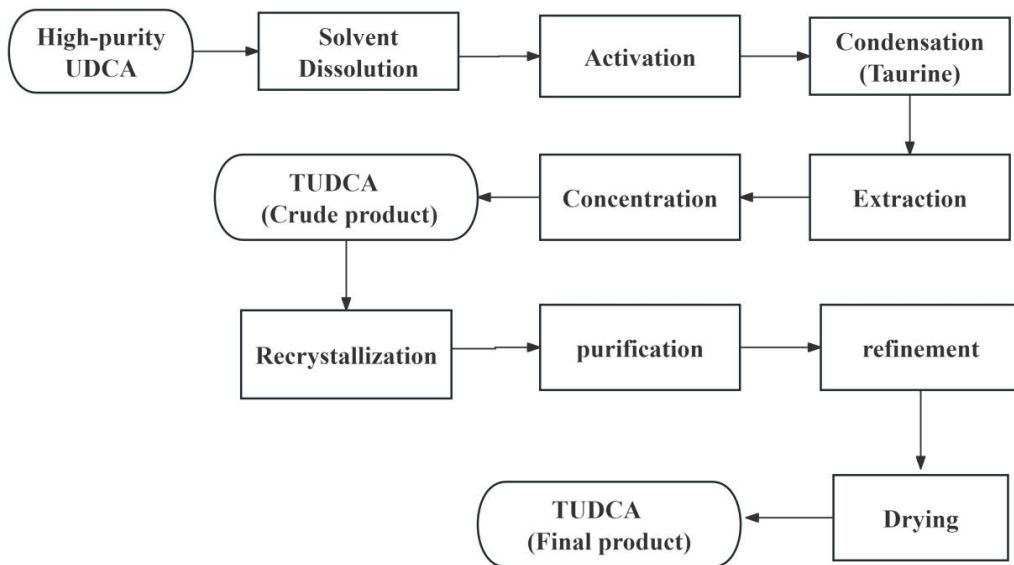


Technical Data Sheet

Product Name		Tauroursodeoxycholic Acid (TUDCA)	
CAS No.	14605-22-2	Molecular Formula	C ₂₆ H ₄₅ NO ₆ S
Molecular Weight	499.7	Ref. standard	In-house
Packaging	25KG/Drum	Origin	China
Solubility	Dissolve in methanol, in ethanol, in water. Donot dissolve in acetone.		
Compliance	Pharmacopoeia Grade		
Brief Introduction	Tauroursodeoxycholic acid (TUDCA) is a naturally occurring bile acid derivative, widely used in pharmaceutical and biochemical fields.		
Item		Specification	Method
Content			
Assay(Tauroursodeoxy cholic Acid)		≥98.0%	HPLC (CP2020-04-0512)
Other ingredients	Ursodeoxycholic Acid	≤0.5%	HPLC (CP2020-04-0512)
	Taurochenodeoxycholic Acid	≤0.5%	HPLC (CP2020-04-0512)
	Other Impurity	≤0.5%	HPLC (CP2020-04-0512)
Typical Analysis			
Appearance		White Crystal Powder	Visual
Particle Size		90% pass 80 Mesh	80 Mesh Sieve
Specifies rotation		+41 °——+47 °	CP2020-04-0621
Identification		Consistent with the standard product	Infrared(CP2020-04-0402)
Loss on Drying		≤3.0%	CP2020-04-0832-1
PH(2% solution)		7.5 ~ 8.5	CP2020-04-0631
Sulphated Ash		≤0.1%	CP2020-04-0841
*Heavy Metal			
Lead (Pb)		≤1.0ppm	GB/T 5009.12
Arsenic (As)		≤1.0ppm	GB/T 5009.11
Cadmium(Cd)		≤1.0ppm	GB/T 5009.15
Mercury (Hg)		≤0.1ppm	GB/T 5009.17
*Microorganism			
Total numbers of Colony		≤1000 cfu/g	GB/T 4789.2
Yeast&Mold		≤100 cfu/g	GB/T 4789.15
E.Coil		≤3 MPN/g	GB/T4789.38
Staphylococcus aureus		Absent/ 1 g	GB/T 4789.10

Item	Specification	Method
Salmonella	Absent/ 25g	GB/T 4789.4
Storage	Store in sealed containers at cool & dry place. Protect from light, moisture, and pest infestation	
Shelflife	24 months if store under the conditions above and stay in original packaging.	
Remark: The items with * are tested periodically.		

Flow Chart (Simplified)



2.Origin & Ingredient			
Country of Origin: China		Origin Statement: available <input checked="" type="checkbox"/>	
Material Type <input type="checkbox"/>		Pure material <input checked="" type="checkbox"/> Compound material <input type="checkbox"/>	
Synthetic	<input checked="" type="checkbox"/>	Starting material:UDCA	Origin: China
Biotechnological Processing	<input type="checkbox"/> Catalysis By Enzymes	Name of Enzyme: / Sources of Enzymes : /	
	<input type="checkbox"/> Fermentation	Source of Medium: / Strain: /	
Botanical Origin	Botanical name:	/	
	Part used:	/	
	Wild or cultivated :	/	
	Country of origin:	/	
	Solvent used :	/	

3.Nutrition Data	
Nutritional Composition	<input checked="" type="checkbox"/> Per 100g <input type="checkbox"/> Per Serving
<input type="checkbox"/> Energy (kJ) <input checked="" type="checkbox"/> Energy (kcal)	Not nutritionally significant at typical use levels.
Fat (g)	0
Carbohydrates (g)	0
Protein (g)	0
Remarks: Nutrition Data Are Obtained By 3 rd Party Lab; Tested on A Yearly Basis	

4. Non-GMO Declaration		
Statement	Complies	Does Not Comply
The product does not contain or consist of GMO	<input checked="" type="checkbox"/>	<input type="checkbox"/>
The product is not produced from GMO or does not contain ingredients produced from GMO (irrespective of whether there is NDA or protein of GM origin in the final production)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
This product is not produced by means of GM microorganism including precursor substances, e.g., with GMOs or Genetically Modified microorganisms processing aids (bacteria, yeast).	<input checked="" type="checkbox"/>	<input type="checkbox"/>
This product is not produced with the help of enzymes, which were obtained from GMOs	<input checked="" type="checkbox"/>	<input type="checkbox"/>
The product contains no ingredients from animals produced with feed from genetically modified crops	<input type="checkbox"/>	<input checked="" type="checkbox"/>
With respect to GMO labelling and traceability requirements under Regulations (EC) No 1829/2003 and 1830/2003, the product does not require GMO labelling based on the manufacturing process.	<input checked="" type="checkbox"/>	<input type="checkbox"/>

5. Allergen Declaration

We have carefully reviewed this product according to **EU Regulation 1169/2011** and its amendments and confirm the following:

Allergen	Direct incorporation (base raw material or derivative)	Cross-contamination on production line	Cross-contamination in production workshop	Cross-contamination in production factory
Cereals containing gluten (1)	No	No	No	No
Crustaceans and products thereof	No	No	No	No
Eggs and products thereof	No	No	No	No
Fish and products thereof (2)	No	No	No	No
Peanuts and products thereof	No	No	No	No
Soybeans and products thereof (3)	No	No	No	No
Milk and products thereof (including lactose) (4)	No	No	No	No
Nuts (5) or products thereof	No	No	No	No
Celery and products thereof	No	No	No	No
Mustard and products thereof	No	No	No	No
Sesame seeds and product thereof	No	No	No	No
Sulphur dioxide and sulphites at concentrations of more than 10mg/kg or 10 mg/l expressed as SO ₂	No	No	No	No
Lupines and products thereof	No	No	No	No
Mollusc and product thereof	No	No	No	No

Notes / Exceptions:

Cereals which contain gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridised strains) except: wheat-based glucose syrups including dextrose, wheat-based maltodextrins, glucose syrups based on barley, cereals used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages;

Except: fish gelatine used as carrier for vitamin or carotenoid preparations, fish gelatine or Isinglass used as fining agent in beer and wine.

Except fully refined soybean oil and fat, natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D-alpha tocopherol acetate, natural D-alpha tocopherol succinate from soybean sources; vegetable oils derived phytosterols and phytosterol esters from soybean sources; plant stanol ester produced from vegetable oil sterols from soybean sources.

Except when used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages, lactitol.

Almond (*Amygdalus communis* L.) hazelnuts (*Corylus avellana*), walnut (*Juglans regia*), cashew (*Anacardium occidentale*), pecan nuts (*Carya illinoensis*), Brazil nut (*Bertholletia excelsa*), pistachio nut (*Pistacia vera*), macadamia nut and Queensland nut (*Macadamia terniflora*) and products thereof, except nuts used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages;

6. Non-Irradiation

(According to EU directive 1999/2/EC & 1999/3/EC)

This product has not been treated with ionising radiation	<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO
None of the raw materials we used for this product have been treated with ionising radiation.	<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO
We confirm above non-Irradiation statement is maintained and available	<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO

7. Nanomaterial

(According to EU Regulation (EU) No. 1363/2013)

This product does not contain any nanomaterials as defined in EU food legislation	<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO
This product has not been made with nanotechnology	<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO
We confirm above Nanomaterial statement is available	<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO

8. Residual Solvents

(According to UE Directive 2009/32 modified by (UE)2010/59; EP5.4; USP476; ICH Q3C(R7))

Typical processing aids may include acids, bases, and organic solvents as per validated manufacturing process.	<input checked="" type="checkbox"/> solvent used. <input type="checkbox"/> solvent not used
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We confirm that solvent residual in this product comply with:	<input checked="" type="checkbox"/> EP 7.0 <input checked="" type="checkbox"/> USP <476> <input checked="" type="checkbox"/> ICH Q3C(R7) <input checked="" type="checkbox"/> Directive 2010/59/EU <input type="checkbox"/> NA
We confirm that the solvent residual statement is maintained and available	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO

9. Pesticide Residual (According to EC 396/2005; EP07; USP <561>)	
This product is of vegetable origin	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO
We confirm that pesticide residues of this product comply with:	<input checked="" type="checkbox"/> EC 396/2005 <input checked="" type="checkbox"/> EP 07/2008 <input checked="" type="checkbox"/> USP<561> <input type="checkbox"/> N/A
We confirm that the pesticide residual statement is maintained and available	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO



10. BSE/TSE Information	
(According to EU No. 2019/319; EP general chapter 5.2.8)	
Cattle, sheep, goats, and other animals naturally susceptible to infection with transmissible spongiform encephalopathy (TSE) agents, or those susceptible to infection through the oral route (excluding humans and non-human primates), are defined as "BSE-relevant animal species." Pigs and birds, however, are not naturally susceptible to infection via the oral route and, therefore, are not considered TSE-relevant species. Similarly, dogs, rabbits, and fish are also not classified as TSE-relevant animal species.	
The product contains no ingredients of ruminant origin and no materials derived from or exposed to ruminants affected by or under quarantine for Transmissible Spongiform Encephalopathy (TSE) / Bovine Spongiform Encephalopathy (BSE).	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
In the manufacturing of this product, no raw or source materials and /or reagents used that is of animal origin (bovine, serum-albumin, enzymes, culture broths are used	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
Equipment, systems, or tools used for processing or storage do not come into contact with materials of animal origin	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
Purification may involve organic solvents; all residual solvents are controlled to meet applicable guidelines (e.g., ICH Q3C)	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
We confirm this product complies with:	<input checked="" type="checkbox"/> EU legislation 999/2001 <input checked="" type="checkbox"/> EP General Chapter 5.2.8
We confirm that the BSE/TSE statement is maintained and available	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO

11. WADA Statement
We confirm that none of the products manufactured or stored within our facility contain any prohormones, stimulants, steroids, or other substances listed on the current WADA (World Anti - Doping Agency) Prohibited list.

12. ETO Free Statement
We hereby confirm that ethylene oxide (ETO), 2-chloroethanol, or any other chemical sterilizing agents are not used during the manufacturing, storage, or transportation of this products.

13. Other Statements	
We confirm Nitrates of this product complies with EU No 1258/2011	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
We confirm that mycotoxins / aflatoxins in this product complies with EU Regulation No 165/2010	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA



We confirm that 3-MCPD in this product complies with EU Regulation No. 2020/1322	<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> NA
We confirm that pyrrolizidine alkaloids in this product comply with Regulation (EU) No. 2020/2040	<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> NA

This document is intended to provide technical and regulatory support information for customers and quality assurance purposes. It does not constitute a regulatory approval or authorization by any authority