter the “inherent nature” of the beta-carotene molecules. Instead, the test is whether the additives give the formulation different characteristics

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<sup>1</sup> Each Betatene beadlet is “approximately 240 to 300 microns in size.” BASF Resp. at 28 n.4. That is not quite “very fine,” as BASF claims, *id.*; it is the size of medium-grain sand. Chester K. Wentworth, *A Scale of Grade and Class Terms for Clastic Sediments*, 30 *J. Geology* 377, 384 (1922).



that render the product “particularly suitable for specific use rather than for general use.” *Roche Vitamins*, 772 F.3d at 732 (finding that Roche’s BetaTab beta-carotene formulation was not rendered particularly suitable for specific use because it had “no ingredients added specifically for tableting,” its stabilizers “were essentially the same as those used to stabilize other vitamins and other beta-carotene products that were marketed for use as colorants,” and it was “well suited for fortifying foods”).

And just as in its opening brief, BASF again ignores that the uncontradicted evidence about *Betatene* in *this* case—not the evidence about *BetaTab* described in *Roche Vitamins*, BASF Resp. at 40–50—establishes that *Betatene* “is not suitable for general uses.” Cantor Report at 9; *see* Gov’t Br. at 18–23. To start, BASF cannot rely on testimony of “Roche Vitamins’ witness” offered in Court No. 04-00175. BASF Resp. at 27. BASF provides no legal authority holding that a plaintiff can rely on a third party’s testimony in a different case concerning a different product with a different formulation as proof of a fact about the plaintiff’s product. But most importantly, BASF’s expert’s inability to opine in a sworn declaration that *Betatene* is suitable for general use is not some technicality, as BASF tries to suggest. BASF Resp. at 45 (suggesting that its expert addressed “suitability” in his report without ever using the word). It is a failure of proof. *See, e.g., Watson v. Allstate Texas Lloyd’s*, 224 F. App’x 335, 342 (5th Cir. 2007) (“no genuine issue of material fact existed” where the plaintiff failed to contradict the defendant’s expert opinion with anything other than speculation); *Wasco v. T Corp.*, 2008 WL 53707, at \*5 (D.D.C. Jan. 3, 2008) (a plaintiff’s “conclusory expert report that in no way respond[ed] to” contrary expert evidence failed to create a “genuine issue of material fact”).

In any event, speculation that manufacturers, who “can do whatever they want,” “might” use *Betatene* to color or fortify, BASF Resp. at 48 n.8 (quotations omitted), is not enough to

survive summary judgment. *Applikon Biotech., Inc. v. United States*, 807 F. Supp. 2d 1323, 1324 n.2 (Ct. Int'l Trade 2011) (“Mere conclusory statements, conjecture, or speculation by the party resisting the motion will not defeat summary judgment.” (quotation omitted)). The expensiveness of microencapsulation, combined with the razor-thin margins in the food industry and the higher margins in the dietary-supplement industry, make it implausible that a manufacturer would use Betatene in anything other than dietary supplements. Gov’t Br. at 21. BASF does not and cannot dispute that commercial reality. *See* BASF Resp. at 48 n.8. Moreover, there is no evidence that any of BASF’s customers has ever used Betatene—the “main purpose” of which is “tableting,” Gov’t Ex. 1 (Köpsel Dep.) at 56:19–57:4—in anything other than a dietary supplement. BASF has never heard of Betatene being used outside dietary supplements. *Id.* at 82:8–83:12. It has never talked with a customer about using Betatene as a colorant or food additive. *Id.* It has never tested Betatene’s suitability for any use other than in dietary supplements. *See id.* at 30:22–31:3; Gov’t Ex. 12. And it has never marketed Betatene for any other use other than in dietary supplements. Gov’t Ex. 5 at 3; Gov’t Ex. 11 at 2.

All that is fatal to BASF’s case. “‘Suitable for use’ as applied in the Customs law means ‘actually, practically, and commercially fit’ for such use.” *W.R. Filbin & Co. v. United States*, 744 F. Supp. 289, 291 (Ct. Int'l Trade 1990) (quotation omitted), *aff’d*, 945 F.2d 390 (Fed. Cir. 1991). “Such suitability does not require that the merchandise be chiefly used for the stated purpose, but it does require more than evidence of a casual, incidental, exceptional, or possible use. There must be a substantial actual use.” *Keer, Maurer Co. v. United States*, 46 C.C.P.A. 110, 114 (1959) (cleaned up). Thus, that a good “‘could’ be used” for certain purposes is not enough to establish suitability, particularly where the good in question has been “‘adapted primarily” for a particular purpose. *Keer, Maurer Co. v. United States*, 41 Cust. Ct. 38, 42

(1958), *aff'd*, 46 C.C.P.A. 110 (1959). The same is true of Betatene: it “could be used” as a colorant or food additive under commercially unrealistic conditions, but it has been “adapted primarily” for use as a tableting ingredient, *id.*, and there is no evidence of “substantial actual” general use or “actual[], practical[], and commercial[] fit[ness]” for general use, *W.R. Filbin & Co.*, 744 F. Supp. at 291 (quotation omitted).

BASF disputes none of these facts, which are material to, and dispositive of, the question of suitability. *See* ECF No. 78-1 ¶¶ 37, 39, 41, 42, 43. Instead, it objects to the statement that “BASF has not tested the suitability or stability of the subject merchandise for any use other than dietary-supplement tablets” as unsupported. *Id.* ¶ 41. Putting aside that all the other undisputed facts still demonstrate Betatene’s unsuitability for general use, a factual assertion can be supported not just by materials in the record (which the Government has done) but also by showing “that an adverse party cannot produce admissible evidence to support the fact.” USCIT Rule 56(c)(1)(B); *see Grimes v. Dist. of Columbia*, 794 F.3d 83, 93 (D.C. Cir. 2015) (“[T]he burden on a defendant moving for summary judgment may be discharged without factual disproof of the plaintiff’s case; the defendant need only identify the ways in which the plaintiff has failed to come forward with sufficient evidence ....”). BASF fails to dispute the Government’s statement that BASF lacks evidence of non-dietary-supplement-related testing with contradictory, admissible evidence. *See* ECF No. 78-1 ¶ 41. The Government’s statement of fact is thus undisputed.

Because Betatene is particularly suitable for specific use in dietary supplements and is not suitable for general use, note 1 to chapter 29 precludes its classification under heading 2936. Betatene accordingly is classifiable under heading 2106.

### III. Betatene Contains More Gelatin And Sucrose Than Necessary For Beta-Carotene's Stabilization For Preservation Or Transport

Related to Betatene's suitability for specific use is the fact that Betatene contains more gelatin and sucrose than necessary to preserve beta-carotene for preservation or transport. Gov't Br. at 17–18. BASF does not dispute that beta-carotene formulations are equally or more stable with 20 and 30 percent concentrations of beta-carotene, and, correspondingly, less gelatin and sucrose. BASF Resp. at 31. The “quantity” of gelatin and sucrose “added” to Betatene therefore “exceeds that necessary for [beta-carotene's] preservation or transport.” *Roche Vitamins*, 772 F.3d at 731 (quotation omitted).

In response, BASF repeats its refrain that “it uses no more ingredients than necessary” due to “cost reasons,” BASF Resp. at 34, but at the same time acknowledges that “companies optimize different beta-carotene formulations for a range of commercial applications,” with levels of beta-carotene that “vary in formulations ... as end users have different needs,” *id.* at 31. This is precisely the Government's point. By including additives in Betatene in quantities that surpass those in stable microencapsulated beta-carotene formulations like Betavit and BetaTab (or even the more stable oil-based formulation from which Betatene is made), BASF has “optimize[d]” beta-carotene for a particular “commercial application[,]” *id.* at 31, rather than merely preserved it. Gov't Br. at 17–18.

Accepting BASF's argument would mean that any beta-carotene formulation—regardless of the quantities of beta-carotene, gelatin, and sucrose—would contain no more than necessary for preservation, so long as the manufacturer promises that it is cost-conscious. *See* BASF Resp. at 29–35 & n.7. If that were true, then the condition that the “quantity” of additives “or the processing in no case exceed[] that necessary for” beta-carotene's “preservation or transport,”

Explanatory Note 29.36, would be meaningless. But it cannot be that any amount of additives is “necessary.” Gov’t Br. at 18.

Put simply, the quantity of gelatin and sucrose added to Betatene cannot be “necessary” for “preservation or transport” because beta-carotene is preservable and transportable with less. Betatene is thus excluded from heading 2936 by note 1 to chapter 29, and must be classified under heading 2106 instead.

#### **IV. Betatene’s Gelatin And Sucrose Do More Than Just Stabilize Beta-Carotene For Preservation Or Transport**

Finally, Betatene’s gelatin-sucrose matrix, as BASF’s own expert concedes, does more than just stabilize beta-carotene for preservation or transport. Gov’t Br. at 14–17. It also emulsifies and “provide[s] desired flexibility and durability in tablet compression,” purposes distinct from stabilization. *Id.* at 15–16 (quoting Gov’t Ex. 7 (Meyers Report) at 14). Accordingly, that Betatene’s gelatin and sucrose were added to prepare beta-carotene for tableting, in addition to other purposes, disposes of BASF’s claim. *Id.*

BASF’s main response is that protecting beta-carotene during the tableting process should be considered a “stabilizing function for purposes of preservation or transport,” BASF Resp. at 19, but that is not what the experts say. BASF’s expert conceded that “the gelatin sucrose matrix doesn’t just stabilize” as it “also provides ... mechanical strength” for tableting, Meyers Dep. at 74:8–12, a concession consistent with his report, Meyers Report at 14. The Government’s expert agreed that “protecting an active ingredient against mechanical stresses” is “[n]ot necessarily ... stabilizing” the ingredient but rather “protecting that dosage form from rupturing” during the tableting or hard-capsule manufacturing process. Gov’t Ex. 9 (Cantor Dep.) at 108:3–10, 111:24–114:8; *see* Cantor Report at 7–8.

That Betatene's gelatin-sucrose matrix does in fact stabilize beta-carotene for preservation or transport, as BASF emphasizes, BASF Resp. at 18–28, is not enough. The Government has never disputed that gelatin and sucrose together can function as stabilizers in a formulation. Indeed, as BASF notes, Explanatory Note 29.36 contemplates this. *Id.* at 23.

The problem, though, is that Betatene's gelatin and sucrose also “specifically prepare [it] for tableting.” *Roche Vitamins*, 772 F.3d at 732 (quotation omitted). That is not stabilization for preservation, as BASF argues. If it were, then presumably the Federal Circuit in *Roche Vitamins* would not have emphasized that “[e]xpert testimony established that the sucrose and gelatin additives [in BetaTab] function as stabilizers *and* do not ‘specifically prepare [BetaTab] for tableting.’” *Id.* (emphasis added) (quotation omitted). The two functions, though complementary, are distinct.

In sum, although gelatin and sucrose additives *can* satisfy note 1 to chapter 29's terms, BASF fails to grapple with the undisputed facts of *this case* demonstrating that Betatene's additives disqualify Betatene from classification under heading 2936 under note 1 to chapter 29. And because Betatene does not satisfy note 1's conditions, it must be classified under heading 2106.

**CONCLUSION**

For these reasons, the Court should grant the Government's cross-motion for summary judgment, deny BASF's motion for summary judgment, and enter judgment in the Government's favor.

Respectfully submitted,

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Dated: April 7, 2025

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**CERTIFICATE OF COMPLIANCE**

I, LUKE MATHERS, a trial attorney in the Office of the Assistant Attorney General, Civil Division, Commercial Litigation Branch, International Trade Field Office, who is responsible for the foregoing brief, relying upon the word count feature of the word processing program used to prepare the brief, certify that this brief complies with type-volume limitation under USCIT Standard Chamber Procedure 2(B) and contains 2,911 words.

/s/ Luke Mathers  
LUKE MATHERS