

LIFE SCIENCES

# TRIS AMINO™ and TRIS Derivatives

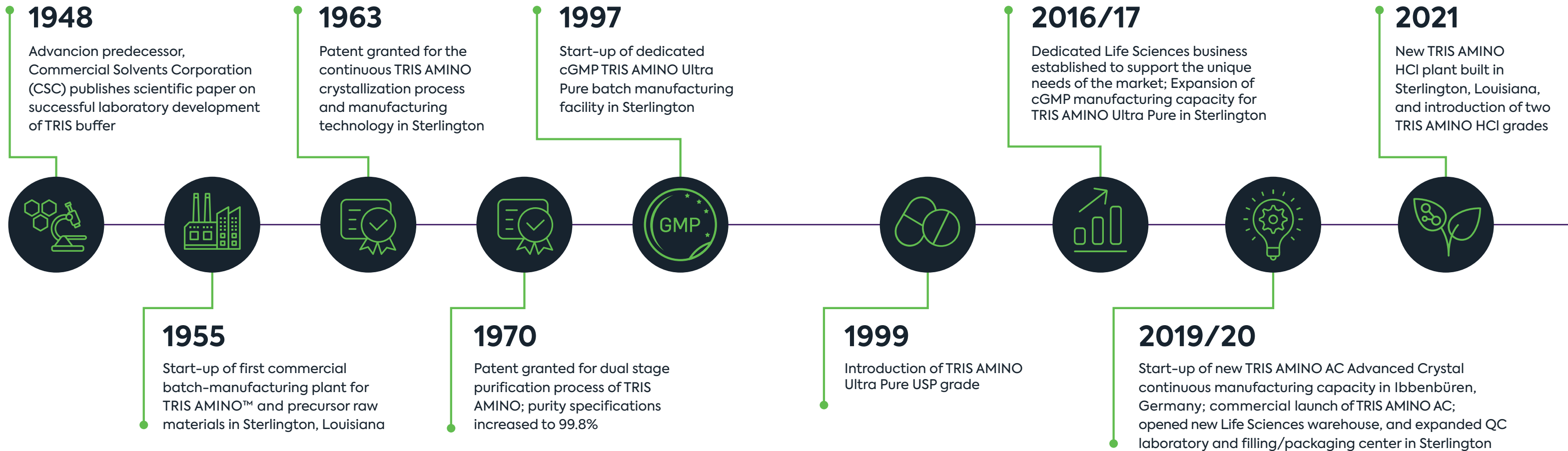
Selection Guide

## We Invent ... It's in our DNA

As the original inventor of the Tromethamine molecule more than 70 years ago, we have proudly built our TRIS AMINO™ brand, representing a strong history of quality, reliability and innovation in the TRIS buffer product space. Developing the right products for R&D, scale-up, and production is not only an ongoing commitment ... **It's what we do.**

## We Innovate ... To Address Industry Challenges with TRIS AMINO™ AC Advanced Crystal

Advancion continues to enhance its capabilities through new innovations in process manufacturing. Our next generation TRIS AMINO Advanced Crystals (AC) are less prone to clumping and hardness – without any change to the molecule itself – and may provide critical operational benefits when it comes to handling and preparation.



## We Invest ... To Provide a Secure, Sustainable Supply

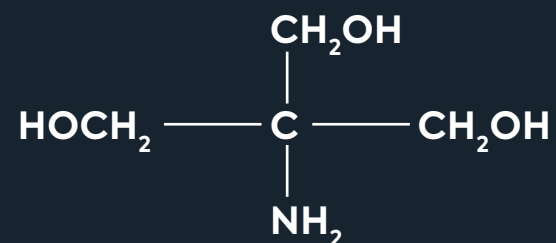
As the world's only fully integrated manufacturer of TRIS and TRIS Hydrochloride buffers, we are uniquely positioned to offer the most transparent and secure supply of these and other essential bioprocessing ingredients. To support our commitment to the Life Sciences market, we have made significant investments in capacity expansion, adding new manufacturing capabilities and strengthening our regulatory support. This includes the completion of a state-of-the-art TRIS AMINO manufacturing plant in Ibbenbüren, Germany, as well as a new TRIS AMINO HCl plant in Sterlington, Louisiana. Both facilities operate under our single Global Quality Management System, and are strategically located in the U.S. and Europe to provide efficient distribution of Advancion products to all regions of the globe.

## Designed with the Highest Standards in Mind, our Two Manufacturing Facilities are Audit-Ready and Offer:

- Adheres to current IPEC guidelines for cGMP compliant manufacturing of excipients
- ISO 9001: 2015 certification
- Automated in-process monitoring and facility control system
- In-house testing utilizing validated analytical methods
- Elemental impurity risk assessment using ICP-MS technology
- Comprehensive validation documentation
- State-of-the-art filling and packaging suites for Life Sciences products

# TRIS AMINO™

(tromethamine, trometamol) is a widely known excipient and processing buffer used in the purification of biological molecules. In addition to providing mild alkalinity for buffering at physiological pH levels, TRIS AMINO offers a number of advantages to bioprocessors, including aiding in chemical stabilization in aqueous formulations and exhibiting minimal salt effects. All grades of TRIS AMINO are GMO-free and BSE/TSE-free.

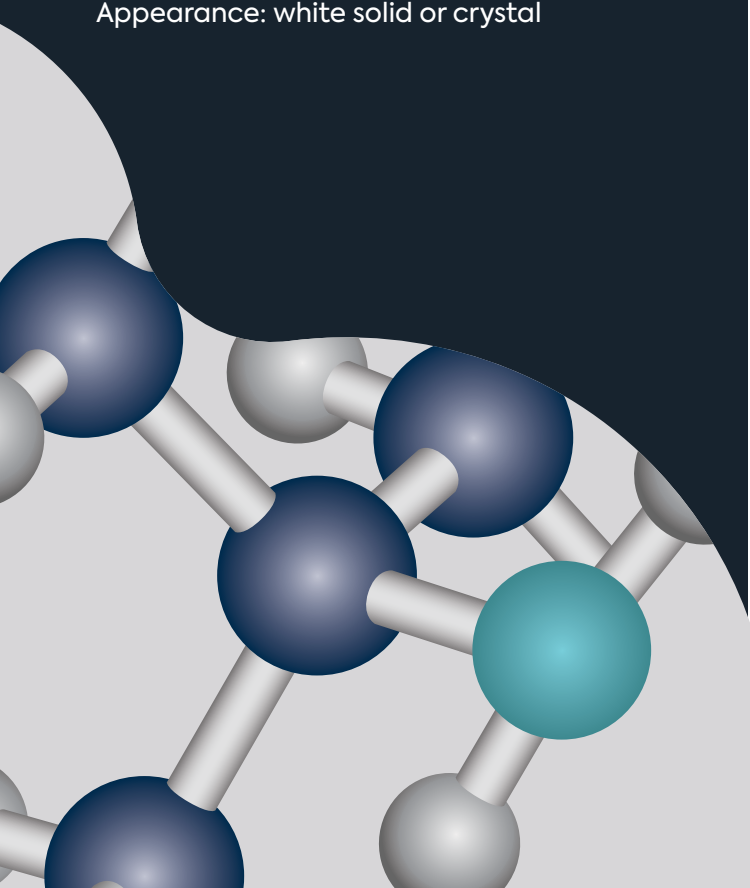


TRIS AMINO tromethamine

CAS No.: 77-86-1

Molecular weight: 121.14

Appearance: white solid or crystal



## TRIS AMINO Buffers And Reagents

|                     | INDUSTRIAL SERIES  | BUFFER SERIES  |  |   | ULTRA PURE SERIES  |   |
|---------------------|--|--|--|---|--|---|
|                     | Ideal for industrial chemical applications and basic R&D.              | Manufactured under ISO with process controls and monitoring in a non-cGMP environment. Buffer grades are ideal for applications where regulatory requirements are less stringent and don't require a monograph. Two purity levels available. |  |   | Highest purity product manufactured under cGMP for use as a critical raw material in pharma or biopharmaceutical production. Meets monograph USP, EP, JPC, ChP testing specifications. Suitable for injectables. |   |
| Product             | Tech Grade   | TRIS AMINO Standard Buffer   | TRIS AMINO ACS Buffer  | TRIS AMINO AC Buffer  | TRIS AMINO Ultra Pure  | TRIS AMINO AC Ultra Pure  |
| Main Differentiator | 99.0% purity, industrial utility product with basic testing performed. | Cost effective buffer for lab and commercial applications requiring moderate purity.   | Tested in compliance with American Chemical Society (ACS) standards, and offers slightly higher purity in comparison to the standard buffer grade. | Advanced Crystal (AC) buffer has a unique morphology that significantly reduces caking making it less prone to clumping and hardness. | Highest purity with the most comprehensive testing. Complaint to cGMP with extensive quality documentation available.  | Identical to Ultra Pure quality and testing but with a unique morphology that significantly reduces caking making it less prone to clumping and hardness. |
| Purity              | 99.0 (titration)   | 99.3 (titration)   | 99.8 (GC)  | 99.8 (GC)   | 99.9 (titration and GC)  | 99.9 (titration and GC)   |
| Shelf Life (Years)  | 5  | 5  | 5  | 5   | 3  | 3   |
| CAS Number          | 77-86-1  | 77-86-1  | 77-86-1  | 77-86-1   | 77-86-1  | 77-86-1   |
| Molecular Weight    | 121.14   | 121.14   | 121.14   | 121.14  | 121.14   | 121.14  |
| Monographs          | None   | None   | ACS  | None  | USP, EP, JPC, ChP  | USP, EP, JPC, ChP   |
| Quality Systems     | ISO  | ISO  | ISO  | ISO   | ISO, IPEC, cGMP, select ICH Q7 principles*   | ISO, IPEC, cGMP, select ICH Q7 principles*  |

### Applications

|  |   |   |   |   |   |   |
|--|---|---|---|---|---|---|
| Industrial                                 | ● |   |   |   |   |   |
| Basic Research                             | ● | ● | ● | ● |   |   |
| Animal Health                              |   | ● | ● | ● |   |   |
| Diagnostics                                |   | ● | ● | ● | ● | ● |
| DNA/RNA Extraction & Purification          |   | ● | ● | ● | ● | ● |
| Electrophoresis / PCR                      |   | ● | ● | ● |   |   |
| Analytical Chromatography                  |   | ● | ● | ● |   |   |
| R&D Protein Purification                   |   | ● | ● | ● |   |   |
| Commercial Protein Purification            |   |   |   |   | ● | ● |
| Non-Sterile Excipient                      |   |   |   |   | ● | ● |
| API/Drug Substance Formulation             |   |   |   |   | ● | ● |
| Molecular Biology (IVF, Cell line Storage) |   |   |   |   | ● | ● |
| Blood Plasma Fractionation                 |   |   |   |   | ● | ● |

\* TRIS AMINO™ Ultra Pure multi-compendial grade product has an excipient registration number with the Chinese Center for Drug Evaluation (CDE). This registration number, F20190000165, can be utilized by customers in order to list Advancions' TRIS AMINO™ product in their regulatory filings with the CDE for new drug products or substances.

## TRIS Derivative Buffers and Reagents

### TRIS Derivative Series

TRIS derivatives are often used in conjunction with TRIS AMINO to adjust pH. They can be used in both upstream and downstream processing applications.

| Product                    | TRIS AMINO HCl   | TRIS AMINO HCl<br>Biologics Plus  | BIS-TRIS  |
|----------------------------|--|---|---|
| <b>Main Differentiator</b> | Highest purity product manufactured under ISO with standard testing available. | Highest purity product manufactured under ISO with ICPMS elemental impurity testing, and extensive** molecular biology and biologics testing. | Primarily used in protein and nucleic acid systems, BIS-TRIS is known to complex with various metals. |
| <b>Purity</b>              | 99.0   | 99.5  | 99.0  |
| <b>Shelf Life (Years)</b>  | 2  | 2   | 4   |
| <b>CAS Number</b>          | 1185-53-1  | 1185-53-1   | 6976-37-0   |
| <b>Molecular Weight</b>    | 157.60   | 157.60  | 209.24  |
| <b>Monograph</b>           | None   | None  | None  |
| <b>Quality Systems</b>     | ISO 9001:2015  | ISO 9001:2015, cGMP, IPEC, Select ICH principles  | ISO 9001:2015, Select ICH principles  |

\*\* Includes testing for biobuden, endotoxin, yeast and mold, DNase, RNase, Protease

# Discover Peace of Mind and Streamline Qualification for TRIS AMINO Products

We understand in order to mitigate risk and meet regulatory guidelines for commercial manufacturing, you need a highly reliable supply chain, access to documentation, and a collaborative approach to understand and address your company's unique compliance requirements.

That's why, as the world's only fully integrated manufacturer for TRIS AMINO, Advancion is uniquely positioned to offer a 100% traceable supply chain, with a clear line of sight back to raw materials — all of which are produced on-site to stringent specifications. This, combined with a single Global Quality Management System, means absolute confidence you can readily qualify material and have a secure, sustainable supply.

## Standard Qualification Documents

- Safety Data Sheets (SDS)
- Product Sales Specifications
- Certificate of Analysis (CoA)
- ISO 9001:2015 Certificate
- High Level Manufacturing Process Flow
- Regulatory Data Sheets\*
- Product Stability Data\*
- cGMP Statement of Conformance\*
- Excipient Information Packages\*
- Precedence of Product Use\*

\*Available for select products

## Did You Know?

Advancion also offers a comprehensive portfolio of high-quality chemistries from the world's leading producers through a qualified, traceable and integrated supply chain. Our single Quality Management System is applicable to all our biochemical, buffer and salt products, including:

- AMINO ACIDS AND DERIVATIVES
- VITAMINS AND NUCLEOTIDES
- BIOCHEMICALS AND BUFFERS
- INORGANIC SALTS

# Improve Your Productivity with our Customized Services and Capabilities

We provide dedicated support for bioprocessing, pharmaceutical and diagnostic applications. Through specialized testing, custom blending, or dosage-specific package quantities, Advancion can help optimize the cost and efficiency of your operations.



## PACKAGING

- Custom packaging
- Multiple container options
- IPEC-PQG compliance



## ANALYTICAL

- ISO 9001:2015 certified
- Customized in-house testing and advanced instrumentation (ICP-MS, GC)
- Adherence with IPEC and select cGLP principles



## WAREHOUSING

- Temperature monitored warehousing
- Adherence with IPEC and select cGMP principles



## PURCHASING

- Global sourcing capabilities
- Formalized supplier lifecycle management program
- Non-animal origin

## Product Stewardship

Through our investments in application and new product development, we have a deep understanding of where our chemistries are (and can potentially be) used to actively address global trends in Life Sciences, Beauty and Personal Care, and other essential industries to help make our lives healthier, and more sustainable and comfortable. To help ensure that Advancion products are not used in ways for which they are not intended, Advancion personnel will assist customers in dealing with environmental and product safety considerations. Before handling any of the products, obtain available product safety information including the Safety Data Sheet(s) and take the necessary steps to ensure safety of use. For assistance, product Safety Data Sheets, or other information, please visit [advancionsciences.com](http://advancionsciences.com) or contact us at [info@advancionsciences.com](mailto:info@advancionsciences.com)

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