



सीमाशुल्क अग्रिम विनिर्णय प्राधिकरण

CUSTOMS AUTHORITY FOR ADVANCE RULINGS

नवीन सीमाशुल्क भवन, बेलाई इस्टेट, मुंबई - ४०० ००१

NEW CUSTOM HOUSE, BALLARD ESTATE, MUMBAI - 400 001

E-MAIL: cus-advrulings.mum@gov.in

The 09th of the February, 2024

Ruling Nos. CAAR/Mum/ARC/17/2024

in

Application No. CAAR/CUS/APPL/67/2023 - O/o Commr-CAAR-MUMBAI

Name and address of the applicant: M/s. Anshul Life Sciences,
401, 4th Floor, Jagdamba House, Peru Baug,
Goregaon East, Mumbai 400063.

Commissioner concerned: The Principal Commissioner of Customs,
Nhava-sheva-1, Jawaharlal Nehru Custom House,
Ta. Uran, Distt- Raigad, Mumbai 400707.

Present for the applicant: Shri. Sushil Kumar Pahade, Asstt. Gen. Manager,
Shri Ramesh Poduvae, Gen. Manager,
Mrs. Seema Trivedi, Sr. Gen. Manager.

Present for the Department: None.

Ruling

M/s. Anshul Life Sciences (having IEC No. 0394051793 and hereinafter referred to as 'the applicant', in short) filed an application (CAAR-1) for advance ruling before the Customs Authority for Advance Rulings, Mumbai (CAAR in short). The said application was received in the secretariat of the CAAR, Mumbai on 01.06.2023 along with its enclosures in terms of Section 28H (1) of the Customs Act, 1962 (hereinafter referred to as the 'Act' also). The applicant is seeking advance ruling to get the clarity of HS code for Sorbitol Special MDF 85 for imports through the port of Mumbai.

2. Applicant has stated as follows in their statement of relevant facts having a bearing on the question(s) raised enclosed with the CAAR-1 application:

2.1 That the applicant is an importer and trader in various excipients and other chemicals etc. In order to know the most appropriate and suitable HS code for "Sorbitol Special MDF 85", (mixtures of Sorbitol, Mannitol and 1, 4 Sorbitans and water)- Make SPI



Pharma, USA, the applicant has decided to seek 'Advance Ruling' and has asked whether the correct CTI is:

38249900 — *Mis Chemicals which states Mis. Chemical.*

OR

3824 6010 — *Sorbitol other than that of sub-heading 2905 4400- in aqueous solution.*

The applicant has submitted a test/analysis report showing chemical composition of Sorbitol Sorbitan Solution NF Sorbitol Special MDF 85 issued by SPI Pharma in the name of the applicant M/s. Anshul Life Sciences which is reproduced below:

SPI Pharma Inc
1711 Tiles Court
Grand Haven, MI 49417
USA
PH: 616-935-6900

Document Number: SPI-SPEC-172, Rev 07

SPI Pharma™
An API Liquidema Company

Sorbitol Sorbitan Solution NF

Sorbitol Special™ MDF 85

Relest Date: 3 year(s) from the date of Mfg.

Product Code : 111-1124

CHARACTERISTICS

(1) Identification Test A	A deep pink or red wine color appears
Identification Test B	Current NF
(1) Identification Test C - EG	NMT 0.10 %
(1) Identification Test C - DEG	NMT 0.10 %

CHEMICAL

1,4 Sorbitan, % (db)	26.0 - 30.0 %
Mannitol, % (db)	Information Only
Sorbitol, % (db)	25.0 - 40.0 %
(1) Residual Solvents, Ethylene Glycol	NMT 310 ppm
(1) Nickel by ICP-MS	NMT 1.0 ppm
Water	15.0 - 17.0 %
pH, 10% (w/w) Solution	5.4 - 6.1
pH 14% (w/w) Solution	4.0 - 7.0
Reducing Sugars	NLT 12.8 mLs
(1) Residue on Ignition	NMT 0.20 %

MICROBIAL

Microbial Total Aerobic Count	NMT 1000 cfu/g
Total Fungi & Yeast Count	NMT 100 cfu/g

2.2 Further, the applicant has submitted a user guide of SPI Pharma which is reproduced as follows:



Sorbitol Special®

Soft Gel Plasticizer

User Guide

The gelatin-plasticizer ratio depends on the quantity and nature of fill material as well as the size of the capsule

Initially, soft gelatin capsules contained simple lipophilic fills such as purified oils, which only requires glycerol as a plasticizer. However, recent products have more complexity and have a hydrophilic or hygroscopic nature.

Hydrophilic soft gelatin capsule fill formulations (like polyethylene glycol) are often chosen to address bioavailability to improve solubility of poorly soluble drugs, or to dispense low-dose and/or high-potency drugs. PEG-based formulations are very susceptible to water migration into the fill, causing increased drying time and other potential migration issues.

Application	Description	Recommended Grades	Advantage
PEG, hydrophilic, hygroscopic fills	Sorbitol Sorbitan Solution	Sorbitol Special	Premium capsule appearance
PEG, hydrophilic, hygroscopic fills	Sorbitol Sorbitan Solution	Sorbitol Special GC	Reduced blooming
PEG, hydrophilic, hygroscopic fills	Sorbitol Sorbitan Solution	Sorbitol Special MDF 85	Improved drying time Premium capsule appearance
Lipophilic fill	Sorbitol Sorbitan Solution	Sorbitol Special	Improved drying time
Lipophilic fill	Sorbitol Sorbitan Solution/Glycerin USP Blend (1:1)	Sorbitol Special and Grade A810	Convenient blend Low cost in use
Difficult fills (e.g. lecithin)	Sorbitol Sorbitan Solution	Sorbitol Special	Reduced failures from leaks
Difficult fills (e.g. lecithin)	Sorbitol Sorbitan Solution	Sorbitol Special MDF 85	Improved drying time
Nutraceutical Actives	Sorbitol Sorbitan Solution/Glycerin USP Blend (1:1)	Sorbitol Special and-Grade A810	Convenient blend Low cost in use

Sorbitol Special and Sorbitol Special MDF 85 (sorbitol/sorbitan blends) act as a barrier to water migration and are ideal excipients in formulations requiring low moisture. In oil-based or lipophilic fills, the addition of Sorbitol Special can improve drying times compared to glycerol. Sorbitol Special can be added to formulations from 20% up to 50% to find the optimum level for drying time improvement. Standard Sorbitol Special can be blended with glycerol to reduce or remove incompatibilities caused by glycerol alone. Grade A-810 is a pre-blended mixture of 50% Sorbitol Special plasticizer and 50% glycerin USP which can be used for general applications. This convenient blend reduces cost in use and adds the drying benefits of Sorbitol Special.

2.3 I have gone through the Safety Data Sheet submitted by the applicant. Relevant extract is reproduced as under:



SPI Pharma **SORBITOL SPECIAL™ MDF 85, Sorbitol Sorbitan Solution, NF**
Safety Data Sheet

according to Regulation (EC) No. 453/2010

Revision date: 01/05/2015

Supersedes: 18/01/2011

Version: 3.0

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form	Mixture
Trade name	SORBITOL SPECIAL™ MDF 85, Sorbitol Sorbitan Solution, NF
SDS code	E-201
Product group	Trade product

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1. Relevant identified uses

Use of the substance/preparation: Food/pharmaceutical products.

1.2.2. Uses advised against

No additional information available.

1.3. Details of the supplier of the safety data sheet

SPI Pharma
Chemin du Vallon du Maire
Septemes - France
T 33 4 91 96 36 00 - F 33 4 91 65 39 03
CBlasquez@spipharma.com

3. Nhava Sheva-I, JNCH which is the concerned jurisdictional Customs Commissionerate has responded to this application vide letter dated 02.11.2023 and the same is reproduced as under:

As per Customs Tariff Act, 1975, the import of Sorbitol Special MDF 85 is specifically classifiable under CTH 38246010 as 'Sorbitol other than that of sub-heading 2905 44: In aqueous solution'.

The Explanatory Notes given as below:

"That sorbitol in particular, (D-glucitol) syrups containing other polyols and in which the D-glucitol content normally ranges from 60% to 80% of the dry matter. Products of this kind are obtained by the hydrogenation of glucose syrups having a high disaccharide and polysaccharide content, without any separation process having taken place. They have the characteristic of being difficult to crystallise and are used in a wide variety of industries (e.g., food, cosmetics, pharmaceuticals, plastics, textiles). As such, it appears that the imported goods are appropriately and rightly classifiable under CTH 38246010".

Now as per the question of law or fact on which advance ruling has been sought of CAAR-I to get the clarity of HS code for Sorbitol Special MDF 85 as per Customs Tariff Act, 1975, it is submitted that as per Customs Tariff Act, 1975 and explanatory notes "Sorbitol Special MDF 85" are classified under CTH 38246010 subject to explanatory notes wherein it should be sorbitol in particular, (D-glucitol) syrups containing other polyols and in which the D-glucitol content normally ranges from 60% to 80% of the dry matter.



4. A personal hearing in the matter was conducted on 21.12.2023 in office of the CAAR, Mumbai. During the personal hearing representatives of the applicant M/s. Anshul Life Sciences, Shri. Sushil Kumar Pahade, Asstt. Gen. Manager, Shri Ramesh Poduvae, Gen. Manager and Mrs. Seema Trivedi, Sr. Gen. Manager reiterated their earlier written submissions made in the application to CAAR, Mumbai. Nobody attended the said personal hearing from the concerned jurisdictional Commissionerate i.e. NS-I, JNCH either personally or online. The said representatives, further, contended that their product/goods fall under CTI 3824 9900 and presented additional submission/rebuttal to the comments of NS-I, JNCH explaining the technical comparison of sorbitol solution and sorbitol sorbitan solution ((Sorbitol Special® MDF 85) and its description, manufacturing process and applications as follows:

► Sorbitol solution-

CAS NO: 50-70-4, Mol wt: 182.17

Description: Sorbitol Solution is an aqueous solution containing [NOTE-A split liner, deactivated with glass wool, is used.] not less than 64.0 percent of D- sorbitol. Sorbitol is a sugar alcohol, C₆H₁₄O₆ found in nature as the sweet constituent of many berries and fruits

Manufacturing Process: produced from starch by enzymatic hydrolysis and catalytic hydrogenation

Application: It has wide applications as a sweetener and humectant in cosmetology and sugar substitute in non cariogenic confectionery and as a carrier in Pharmaceutical oral Liquids

► Sorbitol Sorbitan Solution (Sorbitol Special® MDF 85)

CAS NO: 27299-12-3 and 50-70-4, Mol. Wt: 182.17 and 164.17

Description: Sorbitol Sorbitan Solution is an aqueous solution containing, on the anhydrous basis, not less than 25.0 percent of D-sorbitol (C₆H₁₄O₆) and not less than 15.0 percent of 1,4-sorbitan (C₆H₁₂O₅).

Manufacturing Process: multi-stage process involving an acid-catalyzed partial dehydration (anhydrization) of Sorbitol solution USP followed by co-processing with Sorbitan.

Application: It is plasticizers for Soft Gelatin Capsule. They enhance the capsule finish gloss for a premium appearance, help to prevent leakage, provide consistent pharmaceutical quality, and extend shelf life by maintaining a proper moisture balance within the capsule shell. It is not used as a sweetener or as a carrier.

5. The applicant, in furtherance of their earlier submissions, has submitted Additional Literature and Presentation with details of Sorbitol Sorbitan Solution and Sorbitol Solution (70%) for reference relevant extracts of which is reproduced as under:

Sorbitol Special MDF 85 is Sorbitol Sorbitan Solution which is partially hydrated Sorbitol solution. It is totally a different compound than Aqueous Sorbitol Solution which contains Sorbitol 70% in aqueous solution. Sorbitol Special MDF 85 contains nominally



34% of Sorbitol along with 1,4 Sorbitan at the nominal concentration of 28%. The manufacturing process is also different for both the products. Sorbitol Sorbitan Solution is manufactured by acid-catalyzed partial dehydration (anhydrization) of Sorbitol solution, whereas Sorbitol Solution is manufactured from starch by enzymatic hydrolysis and catalytic hydrogenation. Due to the presence of Sorbitan the properties and applications of Sorbitol Special MDF 85 completely differs from that of Sorbitol Solution. Sorbitol Special MDF 85 acts only as plasticizer in soft gel capsules, whereas Sorbitol solution acts as sweetener and as sugar substitute in Syrups. Sorbitol in Sorbitol Special MDF 85 is acting as a solubilizer for Sorbitan.

-The different grades of Sorbitol Special serve as a humectant and plasticizer in the capsule shell

- 1,4-sorbitan is a direct plasticizer (direct interaction with gelatin)

-Sorbitol is an indirect plasticizer (humectant - draws in water, prevents migration).

-Sorbitan prevents crystallization of sorbitol.

-Far less hygroscopic than glycerine.

Sorbitol Special and glycerine and a 50:50 combination was evaluated as plasticizers in capsules containing sunflower oil (model hydrophilic oil fill). The moisture level of the shell and the hardness development of the capsule with time was measured. Sorbitol Special plasticized capsules develop hardness significantly faster than glycerol. 50:50 combinations of glycerol and sorbitol special attain capsule hardness faster than glycerol alone. Sorbitol Special can be combined with glycerine to modulate the overall plasticizer content in the formulation. Assuming capsule hardness target of 20N, Sorbitol Special plasticized capsules reach drying endpoint at 56% of the time it takes for glycerine, which is significantly faster.

The formation of a soft capsule requires the use of a non-volatile plasticizer in addition of water to guarantee the mechanical stability. Sorbitol Special Plasticizers are engineered to counter-balance the stresses during processing and drying. For most fill types, Sorbitol Special Plasticizers can be used independently or with a glycerine system to reduce drying time.

Sorbitol Special MDF 85 provides a more shiny, robust and rich soft gel capsule than other grades of plasticizer. With a more appealing appearance desired by consumers, manufacturers will appreciate the thicker coating, yielding less leakage, and faster drying times. Sorbitol Special helps increase production efficiency and provide a more appealing appearance desired by consumers. The use of Sorbitol Special for certain PEG based fill formulations can shorten drying times by up to 45% compared to alternative sorbitol based systems.

Application of 1,4- Sorbitan Powder:

-used as a dietary supplement

-Helps to reduce cholesterol levels

-Improving digestion and aiding in weight loss.

-to reduce inflammation.

-Improve skin health.

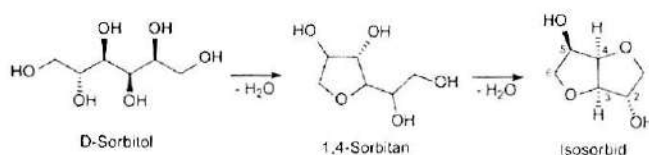
-Boost the immune system.



-reduce the risk of certain types of cancer and heart diseases.

Synthesis of Sorbitan

- Sorbitan is produced by the Sulphuric acid catalyzed dehydration of sorbitol by and is an intermediate in the conversion of sorbitol to isosorbide.
- The dehydration reaction usually produces sorbitan as a mixture of five- and six-membered cyclic ethers with the five-membered 1,4-anhydrosorbitol form being the dominant product.
- Sorbitan is produced selectively, if reaction conditions are carefully controlled.
- It is also available as white powder after recrystallisation from Solution.
- In Sorbitol Special, Sorbitan is not crystallized as it being used as a plasticizer it has to be dissolved again in any solvent
- The percentage of Sorbitol is 25.0-40.0 and Sorbitan is 26-30%



Sorbitol as a Soft-gel Plasticiser

• Advantages:

- Plasticizes mainly through indirect interactions through its hygroscopicity and also weakly through intermolecular interactions between the hydroxyl groups and the hydrophilic groups on gelatin or non-gelatin materials.
- Less hygroscopic, hydrophilic, and lower mobility than glycerin.
- Provides lower humidity susceptibility and gas permeability than glycerin.

• Disadvantages:

- Not a strong direct plasticizer.
- Highly prone to crystallization (blooming, blushing) even with glycerin.

Why Use Sorbitol Special as soft gel plasticizer-

Stable and efficient plasticizer

- Lower mobility in gel - lower migration into fill
- Less incompatibilities than glycerin

Significantly less hygroscopicity

- Low water retention - shorter drying time, lower gas permeability, preservation of functional fills
- Low susceptibility to water migration/permeability

Lower moisture uptake for hotter/moist climate zones

- Hotter/moist regional climate can cause higher oxygen permeability in the softgel
- Regional climate can also lead higher rates of diffusion

Three differentiated Sorbitol Special blends for formulation flexibility



- Investigating improved appearance
- Investigating faster drying time

Introduction of SPI Plasticizers Portfolio:

Chemical Component	USP/EP Specification	Sorbital Special Typical Levels	Sorbital Special MDF 85 Typical Levels
1,4- Sorbitan (dry base)	NLT 15%	21-27%	26-35%
Sorbital (dry base)	NLT 25%	60-67%	33-59%
Mannitol (dry base)	No specs	2-4%	1-6%
High Polychains	No specs	<1%	23-25%
Water	NMT 31.5%	Approx 23%	Approx 15%

The applicant has submitted the abstract about Sulfuric Acid-Catalyzed Dehydration of Sorbitol: Mechanistic Study on Preferential Formation of 1,4-Sorbitan published on 16/04.2015 (Bulletin of the Chemical Society of Japan) which is reproduced as follows: "1,4-Sorbitan is a precursor to environmentally benign surfactants, which can be produced from biomass via sorbitol. Currently, sulfuric acid-catalyzed dehydration of sorbitol is the most widely used route for industrial synthesis of 1,4-sorbitan. In this work, we have studied the mechanism of the sorbitol dehydration by sulfuric acid. Our results show that both thermodynamic and kinetic parameters play significant roles to determine the yield of 1,4-sorbitan. Sorbitol preferentially forms an adduct with sulfuric acid, thereby inhibiting the subsequent dehydration of 1,4-sorbitan to isosorbide. Furthermore, a reaction mechanism is proposed for the dehydration reaction, which involves an SN2 reaction on primary C_t of sorbitol attacked by OH of secondary C₄".

In manufacturing soft gelatin capsules, SPI pharma's grades of specialty plasticizers serve as a humectant and plasticizer for the capsule shell. They function to keep the shell soft and pliable, making it stable and easy to handle. These qualities result in a smooth, shiny, premium-finished appearance that is desirable to consumers. Sorbitol Special plasticizers are not soluble in PEG. They will not leach into the PEG-based fills of the capsule unlike standard plasticizers such as glycerin that are soluble in PEG. Using Sorbitol Special can result in a more stable shell, reducing failures from leaking capsules and increasing quality and output. Sorbitol Special can also inhibit blooming-white discoloration on the surface of the capsule. Left alone, PEG can react with gelatin plasticizers, allowing moisture to migrate away from the shell, causing the capsule to break down. Sorbitol Special plasticizers can help keep moisture well -adjusted to help prevent this failure.

6. I have taken into consideration all the materials placed on record in respect of the subject goods including the submissions made by the applicant during the course of personal hearing. I have gone through the response from the NS-I, JNCH and the rebuttal to that filed by the applicant. I therefore proceed to decide the present application regarding classification of Sorbitol Special MDF 85 on the basis of the information on record as well as the existing legal framework having bearing on the classification of the Sorbitol Special MDF 85 under the First Schedule of the Customs Tariff Act, 1975.



6.1 On plain reading of submissions presented by the applicant, at first it is clear that the product in question i.e. Sorbitol Special MDF 85 is a mixture of Sorbitol, Mannitol and 1, 4 Sorbitans and water as is stated by the applicant itself. So, mainly four components Sorbitol, Mannitol and 1, 4 Sorbitans and water are present in the product in question. Further, the applicant has also submitted a test/analysis report showing chemical composition of Sorbitol Sorbitan Solution NF Sorbitol Special MDF 85 reproduced in para 2.1 on page no. 2 *supra* and on plain reading of the same it is clear the Sorbitol Special MDF 85 contains 25 to 40% of Sorbitol along with 1,4 Sorbitan at the nominal concentration of 26 to 30% and 15 to 17% water and rest other components.

I have gone through the synthesis process of Sorbitan explained by the applicant and reproduced in para 5 *supra* and first and second point of which is that Sorbitan is produced by the Sulphuric acid catalysed dehydration of sorbitol and is an intermediate in the conversion of sorbitol to isosorbide. This dehydration reaction usually produces sorbitan as a mixture of five- and six-membered cyclic ethers with the five-membered 1,4-anhydrosorbitol form being the dominant product. This analysis clears that 1,4-Sorbitan is produced from Sorbitol. 1,4-sorbitan (C₆H₁₂O₅) is dehydrated derivative of D-sorbitol (C₆H₁₄O₆). It can be inferred by the above analysis that Sorbitol Special MDF 85 contains Sorbitol and its dehydrated derivative 1,4-Sorbitan nominally 60 to 70% altogether.

6.2 Now let me deliberate upon the applications of the both the products i.e. Sorbitol and 1,4-Sorbitan. The applicant has submitted that 1,4-Sorbitan is a direct plasticizer while Sorbitol is an indirect plasticizer. It is understood from the perusal of this submission that both Sorbitol and 1,4-Sorbitan are plasticizers. Hence, the contention of the applicant that due to the presence of Sorbitan the properties and applications of Sorbitol Special MDF 85 completely differs from that of Sorbitol Solution and Sorbitol Special MDF 85 acts only as plasticizer in soft gel capsules, whereas Sorbitol solution acts as sweetener and as sugar substitute in Syrups is not completely grounded in facts, as the applicant itself has mentioned that both Sorbitol and 1,4-Sorbitan are plasticizers, although, one is direct plasticizer and another is indirect plasticizer.

I have perused the additional literature and presentation with details of Sorbitol Sorbitan Solution and Sorbitol Solution submitted by the applicant wherein some graphs are displayed showing comparison among efficiency of three plasticizer systems i.e. SPI Pharma's Sorbitol Special, Sorbitol Special MDF 85 and a competitive system (Competitor P) in terms of hardness and drying time and it is amply clear that both sorbitol and Sorbitol Special MDF 85 are plasticizers, although, it is pertinent to mention that Sorbitol solution also acts as sweetener and as sugar substitute in Syrups, but, it does not disqualify Sorbitol from being a plasticizer. This contention of the applicant that Sorbitol in Sorbitol Special MDF 85 is acting as a solubilizer for Sorbitan shows only additional function/application of Sorbitol.

6.3 The applicant has submitted advantages and disadvantages of Sorbitol as a soft-gel plasticizer and why Sorbitol Special are to be used which is reproduced in para 5 *supra*. It is revealed from this analysis or comparison that both Sorbitol and Sorbitol special are plasticizers. Disadvantages of Sorbitol is that it is not a strong direct plasticizer and highly



prone to crystallization (blooming; blushing) even with glycerine. Sorbitan which is a dehydrated derivative of Sorbitol prevents crystallisation of sorbitol and sorbitan itself is a direct plasticizer.

6.4 Sorbitol Special MDF 85 is a Soft Gel plasticizer. Headword of the user guide cited by the applicant is "Sorbitol Special Soft Gel Plasticizer". Further, on perusal of this user guide it is observed that advantages of the product described as "Sorbitol sorbitan solution" of the recommended grades "*Sorbitol Special MDF 85*" is to improve drying time and for premium capsule appearance; that "*Sorbitol Special MDF 85*" is a grade of the "Sorbitol sorbitan solution". It is observed from the extract of the Safety Data Sheet reproduced in para 2.3 (supra) that the trade name of the product in question is "*SORBITOL SPECIAL MDF 85, Sorbitol Sorbitan Solution, NF*" and its relevant identified uses are in "Food/pharmaceutical products". The trade-name itself reveals that the main components of the product in question are Sorbitol and Sorbitan. Further, Sorbitan is a dehydrated derivative of Sorbitol and both Sorbitol and Sorbitan constitute around 65 to 70% part of the Sorbitol Special MDF 85.

From the above discussion, it can be logically inferred that Sorbitol Special MDF 85 has the essential characteristics of Sorbitol and classifying it in a residual entry of the Customs Tariff Act, 1975 would be completely disregarding the General Interpretation Rules.

6.5 Sorbitol, less commonly known as glucitol, is sugar alcohol with a sweet taste which the human body metabolizes slowly. It can be obtained by reduction of glucose, which changes the converted aldehyde group (-CHO) to a primary alcohol group (-CH₂OH). Most sorbitol is made from potato starch but it is also found in nature, for example in apples, pears, peaches, and prunes. It is converted to fructose by sorbitol-6-phosphate 2-dehydrogenase. *Sorbitol is an isomer of mannitol, another sugar alcohol*; the two differ only in the orientation of the hydroxyl group on carbon 2. While similar, the two sugar alcohols have very different sources in nature, melting points, and uses. As an over-the-counter drug, sorbitol is used as a laxative to treat constipation.

7. In view of the above findings, now let me delve into the Heading 2905 and 3824 to pass the advance ruling on the question of classification of Sorbitol Special MDF 85 for imports.

The classification of the goods under the Customs Tariff is governed by the principles as enumerated in the General Rules of Interpretation ('GRI') set out in the First Schedule to the Customs Tariff Act, 1975 ('Tariff'). *As per Rule 1 of the GRI, classification of the imported products shall be determined according to the terms of the headings and any relative Section or Chapter Notes and, provided such headings or Notes do not otherwise require, according to the remaining Rules of the GRI.* GRI 1 stipulates that the goods under consideration should be classified in accordance with the terms of the Headings and any relevant Section or Chapter Notes. These Section or Chapter Notes and Sub-Notes give detailed explanation as to the scope and ambit of the respective Sections and Chapters. These Notes have been given statutory backing and have been incorporated at the top of each Section / Chapter.



D-glucitol (Sorbitol) is covered under Heading 2905: Acyclic alcohols and their halogenated, sulphonated, nitrated or nitro-sated derivatives and more specifically -Other polyhydric alcohols: under CTI 2905 4400. Relevant extracts of the Explanatory notes of 2905 are reproduced as follows:

Acyclic alcohols are derivatives of acyclic hydrocarbons obtained by replacing one or more atoms of hydrogen by the hydroxyl group. They are oxygenated compounds which react with acids giving the compounds known as esters.

The alcohols may be primary (containing the characteristic group $-CH_2OH$), secondary (containing the characteristic group $>CHOH$) or tertiary (containing the characteristic group $>COH$).

This heading covers the acyclic alcohols described below and their halogenated, sulphonated, nitrated, nitrosated, sulphohalogenated, nitrohalogenated, nitrosulphonated, nitrosulphohalogenated or other compound derivatives (e.g., the monochlorohydrins of glycerol and of ethylene glycol). Aldehyde-bisulphite compounds and ketone-bisulphite compounds are classified as sulphonated derivatives of alcohols, e.g., acetaldehyde sodium bisulphite, formaldehyde sodium bisulphite, valeraldehyde sodium bisulphite and acetone sodium bisulphite. The heading also covers metal alcoholates of alcohols of this heading and of ethanol.

Under Heading 2905 Explanatory notes (C) DIOLS AND OTHER POLYHYDRIC ALCOHOLS (II) Other polyhydric alcohols are:

- (4) **Mannitol***. White crystalline powder or granules. Found in the vegetable kingdom (sap of the *Fraxinus ornus*); obtained by synthesis. Used as a mild laxative and in the manufacture of explosives (mannitol hexanitrate).
- (5) **D-glucitol (sorbitol)**. White crystalline powder which is hygroscopic. Used in perfumery, in the manufacture of ascorbic acid (used in medicine) and of surface-active agents, as a substitute for glycerol and as a humectant (i.e., moisture-conditioning agent).
- (6) **Pentanetriol, hexanetriol, etc.**

This heading excludes sorbitol of heading 38.24.

So, it is clear from these Explanatory notes that heading 2905 excludes sorbitol of heading 3824. Relevant extract of Heading 3824 is reproduced as under:

38.24 - Prepared binders for foundry moulds or cores; chemical products and preparations of the chemical or allied industries (including those consisting of mixtures of natural products), not elsewhere specified or included (+).

3824.10 - Prepared binders for foundry moulds or cores

3824.30 - Non-agglomerated metal carbides mixed together or with metallic binders

3824.40 - Prepared additives for cements, mortars or concretes

3824.50 - Non-refractory mortars and concretes

3824.60 - Sorbitol other than that of subheading 2905.44

....

....



3824.92 - - Polyglycol esters of methylphosphonic acid

3824.99 - - Other

Relevant extracts of the Explanatory notes of heading 3824 are reproduced as under:

Subject to the above conditions, the preparations and chemical products falling here include :

- (1) **Naphthenic acids** (by-products of the refining of certain petroleum oils and of certain oils obtained from bituminous minerals), **and their salts, other than the water-soluble naphthenates of heading 34.02, and salts of headings 28.43 to 28.46 and 28.52.** The heading covers, for example, calcium, barium, zinc, manganese, aluminium, cobalt, chromium, lead, etc., naphthenates, some of which are used for the preparation of driers or additives for mineral oils, and copper naphthenate used for the preparation of fungicides.
- (2) **Non-agglomerated metal carbides** (tungsten carbide, molybdenum carbide, etc.) mixed together or with metallic binders (such as cobalt), for the manufacture of the tips or the like for tools of heading 82.09.
- (3) **Prepared additives for cements, mortars or concretes**, for example, anti-acid additives with a basis of sodium or potassium silicate and sodium or potassium fluorosilicate, and waterproofing preparations (whether or not containing soap), e.g., based on calcium oxide, fatty acids, etc.
- (4) **Non-refractory mortars and concretes.**
- (5) **Sorbitol other than that of heading 29.05.**

This category covers, in particular, sorbitol (D-glucitol) syrups containing other polyols and in which the D-glucitol content normally ranges from 60 % to 80 % of the dry matter. Products of this kind are obtained by the hydrogenation of glucose syrups having a high disaccharide and polysaccharide content, without any separation process having taken place. They have the characteristic of being difficult to crystallise and are used in a wide variety of industries (e.g., food, cosmetics, pharmaceuticals, plastics, textiles).

Sorbitol meeting the requirements of Note 1 to Chapter 29 is classified in heading 29.05. Sorbitol of this kind is usually obtained by the hydrogenation of glucose or invert sugar.

From the above, it is observed that Sorbitol covered under heading 3824 is sorbitol (D-glucitol) syrups containing other polyols and in which the D-glucitol content normally ranges from 60% to 80% of the dry matter. Sorbitol Special MDF 85 contains Sorbitol and its dehydrated derivative 1,4-Sorbitan nominally 60 to 70% altogether. Further, from the chemical composition of Sorbitol Sorbitan Solution NF Sorbitol Special MDF 85 issued by SPI Pharma in the name of the applicant M/s. Anshul Life Sciences which is reproduced in para 2.1 (*supra*), it is observed that the product in question i.e. Sorbitol Special MDF 85 also contains Mannitol which is a polyol. D-glucitol is obtained by the hydrogenation of glucose. Further condition of Explanatory Note of 3824 is that heading 3824 covers the Sorbitol which have the characteristic of being difficult to crystallise and are used in a wide variety of industries (e.g. food, cosmetics, pharmaceuticals, plastics, textiles). Applicant has submitted that Sorbitan prevents crystallisation of sorbitol and Sorbitol Special MDF 85 will be used soft gel plasticizer which enhance the capsule finish gloss for a premium appearance, help to prevent leakage, provide consistent pharmaceutical quality, and extend shelf life by



maintaining a proper moisture balance within the capsule shell. Hence, by virtue of this submission of the applicant this condition of Explanatory Note that Sorbitol of heading 3824 are used in a wide variety of industries (e.g. food, cosmetics, pharmaceuticals, plastics, textiles) is satisfied as the product in question i.e. Sorbitol Special MDF 85 is used in pharmaceutical industries.

8. In the case of Commissioner of Central Excise Versus Wockhardt Life Sciences Ltd. {2012 (277) E.L.T. 299 (S.C.)}, it was held that "*Classification of goods – Determination of – it cannot be under residuary entry in presence of specific entry, even if it requires product to be understood in technical sense – Residuary entry can be taken refuge of only in absence of specific entry*".

In the case of Western India Plywoods Ltd. Versus Collector of Customs, Cochin {2005 (188) E.L.T. 365 (S.C.)} it was held that "*Classification of goods-application of residuary entry to be made with extreme caution, being attracted only when no other provision expressly or by necessary implication applies to goods in question*".

9. General Interpretation Rule 3: Where any article is classifiable under two or more headings –

(a) In case of where an article is classifiable under two or more headings, the article should be classified under specific heading instead of general heading.

(b) Mixture, composite goods consisting of different materials or made up of different components cannot be classified by referring rule 3(a). However, it should be classified as if it consists of the material or component which gives them their essential character.

The applicant has submitted that Sorbitol Special MDF 85 is a mixture of Sorbitol, Mannitol and 1, 4 Sorbitans and water. The trade-name itself reveals that the main components of the product in question are Sorbitol and Sorbitan. Further, Sorbitan is a dehydrated derivative of Sorbitol and both Sorbitol and Sorbitan constitute around 65 to 70% part of the Sorbitol Special MDF 85. it can be logically inferred that Sorbitol Special MDF 85 has the essential characteristics of Sorbitol and classifying it in the residual entry as claimed by the applicant under 3824 9900 is not in consonance with principle of General Interpretation Rule 3(a) as there are specific headings 2905 4400 and 3824 6010 available for Sorbitol under the First Schedule to the Customs Tariff Act, 1975. By virtue of the Explanatory Note (B)(5) to the heading 3824 and analysis thereof in para 7 (supra), it is amply clear the product in question i.e. Sorbitol Special MDF 85 satisfy the conditions of Explanatory Note (B)(5) to the heading 3824 to cover this product under heading 3824. Further, the applicant has submitted that Sorbitol Special MDF 85 contains around 15% water and also from the perusal of Section 9 of the Safety Data Sheet i.e. about Physical and chemical properties of Sorbitol Special MDF 85 it is clear that its physical state is 'Liquid' and its appearance is 'clear, viscous liquid'. So, by this analysis Sorbitol Special MDF 85 cannot be classified under CTI 3824 6090.



10. On the basis of foregoing discussions and findings, I reach to the conclusion that "Sorbitol Special MDF 85", (mixtures of Sorbitol, Mannitol and 1, 4 Sorbitans and water) merits classification under Custom Tariff Heading 3824, specifically under CTI 3824 6010 "sorbitol other than that of sub-heading 2905 44: In aqueous solution" of Chapter 38 of the First Schedule of the Customs Tariff Act, 1975, and I rule accordingly.

Prabhat Kamal Rameshwaram
9/12/24

(PRABIAT KAMAL RAMESHWARAM)

Customs Authority for Advance Rulings,
Mumbai.

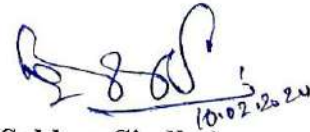


F. No. CAAR/CUS/APPL/67/2023-O/o Commr-CAAR-Mumbai

Dated:

This copy is certified to be a true copy of the ruling and is sent to: -

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