Supplier Audit Checklist for Triazinamide in Agrochemical Intermediates

---

1. Introduction

This Supplier Audit Checklist is designed to ensure the quality, safety, and regulatory compliance of Triazinamide supplied for agrochemical intermediate manufacturing. Given the critical role of Triazinamide in downstream pesticide synthesis, rigorous supplier auditing is essential to mitigate risks related to product purity, batch consistency, and supply chain reliability. The primary objective of this audit is to evaluate the supplier's Quality Management System (QMS), manufacturing capabilities, and documentation practices to verify alignment with international agrochemical industry standards. The scope encompasses qualification, raw material control, manufacturing processes, product quality, storage, packaging, traceability, and corrective action management.

2. Supplier Qualification Review

Business and Production Licenses

- Verify the validity of the business license and confirm that the registered business scope explicitly includes the production of chemical intermediates or agrochemicals.
- Confirm possession of required environmental and safety permits specific to chemical manufacturing.

Agrochemical Intermediate Production Qualifications

- Review regulatory approvals or registrations relevant to Triazinamide or similar triazine derivatives.
- Verify compliance with local and international regulations governing pesticide intermediates.

Management System Certifications

- Confirm active ISO 9001 (Quality Management), ISO 14001 (Environmental Management), and OHSAS 18001/ISO 45001 (Occupational Health and Safety) certifications.
- Review the latest certification audit reports and any non-conformances identified.

Audit History and Validity

- Review previous audit reports, including internal and third-party assessments.
- Confirm the current audit cycle is within the approved validity period (typically 24–36 months).
- Assess the supplier's track record for addressing prior audit findings.

3. Raw Material Quality Audit

Source and Quality Control of Starting Materials

- Identify the source and grade of key starting materials (e.g., 2-amino-4-chloro-6-methyl-s-triazine).
- Review the supplier's qualification program for raw material vendors, including on-site audits or questionnaire assessments.

Certificate of Analysis (COA) Review for Raw Materials

- Verify that each batch of starting material is accompanied by a COA from the manufacturer.
- Confirm that COA parameters match the supplier's approved specifications.

Purity Standards and Impurity Limits

- Review established purity specifications and impurity profiles for starting materials.
- Ensure impurity limits are aligned with the impact on Triazinamide synthesis and final product quality.

Supplier Change Management

- Evaluate the supplier's change control procedure for raw material sources.
- Confirm that any change in starting material supplier or grade triggers a formal notification and requalification process.

4. Manufacturing Process Audit

Synthesis Route and Process Parameter Control

- Review the documented synthesis route for Triazinamide and confirm it matches the approved process.
- Verify that critical process parameters (temperature, pressure, reaction time, pH) are defined, monitored, and controlled.

Control Points for Key Process Steps

- Identify and assess control points for critical unit operations such as cyclization, purification, and crystallization.
- Confirm that in-process specifications are established for each critical step.

In-Process Control (IPC) Standards and Methods

- Review IPC testing methods and acceptance criteria.
- Verify that IPC testing is performed at defined intervals and results are documented.

Batch Record Completeness

- Sample batch production records (BPR) for completeness, accuracy, and timeliness.
- Confirm that all critical process parameters, IPC results, and operator verifications are recorded.

Cross-Contamination Prevention

- Assess cleaning validation procedures for shared equipment.
- Review segregation practices for different product campaigns to prevent cross-contamination.

5. Product Quality Audit

Finished Product Specifications

- Verify that Triazinamide specifications meet agreed standards (e.g., Assay ≥98%, Moisture ≤0.5%).
- Confirm specifications are documented and approved by both parties.

Related Substances and Impurity Profile Analysis

- Review HPLC/GC methods used for impurity profiling.
- Confirm that method validation or verification has been performed per ICH Q2 guidelines.

Residual Solvent Control

- Verify residual solvent testing by GC per ICH Q3C guidelines.
- Confirm that solvent limits are within acceptable thresholds.

Melting Point Determination

- Review melting point range specifications and testing procedures.
- Confirm consistency between batches and alignment with reference standards.

Packaging Identification and Batch Traceability

- Verify that each batch is uniquely identified with a batch number.
- Confirm that packaging labels include all required traceability information.

6. COA Review Checklist

Mandatory COA Parameters

- Confirm COA includes: Assay, Purity, Moisture, Melting Point, Residual Solvents, Heavy Metals, and Impurity Profile.

Test Method Standards

- Verify that test methods reference recognized standards (Pharmacopoeia, internal validated methods, or industry standards).
- Confirm method version and effective date are documented.

Comparison of Results vs. Specification Limits

- Review whether all reported results fall within approved specification limits.
- Flag any results approaching specification boundaries for trend analysis.

Out-of-Specification (OOS) Handling

- Review the supplier's OOS investigation procedure.

• Confirm that OOS events are properly investigated, documented, and resolved before batch release.

COA Authorization and Approval

• Verify that COAs are signed or electronically approved by authorized Quality Unit personnel.

• Confirm that COA issuance follows an approved document control procedure.

7. Storage Condition Verification

Storage Environment Requirements

• Confirm storage conditions (temperature, humidity, light protection) match product stability data.

• Verify that storage areas are designated, controlled, and monitored.

Packaging Integrity Inspection

• Inspect packaging for seal integrity, moisture barriers, and light protection.

• Confirm that packaging materials are compatible with Triazinamide.

Shelf Life and Retest Periods

• Review established shelf life or retest period based on stability data.

• Verify that inventory is managed on a FIFO (First-In, First-Out) basis.

Temperature and Humidity Monitoring Records

• Review continuous monitoring records for storage areas.

• Confirm that excursions are investigated and documented.

Non-Conforming Material Isolation

• Verify that rejected or quarantined materials are physically or electronically segregated.

• Review disposition procedures for non-conforming stock.

8. Packaging and Labeling Audit

Packaging Material Compatibility

- Confirm packaging materials have been evaluated for chemical compatibility with Triazinamide.
- Review packaging material specifications and supplier qualifications.

Label Information Completeness

- Verify labels include: Product Name, Batch Number, Manufacturing Date, Expiry/Retest Date, Storage Conditions, Net Weight, and Supplier Information.
- Confirm label content matches the approved label template.

Hazard Communication (If Applicable)

- Verify that GHS hazard labels and safety statements are applied if Triazinamide is classified as hazardous.
- Confirm that SDS is current and accessible.

Shipping Packaging and Protective Measures

- Assess outer packaging for adequate protection during transport.
- Verify that packaging meets regulatory requirements for chemical shipment.

9. Documentation and Traceability Audit

Batch Production Record (BPR) Completeness

- Review BPR for completeness, including all manufacturing, IPC, and packaging steps.
- Confirm that BPRs are reviewed and approved prior to batch release.

Deviation and Change Control Records

- Review deviation reports for impact assessment, root cause analysis, and CAPA linkage.
- Verify that all changes to process, equipment, or specifications follow formal change control.

Stability Study Data

- Review ongoing and completed stability studies for Triazinamide.

• Confirm that stability data supports shelf life and storage conditions.

Material Balance Calculations

• Verify material balance calculations for each batch.

• Investigate significant deviations from expected yield.

Traceability System (Raw Material to Finished Product)

• Confirm end-to-end traceability from starting materials through to finished goods.

• Verify that lot genealogy can be reconstructed within a defined timeframe.

10. Corrective and Preventive Actions (CAPA)

Classification of Audit Findings

• Categorize findings as Critical, Major, or Minor based on risk to product quality and patient/consumer safety.

• Apply consistent classification criteria across audits.

CAPA Development and Tracking

• Verify that CAPA plans include root cause, corrective action, preventive action, responsible party, and due date.

• Track CAPA progress through a centralized system.

Effectiveness Verification and Closure Criteria

• Confirm that CAPA effectiveness is verified through objective evidence.

• Close CAPA only after successful verification and management approval.

11. Summary and Recommendations

Audit Scorecard Template

Category	Weight (%)	Score (1–5)	Weighted Score	Comments
Supplier Qualification	10			
Raw Material Quality	15			
Manufacturing Process	20			
Product Quality	20			
COA Review	10			
Storage Conditions	5			
Packaging & Labeling	5			
Documentation &	10			

Traceability				
CAPA Management	5			
Total	**100**			

Supplier Rating Criteria

- A Grade (≥90): Approved supplier; standard reaudit cycle (24 months).
- B Grade (75–89): Conditionally approved; corrective actions required; reaudit within 12 months.
- C Grade (<75): Not approved; immediate corrective action plan required; reaudit within 6 months or disqualification.

Recommended Reaudit Frequency

- A Grade: Every 24 months.
- B Grade: Every 12 months.
- C Grade: Every 6 months until upgraded or disqualified.
- Trigger-based reaudit: Significant quality event, regulatory change, or major process change.