The Dow Chemical Company supplies various different Amines to numerous customers and distributors around the world, who in turn supply to their customers the product or products produced using these Amines.

European customers may have numerous manufacturing facilities and may sell their final products into regulated markets around the globe. These customers can be assured that Dow can supply the highest-quality Amines which these applications require.

This document answers the questions many customers frequently ask regarding Dow’s quality control system and is provided to customers in lieu of completing individual questionnaires.
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Purpose
Various Amine grades, manufactured by Dow, may be found in regulated markets such as the pharmaceutical, and food industries. The purpose of this document is to communicate the systems and procedures that Dow uses to ensure product quality and to protect it from adulteration during the manufacturing, storage and distribution of its Amine products.

Related Documents
1. Dow Ethanolamines Storage & Handling
2. Ethanolamines Brochure
3. Ethyleneamines Best Practice Manual
4. Ethyleneamines Brochure
5. Isopropanolamines (Basic Chemicals with Surfactants Prop. for Personal Care Products)
6. Toxicology Overview Isopropanolamines
7. Dow Operating Discipline Management System (ODMS)
8. Notification of Change Policy for the Pharmaceutical Industry
9. Dow’s Amines website
10. The Dow Chemical Company website
11. Amines Answer Center

Scope
This document refers only to the following manufacturing locations and products:

Plaquemine, LA (USA) - Dow Isopropanolamines
Seadrift, TX (USA) - Dow Ethanolamines
Taft, LA (USA) - Dow Ethanolamines & Dow Ethyleneamines
Terneuzen (NL) - Dow Ethyleneamines

Manufacturing Locations
All Dow production units operate following a common Quality Management System (ODMS). Amine quality from all Dow’s manufacturing sites meets or exceeds all the requirements listed in the relevant product sales specification.

ISO9001 Certification
All plants within the scope of this document are certified to ISO9001. Copies of the current certificate can be obtained from the Customer Interface Group.

Responsible Care
Responsible Care is a voluntary initiative within the global chemical industry to safely handle our products from inception in the research laboratory, through manufacture and distribution, to ultimate disposal, and to involve the public in our decision-making processes. While Responsible Care goes above and beyond what is legally required in most countries, we hold ourselves accountable by making Responsible Care a “condition of membership” in industry associations. Today, Responsible Care is taking leading chemical companies above and beyond their prior accomplishments, to achieve even higher standards of performance and generate greater value for their businesses.

In January 1999, Dow signed on to these more stringent Responsible Care Guiding Principles with other members of the U.S. American Chemistry Council (ACC). These Principles apply to Dow globally.
Sourcing
Dow makes every effort to source customers and terminals from the same location each time. However, in order to avoid outages due to manufacturing and logistics considerations, customers may from time to time receive product from another qualified manufacturing location.

Product Information and Quality Programs
Dow's Amine products covered in the scope of this document, find use in a wide variety of applications, including in the manufacture of herbicides, personal care products, pharmaceuticals, fabric softeners and a variety of other applications that specify adherence to quality standards.

Dow's Amine products are manufactured in Dow facilities in Terneuzen (NL), Seadrift (Tx) USA, Taft (La) USA and Plaquemine (La) USA under rigorous quality control and operational procedures documented in our Corporate Operating Discipline Management System (ODMS) to provide the quality and product reliability that customers require. However, it is the responsibility of the user of any Amines as a Direct or Indirect Food Additive to read and understand any applicable FDA regulations in Title 21 of the Code of Federal Regulations (21 CFR) to determine any limitations or restrictions on the proposed use. Furthermore, it is the responsibility of the user to determine that any such use is suitable, safe, and FDA-compliant.

Dow is sometimes asked about the use of Good Manufacturing Practice (GMP) for its manufacture and distribution of Amines. GMP’s are FDA, EC and compendial guidelines for ensuring that components used in food and pharmaceutical products are not adulterated or contaminated. Dow’s Amines Business in Europe has not implemented Good Manufacturing Practices (GMP) as defined in the IPEC guide “Good Manufacturing Practices Guide for Bulk Pharmaceutical Excipients” © 2001 for the manufacture of it’s Amine products in Terneuzen, Taft, Seadrift or Plaquemine. However, many aspects of GMP are addressed including dedicated facilities for production and product handling, a totally enclosed production process, extensive quality assurance testing, dedicated bulk storage and transportation label management and personnel qualification and training programs.

Shelf-Life
Dow has established a re-evaluation time (shelf life value) for its ethanolamine (MEA), DEA and TEA) and its Isopropanolamines (MIPA DIPA and TIPA). If properly stored and protected from contamination, the product, in unopened, Dow-packed drums, should be re-evaluated after 24 months in inventory to reconfirm fitness for use in the application. The corresponding time for product in bulk storage is 6 months. During these periods, some increase in color values may be expected and is natural.

Ethyleneamine products, in most cases when stored in sealed containers will be stable for a number of years. However, it is possible that undetected conditions can arise that will accelerate its decomposition. For bulk ethyleneamines, a shelf life of 6 months is recommended and for drums 24 months.

The test that is most sensitive to aging is color. For example, the APHA color of EDA is typically below 10 Pt.-Co; and the specification limit is currently 15 Pt-Co. If a sample shows a color reading much above this typical value, it is showing signs of deterioration and/or contamination. The color is caused by polymeric products of oxidation present at less than readily detectable levels. The purity and activity of EDA that has risen in color generally does not show measurable change unless the color has risen to levels of greater than 100 Pt-Co.
Kosher/Allergens/BSE & TSE
As manufactured, Dow’s Amine products do not contain any animal or plant derived products and, therefore, no allergens, glutens, sulfites nor genetically modified or BSE/TSE-risk materials.

Product Information: Physical Properties:
For further information on Dow’s Amines, please visit the Dow Amines website or Dow’s Answer Center.

Organization
As indicated in the following diagram, the quality function is independent of the production unit (see dotted blue lines) and is responsible for making decisions regarding raw material acceptance and product release, or process changes that might impact quality.
Process Description and Chemistry
In Europe, Dow produces Ethyleneamines by means of the Ethylenedichloride (EDC) based process. (Note: In the USA the Reductive Amination Process (RA) is used.)

1. \( \text{C}_2\text{H}_4\text{Cl}_2 + 2\text{NH}_3 \rightarrow \text{HCl} \cdot \text{H}_2\text{N} \cdot \text{C}_2\text{H}_2\text{N} \cdot \text{HCl} \) (EDC) (EDA Hydrochloride)
2. \( \text{EDC} + \text{EDA} \cdot \text{HCl} + \text{NH}_3 \rightarrow \text{DETA} \cdot \text{HCl} + \text{Higher EA's} + \text{NH}_4\text{Cl} \)
3. \( \text{EA} \cdot \text{HCl} 's + \text{NaOH} \rightarrow \text{EA} 's + \text{NaCl} + \text{H}_2\text{O} \)

The output of this process is a mixture of Ethyleneamines which are separated by distillation.

Ethanolamines and Isopropanolamines are produced by the ethoxylation / propoxylation respectively of Ammonia by the reactions:

\[
\text{NH}_3 + \text{C}_2\text{H}_4\text{O} \text{ (EO)} \rightarrow \text{H}_2\text{NCH}_2\text{CH}_2\text{OH} \quad \text{(MEA) or}
\]
\[
\text{or C}_3\text{H}_7\text{O} \text{ (PO)} \quad \text{H}_2\text{NCH}_2\text{CHOHCH}_3 \quad \text{(MIPA)}
\]
\[
\rightarrow \text{HN(CH}_2\text{CH}_2\text{OH)}_2 \quad \text{(DEA) or}
\]
\[
\text{HN(CH}_2\text{CHOHCH}_3)_2 \quad \text{(DIPA)}
\]
\[
\rightarrow \text{N(CH}_2\text{CH}_2\text{OH)}_3 \quad \text{(TEA) or}
\]
\[
\text{HN(CH}_2\text{CHOHCH}_3)_3 \quad \text{(TIPA)}
\]

Raw Materials
- Ethylenedichloride, Ethylene Oxide and Propylene Oxide are produced internally by Dow. However, there may be times when Dow needs to purchase these materials from other suppliers.
- Ammonia is purchased by Dow from reputable suppliers.
- The quality requirements for all raw materials are documented in raw material specifications.
- Dow’s Amines are not produced from, nor do they contain, any plant or animal products or by-products.
Process Control

Ethyleneamine and Ethanolamine production are both continuous, computer-controlled processes. Isopropanolamine production is a semi-continuous process shared with Alkyl Alkanolamine production. A stringent cleaning procedure is employed to protect against cross-contamination when changing from one product family to the other. Both are carried out in closed systems, isolated from the atmosphere. Process personnel control the production processes in accordance with daily operational schedules using computer process control (e.g. MOD V) and process data systems with documented operating conditions.

Job procedures are documented and include procedures for startup, routine operation, shutdown, maintenance, cleaning and return to service.

Production records, such as transfer log sheets and logbooks, are maintained according to defined record control procedures and retention schedules.

Plant process data is maintained within the process control computer systems; defined procedures exist for retention, backup, change authorization, and verification of data. Production data and inventories are maintained using SAP software. The process systems, including computer control systems are routinely validated.

Critical equipment has a documented preventive maintenance program. Records of all repairs and scheduled activities such as lubrication and calibrations are maintained electronically within a computer based Global Engineering and Maintenance Tracking System. The maintenance group consists of trained craftsmen, reliability engineers, technicians, technical specialists, activity coordinators and planners who are responsible for repairs, preventive maintenance, and regulatory inspections.

Laboratory

International standard test methods (ASTM) or internally validated methods (DOWM) are used to analyze processes and finished product samples. Calibration checks of critical laboratory equipment are routinely performed in accordance with written procedures and recorded in the Laboratory Information Management System. Equipment history and recommendations from the manufacturer determine the interval of these checks.

Out of calibration instruments are evaluated using a validity assessment program (root cause investigation). Records are maintained on each instrument to document performance, including maintenance and repairs.

Gas chromatograph results are controlled by a chromatography data system. All analytical results are recorded in the Laboratory Information Management System (LIMS). A re-validation process is in place for handling out-of-spec results, which includes root cause determination.

Sampling and Testing

Qualified and appropriately trained individuals complete all in-process and finished product testing.

In-process testing is conducted at defined locations and times according to a control plan, to ensure the process is operating within established process parameters.

Testing Protocols define what key variables shall be tested at defined intervals and sample points.

Retained samples In Europe, representative samples of each bulk delivery and every specific drummed lot, are maintained for three months and two years respectively.
**Product Release Procedures**

Product specifications are stored in the Global Product Data Information System (GPDIS). Analytical results from LIMS are automatically compared to specifications through a computer interface (see diagram below). Product is released as available for sale only when each test item is within specification.

![Diagram](image)

**Traceability**

Raw materials are analyzed for critical parameters and are identified by date & time of the sampling, and tank/drums numbers. Analysis results are recorded in LIMS.

Process auxiliary materials are positively identified before use and are identified as being released for use by a yellow tag label. Documentation takes place in LIMS and in the yellow tag book.

Final products (bulk) are identified by date & time of the sampling, sample point. Analysis results are recorded in LIMS.

Final products (drums) are identified using Dow standard & business defined lot numbering code.

The traceability is ensured by the following SAP records: Delivery Note, Order Number, day & time of loading, analysis in LIMS.

The entire system allows traceability of the product back to incoming raw materials, according to written procedures.

Lot assignment for drummed materials is based on the following numbering system:

<table>
<thead>
<tr>
<th>Year Code</th>
<th>Month Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>A = pre-1987</td>
<td>A = January</td>
</tr>
<tr>
<td>B = 1987</td>
<td>B = February</td>
</tr>
<tr>
<td>C = 1988</td>
<td>C = March</td>
</tr>
<tr>
<td>..........</td>
<td>..........</td>
</tr>
<tr>
<td>U = 2006</td>
<td>K = November</td>
</tr>
<tr>
<td>V - 2007</td>
<td>L = December</td>
</tr>
</tbody>
</table>
External Storage
Products imported by Dow may be stored at designated locations in Dow dedicated tanks which are maintained under strict conditions of cleanliness, temperature etc in accordance with Dow instructions. Product stored in these locations are quality controlled by a Dow selected qualified testing and verification company.

Change Control
Dow’s global Management of Change process establishes the minimum requirements for change control. An electronic tool (eMOC) is used to facilitate the process. A change is defined as “any alteration, whether temporary or permanent, that could affect the control or integrity of a process/system that goes beyond the established safe operating range, recipe, or proven raw material supplier.”

Proposed changes are reviewed by appropriate multiple functional groups. If it is determined that there is potential impact on quality issues, then the Business Quality Leader (BQL) or designee must approve any changes. The BQL role is independent of manufacturing.

Together with Management of Change, a Notification of Change protocol has been established, which defines whether a change is significant and the person responsible for customer notification.

Any of the following changes require notification to customers:
• A change in the limits of any property listed in the Requirements Section of the standard sales Specifications.
• A change in the limits of any property listed in the Requirements Section of the Customer Specifications.
• Discontinuation of an existing customer specification.

Any of the following changes in the manufacturing process will require a documented assessment to determine if any significant, product or process property, performance or regulatory status changes could be experienced by the customer. If potential changes are judged to affect product performance, process property, or regulatory status, customers will be notified prior to receiving the modified product:
• A change in raw material type or raw material supplier.
• A change in catalyst type or catalyst supplier.
• Addition, modification, or removal of major process equipment.
• Addition, modification, or removal of major process steps.
• Major modifications of process conditions.
• Substitution of out-sourced material.
• A geographic change of the restock terminal.
• Addition, modification, or removal of an additive from the formulation.
• Blending of material having unusual properties.
• A geographic change of the producing location for the product.

Training
Training is a vital part of the Operate Plant Work Process. Needs assessments are performed for each employee and a training matrix is developed based on the results. Course-work may include computer-aided training, In-Plant-Training (IPT) modules or formal classroom courses.
Customer Notice
Dow encourages its customers to review their applications of Dow products from the standpoint of human health and environmental quality. To help ensure that Dow products are used in ways for which they were intended or tested, Dow personnel are willing to assist in dealing with ecological and product safety considerations. Your Dow representative can arrange the proper contacts.

For Additional Information
For additional information, contact your Dow representative or the Dow Customer Information Group in your area:
U.S. and Canada: 1-800-441-4DOW (4369)
Mexico: 95-800-441-4369
Latin America: 989-832-1426
Europe: 32-3-450-2240
Pacific: 60-3-7958-3392
China: 800-600-0015
Brazil: 55-11-5188-9222

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