STANDARD MANUFACTURING PROCESS

I. PURPOSE

To define the content required in the Standard Manufacturing Process Document. To define responsibility for preparation and use of the document and the delegation of authority to amend process operating practices and variables. The primary purpose of the Standard Manufacturing Process is to document the technology of the process. It provides a source document for process control and is an integral part of the Process Control system described in the "Guideline for Management of Process Control," Procedure OM-19. This Procedure OM-13 describes the minimum requirements for the Standard Manufacturing Process Document, the must items for all divisional products. Detailed explanation of intent for each section plus a guide for preparation and supplemental considerations are included in the "Guide for Preparation of the Standard Manufacturing Process Document." Both the procedure and the guide should be considered when preparing, revising, using or evaluating the Standard Manufacturing Process Document.

II. POLICY

The Standard Manufacturing Process will exist for every established manufacturing operation.

The operating control limits and methods for process start-up will initially be described in the Tentative Process as prepared by Research in accordance with Procedure OR-17.

A Standard Manufacturing Process will be prepared to supersede the Tentative Process either within six months afer process demonstration is completed or within one year after initial operation, whichever occurs first. A Standard Manufacturing Process will supersede a Tentative Process only for a specific location. The Tentative Process with amendments holds for any other location until the Standard Manufacturing Process is prepared and approved for that location.

In no case will a manufacturing facility be intentionally operated under conditions other than as specified in the Tentative Process or Standard Manufacturing Process unless specifically described in an approved Tentative Amendment.

The Standard Manufacturing Process is to be used as the established process standard against which the process results will be compared. Therefore, the working copy must be maintained in a current condition. A complete revision will be made as required and needed. It will be reviewed, revised, re-approved and re-issued at least once every 24 months.

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III. RESPONSIBILITIES

A. Tentative Process

A Tentative Process is a comprehensive description of the chemical and physical requirements needed to prepare a product with minimal risks to safety, quality and economy. It may be used for sample preparation, pilot plant demonstration, economic evaluation, engineering design, interim and full-scale manufacture.

Research normally has the responsibility for the preparation of Tentative Processes (Organic Research Reference OR-17) though Manufacturing may also issue this type document under special circumstances. Review and approval of Tentative Processes will be by the appropriate Business Group Research Manager and Manufacturing Manager as well as by the Process Technology Section Manager or appropriate TSD Superintendent if their groups are involved.

The Manufacturing Manager assigned the product will have the responsibility of reviewing the Tentative Process before engineering design starts. He will have authority to accept or reject the process documentation for Manufacturing. He will include the Manufacturing Representative or General Manufacturing Superintendent in the evaluation of process adequacy when the plant location has been selected.

No process manufacturing operation will be initiated without an approved process unless special approval has been obtained from the Director of Manufacturing.

Research will be responsible for development of any process changes or amendments to the Tentative Process that may become necessary to accomplish the start-up objectives. Normally, this will be to manufacture a product that meets specifications and to achieve design rate and yields. The Manufacturing Manager involved will have the authority to approve the proposed changes for manufacturing until the Tentative Process has been incorporated into the Standard Manufacturing Process document.

B. Standard Manufacturing Process

A Standard Manufacturing Process is a written record

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of vital physical, chemical and chemical engineering data for a process, and basic operating conditions for a specific facility. For this purpose it supersedes the Tentative Process. It is prepared to maintain continuity in the process with the passage of time and to serve as a technical reference.

The individual revising an existing Standard Manufacturing Process Document will have the primary responsibility of comparing the revised document with the existing document and highlighting in writing any proposed deviation in operating method, range of variable or other pertinent process data. This synopsis of proposed changes may be forwarded with the proposed new Standard Manufacturing Process document as either a proposed Tentative Amendment or a summary report, whichever is appropriate.

The General Superintendent bears primary responsibility for adequacy and quality of the document and safe operation of the process. The General Superintendent, the appropriate Process Technology Research or Business Group Leader and Manufacturing Manager will each formally approve the Standard Manufacturing Process document and each subsequent revision.

Copies of either the new or revised Standard Manufacturing Process will be forwarded to the appropriate plant Production Superintendent and Supervisor, Technical Services Department Superintendent, Plant Research and Development Group Leader, Manufacturing Manager, Technical Production Specialist and Business Group Research Manager. These individuals or their delegates have the responsibility to review the document, evaluate its adequacy and quality, make constructive criticisms, challenge any recognized risk to safety or profitability and communicate their thinking to the Production Supervision.

Each Plant Manager (Guest Superintendent) will annually forward a status report to the Director of Manufacturing listing all Organic Division Processes at his location, the date of most recent revision of both the Standard Manufacturing Process and the Operating Instructions and the objectives for bringing the documents up to date where appropriate. This report is due by January 31 of each year.

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C. Process Amendments

The Standard Manufacturing Process will be maintained in a current condition by a formal amendment program.

The originator, usually a plant Technical Services Department Engineer or a Production Supervisor, will prepare the "Proposed Tentative Amendment" to the Standard Manufacturing Process. The document will be typed and follow the formal format as illustrated in Appendix G. The Production Supervisor will indicate his agreement and support of the change by endorsing the "Proposed Tentative Amendment."

Formal approval of all Tentative Amendments is required from the following:

Production Supervisor
Manufacturing Group Superintendent
Business Group Research Group Leader
Business Group R&D Manager
Research Safety Review Committee (3)
Manufacturing Manager

At the option of each individual plant other approvals may be required from TSD Superintendents, PR&D Group Leaders and Plant Managers.

The Manufacturing Group Superintendent bears responsibility as to the necessity for a formal Safety Review at the plant level.

In cases where the product involved is marketed or used by more than one Business Group, approval by both R&D Managers and Manufacturing Managers is required.

The Production Supervisor is responsible for directing the operations under the proposed conditions as specifically described in the Tentative Amendment.

If the amendment involves changes that are of an emergency nature, the Production Supervisor can use the telephone or teletype system to obtain authorization and advice, also the appropriate individuals involved. Such emergency actions must be approved by the Production General Superintendent and promptly followed by preparation and distribution of the formal amendment document.

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After demonstration of the Process Amendment and within six months of issuing the Tentative Amendment, the originator will summarize the results of the demonstration. He will notify the holders of the Standard Manufacturing Process that the amendment is to be either included as a portion of the process or rejected and state reasons for this action. The plant Standards Section usually serves as a cross-check on timing of finalization of amendments.

The Production Supervisor will be responsible for promptly incorporating demonstrated process changes into the Operating Instructions and any other departmental control tools or procedures.

Every individual involved is responsible for handling the Tentative Process, Standard Manufacturing Process and Amendments by "Company Confidential" methods.

IV. FORMAT AND PROCEDURE

The Standard Manufacturing Process is a written record of the procedure for manufacture of the product which sets forth the process conditions and control limits to be followed. It describes the effect of deviations from these conditions and limits regarding safety, quality and process performance. It also contains vital physical, chemical and engineering data. It is not intended to replace the Operating Instructions that are used for day-to-day operations of the process, but will serve as the basis for these operating instructions. It is prepared to maintain continuity and uniformity of the process with the passage of time and to serve as a technical reference.

Details for preparation of the various sections and points for individual consideration and decision are included in the Organic Chemicals Division "Guide for Preparation of the Standard Manufacturing Process Document."

A. Format

The following sections will be included in all Standard Manufacturing Processes:

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TITLE SHEET
DISTRIBUTION SHEET
TABLE OF CONTENTS
SECTION I: SYNOPSIS OF PROCESS
SECTION II: FLOW SHEETS
SECTION III: PROCESS IN DETAIL
SECTION IV: COMMENTS ON THE PROCESS
SECTION V: PROCESS CONTROL MANAGEMENT PROCEDURES
APPENDIX A: MATERIAL BALANCES
APPENDIX B: MATERIAL SPECIFICATIONS-ANALYTICAL PROCEDURES
APPENDIX C: PHYSICAL CONSTANTS
APPENDIX D: PACKAGING AND SHIPPING
APPENDIX E: SAFETY, TOXICITY DATA AND ACCIDENT REPORTS
APPENDIX F: ENVIRONMENTAL CONTROL AND WASTE DISPOSAL
APPENDIX G: FORM FOR TENTATIVE AMENDMENT TO STANDARD MANUFACTURING PROCESS

B. Content

1. Title Sheet

An example of a title sheet is condensed as follows:

MONSANTO COMPANY
ORGANIC CHEMICALS DIVISION

Standard Manufacturing Process for

Enter Product Name
Department Number

****

Prepared by: Approved by:

Supersedes: Issued: (Actual date - month and year)

Research Tentative Process (Number & Date)
Standard Manufacturing Process (Date)

Copy____ of _____

COMPANY CONFIDENTIAL INFORMATION

This process is the property of Monsanto Company and the recipient is responsible for its safe-keeping. It contains confidential information of Monsanto Company which must not be reproduced, revealed to unauthorized persons or sent outside

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the company without proper authorization. Either retain in a secure file or return to the Standards Department.

2. Distribution Sheet

Copies of all Standard Manufacturing Process documents will be distributed to:

Technical Information Center St. Louis Research	2 copies
Vital Record Center General Offices	1 copy
Business Group Research Manager	1 copy
Process Technology Research or Bus. Group Leader	1 copy
Organic Division Administration (Technical Production Manager)	1 copy
Plant General Superintendent of Production	1 copy
Technical Production Specialist (when appointed)	1 copy
Department Production Supervisor	1 copy
Plant Technical Service Department Superintendent	1 copy
Plant Process Research and Develcpment Section	1 copy
Plant Record Center (Master Copy)	1 copy
*Foreign Subsidiaries (Common Producers)	copies as needed

Note: Plant copies may be distributed at the discretion of the location Plant Manager.

*Common Product Agreements require that current copies will be exchanged between locations. Coordination of this work and distribution of the document is handled by the Manager of Foreign Manufacture.

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3. Table of Contents

List of each subject and subheading with the appropriate page number.

4. Section I - Synopsis of Process

A brief description of the process and balanced chemical equations for all important reactions. Equations should show structural formula, molecular weights, standard and theoretical yields.

5. Section II - Flow Sheets

A schematic diagram of equipment picturing flow of material should be included. Preferably the chart will be on one or more $8\frac{1}{2}$ x 11 inch sheets, and may be either block diagrams or pictorial. Other layouts are acceptable if necessary to achieve clarity. Separate sheets are recommended for each unit operation of a process. The flow sheets and comments on the process, Section IV, should compliment each other.

The flow sheet should show the major equipment commonly used in operation, including name and approximate concentration of important streams. Direction of flow and special appetencies should also be noted.

6. Section III - Process in Detail

A step-wise, comprehensive description of the operating process covering each phase of the operation. It should be sub-divided into major operating steps or unit operations and define the function of each step.

This section should provide a basic description of the chemistry of the process, including the names of the major chemicals and approximate concentration when appropriate.

7. Section IV - Comments on the Process

Process comments are based upon experience and should include the reason for the establishment of operating conditions and known conditions that must be followed. It includes critical points in the process and conditions contributing to safety, yield, rate or quality production difficulties, waste disposal, air and stream pollution, etc.

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The key process variables should be described, including the standard range, the normal operating range, the effect of the variable on the process and the effect of operating outside the standard range.

A listing should be included of time cycles and either batch weight or throughput rate whichever is appropriate. Bottlenecks in the process should be discussed, together with their limiting factors.

8. Section V - Process Control Management Procedures

Each Supervisor develops a system both formal and informal by which he monitors and controls the safety, quality, yield, rate and overall performance for the manufacture of a product. It is important that this system be documented for reference and use by future Supervisors, other personnel involved in the process and co-producers at other locations.

Each process step of the operation should be broken down to include the control methods and practices currently in use to manage that step. The control tools may be graphs, check lists, data tabulation, etc. Routine sampling points for control samples with expected limits should be described and timing on all control practices should be included. Also, a description of the place where data is taken for recognized key variables. The normal control ranges can be included for emphasis and despite redundancy from Section IV. The action to be taken if the variable is out of control limits and the significance of the particular control tool in use should be briefly described.

This system may also include a discipline of periodic checks for calibration of certain key instruments, meters, scales, or of the condition of specific equipment items that significantly effects control.

9. Appendix A - Material Balances

All known information concerning the material balance should be listed.

10. Appendix B - Material Specifications - Analytical Procedur

Current specification sheets for all raw materials, intermediates and finished goods should be included.

The analytical procedures for analyzing raw materials, intermediates and finished goods are an important part of process technology and control. The analytical methods used are approved as part of either the

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Tentative Process or Standard Manufacturing Process and any significant change in method should be handled through the Tentative Amendment Procedure described in Appendix G. A listing of the approved laboratory method number should be included with the specification sheets.

11. Appendix C - Physical Constants

Current physical constant data sheets for finished products, intermediates and major raw materials will be included.

12. Appendix D - Packaging and Shipping

Include type, sizes and special materials of construction of containers used. Any special requirements such as liners, inhibitors, stabilizers, etc. should be noted.

13. Appendix E - Safety, Toxicity Data and Accident Reports

A copy of the current "safety audit" should either be included in this appendix if such a document is available or a reference made to the document and where it is located. If the audit document duplicates other sections of the Standard Manufacturing Process document, the safety audit check list could be sufficient for the purposes of this Appendix.

All safety precautions and safety equipment required in manufacture of the product should be listed. Toxicity data plus references are required. Special characteristics of any raw material, intermediate or the product should be emphasized.

Chemicals that produce dermatitis or are lachrymators or other unique situations should be specifically mentioned including necessary precautions.

Reports of accidents which are process related should be synopsized.

14. Appendix F - Environmental Control and Waste Discharge

All significant atmospheric and stream effluents should be listed. The quantities at maximum rate of operation should be shown. The quantity of solids taken to the dum and special comments on tixicity or handling should be noted.

15. Appendix G - Form for Tentative Amendment to the Standard Manufacturing Process

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The following format will be used for both the "Proposed Tentative Amendments" and the Approved Tentative Amendment.

(Date) _____

Tentative Amendment No. _____

Standard Manufacturing Process for (Product) _____

Product Code No. _____

Issuance Date of Current Process Document _____

Title of Amendment: Give goal of modification

Suggested outline (not sub-heading) to follow in writing:

a. Present practice - brief description.

b. Suggested changes - magnitude of the change.

c. Justification - predicted end result.

d. History of change - new idea or a brief synopsis of any previous experience.

e. Source of data supporting the reasons for suggested change.

f. Safety.

g. Quality - process constraints - analytical methods involved.

h. Extent of demonstration for which approval is asked including:

1) Number of test batches.

2) Length of run.

3) Key variable involved, frequency of measuring and data to be taken for system variables which are expected to change during the test.

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4) Will the modification be continued indefinately if successful, or is it limited only to the limited series of batches proposed.

i. Criteria which will determine whether change is permanently adopted or rejected. (Example: if finished goods color does not rise above

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10 APHA, the experiment will be considered successful.)

j. Potential problems and preventative or contingent actions proposed. (Example: actions to be taken if the experiments fail, will off-quality product be blended off, a "hot" batch dumped, etc.)

Orginated by: _____

Endorsed by: _____
(Production Supervisor)

APPROVED BY:

_____ Mfg. Group Supt.

_____ Research Group Leader

_____ Research Manager

SAFETY REVIEW COMMITTEE

_____ _____

_____ _____

_____ _____

_____ _____
Manufacturing Manager

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