

PharmaSuite®



MATERIAL TRACKING PHASES

RELEASE 8.4 FUNCTIONAL REQUIREMENT SPECIFICATION

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Rockwell Software PharmaSuite® 8.4 - Functional Requirement Specification Material Tracking Phases

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Introduction

This document details the requirements of the functions implemented by the phases specific to material tracking. The phases are executed in the Production Execution Client of PharmaSuite.

Each requirement is composed of a name and a unique identifier (e.g. Instruction (SR0050.8.1)). If a requirement's meaning is for requirement grouping only, the identifier is appended by a plus sign (e.g. Process parameters (SR0050.8+)).

For requirements with **Framework capability** as identifier, see "Functional Requirement Specification Execution Framework" for their unique identifier, [A1] (page 45).

The revision history (page 47) lists the changes made to the document with PharmaSuite 8.3 as the comparison baseline. Changes related to a requirement are marked as "Editorial", "Update", "New", or "Deleted", changes to the additional context information are marked as "Context information-related".

Typographical Conventions

This documentation uses typographical conventions to enhance the readability of the information it presents. The following kinds of formatting indicate specific information:

Bold typeface

Designates user interface texts, such as

- window and dialog titles
- menu functions
- panel, tab, and button names
- box labels
- object properties and their values (e.g. status).

Monospaced typeface

Designates code examples.

Rockwell Software PharmaSuite® 8.4 - Functional Requirement Specification Material Tracking Phases

Identify Material Phase (SR0050+)

The **Identify material** phase allows an operator to identify material on sublot level for further processing.

Example use cases are:

- Identify material prior to dispensing The batch status of the materials must be **Released**. This material-specific requirement can be defined and corresponding violations can be tracked as exceptions.
- Identify material before mixing Only allocated batches are allowed to be utilized in the mixing process. An allocation check is specified in the phase. Identification of other batches can be tracked as exceptions.
- Unidentify material Material that has been identified is bound to an order step. As long as none of the previously identified sublots has been accounted, their identification can be revoked. This unbinds the material from the order step and makes it available for identification elsewhere.

Scanned or manually entered batches and sublots are checked against configurable settings

- status
- expiry date
- batch allocation

and built-in settings

- material is MFC-relevant
- sublot is produced for the current order step (only for intra materials)
- sublots are exclusively used by the current order.

The list of identified sublots with their quantities and material-related information is stored in the batch record, thereby becoming available for documentation purposes in the sub-report and batch report (page 6).

Anomalies that occur during processing are covered by the phase exception handling (page 14) (e.g. revoking an identification).

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After completion the phase displays the identified material with the following data in the Execution Window:

- batch and/or sublot identifiers
- planned quantity
- identified quantity.

The Navigator displays the ratio between identified quantity and planned quantity in percent and provides access to the post-completion exceptions.



Figure 1: Identify material during execution



Figure 2: Reactivated Identify material during execution with Comment to execution

Layout

The phase provides individual layouts for its representation during execution (page 4), in the Navigator (page 6), and in the sub-report (page 6).

Representation during Execution (SR0050.1+)

The representation during execution depends on the phase mode.

Preview mode (SR0050.1.3)

1. <Instruction text> (taken from **Instruction** (**SR0050.8.1**) process parameter (page 10))

- 2. Box for scanner input
- 3. List of materials available for identification (Table of materials (SR0050.1.2) (page 5))
 (taken from material input parameters (SR0050.6.1) (page 9))
- Material-related comment to execution (only visible if comment is maintained for the order step input)
- Enable button (disabled).
 The button is not visible in case a phase completion signature was configured during authoring.
- 6. **Confirm** button (disabled).

Active mode (SR0050.1.1)

- 1. <Instruction text> (taken from **Instruction (SR0050.8.1)** process parameter (page 10))
- 2. Box for scanner input
- 3. List of materials available for identification (Table of materials (SR0050.1.2) (page 5))
 (taken from material input parameters (SR0050.6.1) (page 9))
- 4. Material-related comment to execution (only visible if comment is maintained for the order step input)
- Enable button (unlocks the Confirm button).
 The button is not visible in case a phase completion signature was configured during authoring.
- 6. **Confirm** button.

Table of materials (SR0050.1.2)

Data available per sublot/batch:

- Material ID (taken from material input parameters (SR0050.6.1) (page 9))
- Material short description (taken from material input parameters (SR0050.6.1) (page 9))
- Batch ID
- Sublot ID
- Planned quantity (taken from material input parameters (SR0050.6.1) (page 9))
- Identified quantity

Completed mode (SR0050.1.4)

- <Instruction text>
 (taken from Instruction (SR0050.8.1) process parameter (page 10))
- 2. Box for scanner input
- List of materials available for identification (Table of materials (SR0050.1.2) (page 5))
 (taken from material input parameters (SR0050.6.1) (page 9))
- 4. Material-related comment to execution (only visible if comment is maintained for the order step input)
- Enable button (disabled).
 The button is not visible in case a phase completion signature was configured during authoring.
- 6. **Confirm** button (completed).

Representation in Navigator (SR0050.4+)

The Navigator provides the following details:

Phase column (Framework capability)

- <Phase name>
 - Example: Identify mixing inputs

Information column (SR0050.4.1)

- <Ratio between identified quantity and planned quantity in percent>
 - Example: 98%

Action column (SR0050.4.2)

- Identify, identify another sublot.
- Undo, revoke identification of a sublot.

Representation in Sub-report (SR0050.5+)

The sub-report contains the following information:

Common sub-report elements (Framework capability)

- <Start time>
- <Completion time>

- <Unit procedure> / / / <phe>
- <Work center> / <station> / <device> <phase completion user>

Sub-report elements (SR0050.5.1)

- Material: <identifier> / <short description>
- List of identified sublots per material including planned and identified quantities
- Material-related comment to execution (only visible if comment was visible during execution, i.e. was maintained for the order step input at that time)

Business Logic (SR0050.2+)

The phase implements the following business logic.

Identify material (SR0050.2.1)

■ Function: Identify pre-defined materials

■ Trigger: Phase becomes active

■ Postcondition: Pre-defined materials are identified

Step	#	Description
Phase activation	10	Phase displays its user interface according to the Active mode (SR0050.1.1) layout (page 5).
Operator scans barcode	20	The Scan material barcode (SR0050.2.2) function (page 8) becomes active.
Phase performs	30	If one of the following checks is violated, phase displays an error message:
fixed checks		 Identified material must be MFC-relevant, MFC check failed (SR0050.3.6.1) error message (page 19).
		2. Sublots must be produced for the current order (only for intra materials), Wrong order (SR0050.3.6.2) error message (page 20).
		3. Sublot must not be identified by another order, Sublot already identified (SR0050.3.6.3) error message (page 20).
Minimum batch status check	40	According to Batch status check configuration (SR0050.8.7) process parameter (page 10), batch status is greater than or equal to the configured minimum batch status. If the check fails, phase creates the Failed batch status check (SR0050.3.2.5) system-triggered exception (page 15).
Batch allocation check	50	According to Allocation check configuration (SR0050.8.9) process parameter (page 11), batch allocation must be met. If the check fails, phase creates the Failed batch allocation check (SR0050.3.2.6) system-triggered exception (page 15).

Step	#	Description
Expiry date check	60	According to Expiry date check configuration (SR0050.8.8) process parameter (page 11), expiry date must be defined and beyond the current date plus the configured time to expire. If the check fails, phase creates the Failed expiry date check (SR0050.3.2.7) system-triggered exception (page 15).
	70	If all checks have passed successfully, material has been identified.

Scan material barcode (SR0050.2.2)

■ Function: Scan of material barcode

■ Trigger: Operator scans barcode

Postcondition: Material barcode is scanned

Step	#	Description
Operator scans barcode	10	Phase reads scanned data.
	20	If barcode reading was technically successful, phase updates background color of phase representation according to style sheet in order to confirm the reading.
		If barcode reading was technically not successful, phase remains in listening mode.
		If barcode reading was not successful, phase displays a corresponding error message.

Unit procedure context (SR0050.2.5)

■ Function: Define unit procedure context

■ Trigger: Pre-defined materials are identified

■ Postcondition: Unit procedure context is defined

Step	#	Description
Phase defines unit procedure context	10	Phase assures that identified materials are only recognized within the given unit procedure.

Auto consumption (SR0050.2.6)

■ Function: Support of automatic consumption

■ Trigger: Pre-defined material is identified

■ Postcondition: Consumption of entire sublot quantity is recorded automatically

Step	#	Description
Automatic consumption	10	According to Consumption configuration (SR0050.8.4) process parameter (page 12), phase records the identified sublot as fully consumed and flags the sublot as logically deleted.

Phase completion (SR0050.2.7)

■ Function: Completion of phase

Trigger: Pre-defined material is identified

■ Postcondition: Phase is completed

Step	#	Description
Operator		In order to be completed, the phase requires all system-triggered exceptions
confirms phase		to be recorded.

Recipe Parameters

The phase provides material input parameters as process inputs (page 9) and process parameters (page 9).

Process Inputs (SR0050.6+)

Material input parameters (SR0050.6.1)

The default material input parameters are available to define which materials can be identified during execution.

Quantity definitions of the material input parameters are populated to the **Table of materials** (**SR0050.1.2**) list (page 5) that is displayed during execution. This includes the reflection of quantity-related calculations during order explosion.

Process Parameters (SR0050.8+)

The following process parameters define the behavior of the phase.

BASIC PARAMETERS

Instruction (SR0050.8.1)

For recent changes, see revision history (page 47).

Attribute	Туре	Comment
Column 1	HTML text	Instruction text to be displayed. Restriction: Maximum length is 2000 characters (including HTML tags).
Column 2	HTML text	Not used.
Column 3	HTML text	

CONFIGURATION OF SYSTEM-TRIGGERED EXCEPTIONS

Batch status check configuration (SR0050.8.7)

Attribute	Туре	Comment
Enabled	Flag	Controls if a check is performed. If so, ensure that the Minimum batch status attribute of the Batch check definition (SR0050.8.3) process parameter (page 12) is set.
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment). Default setting: High.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 2000 characters.

See also **Failed batch status check (SR0050.3.2.5)** system-triggered exception (page 15).

Expiry date check configuration (SR0050.8.8)

Attribute	Туре	Comment
Enabled	Flag	Controls if a check is performed. If so, ensure that the Minimum time to expire attribute of the Batch check definition (SR0050.8.3) process parameter (page 12) is set.
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment). Default setting: High.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 2000 characters.

See also Failed expiry date check (SR0050.3.2.7) system-triggered exception (page 15).

Allocation check configuration (SR0050.8.9)

Attribute	Туре	Comment
Enabled	Flag	Controls if a check is performed. If so, the check is only performed if there are allocation requirements.
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment). Default setting: High.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 2000 characters.

See also Failed batch allocation check (SR0050.3.2.6) system-triggered exception (page 15).

Batch check definition (SR0050.8.3)

Attribute	Туре	Comment
Minimum batch status	Choice list	Defines the minimum batch status required for material identification. Default setting: Released.
Minimum time to expire	Numeric	Defines the number of days allowed between the actual identification date and expiry date.

PROCESSING PARAMETER

Consumption configuration (SR0050.8.4)

Attribute	Туре	Comment
Auto consume	Flag	Controls if the identified sublot is registered as fully consumed when the phase is completed with the Confirm button. If you have more than one phase sharing the same material within one operation, all sublots will be consumed even if the flag is set only for one of the phases.

CONFIGURATION OF USER-TRIGGERED EXCEPTIONS

Identify manually (SR0050.8.10)

Attribute	Туре	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment). Default setting: High.

Attribute	Туре	Comment
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 2000 characters.

See also Identify manually (SR0050.3.1.1) user-triggered exception (page 16).

Undo identification (SR0050.8.11)

Attribute	Туре	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment). Default setting: High.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 2000 characters.

See also **Undo identification** (SR0050.3.1.2) user-triggered exception (page 16).

CONFIGURATION OF POST-COMPLETION EXCEPTIONS

Post - Identify additionally (SR0050.8.12)

Attribute	Туре	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment). Default setting: High.

Attribute Type Comment

Exception text Text Defines the exception description used during exception handling and within the batch record.

Maximum length is 2000 characters.

See also Identify additionally (SR0050.3.3.1) post-completion exception (page 17).

Post - Undo identification (SR0050.8.13)

Attribute	Туре	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment). Default setting: High.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 2000 characters.

See also Undo identification (SR0050.3.3.2) post-completion exception (page 18).

Exceptions (SR0050.3+)

The phase supports user-defined, user-triggered (page 16), system-triggered (page 14), and post-completion exceptions (page 17) and their configuration by means of process parameters (page 9).

User-defined exceptions cannot be configured by process parameters since they are provided by the framework and independent of phases.

System-triggered Exceptions (SR0050.3.2+)

For recent changes, see revision history (page 47).

A system-triggered exception is represented in a message dialog along with an **Exception** button, in the Exception Window as the read-only description of the exception, and in the batch report.

The following system-triggered exceptions are available.

Failed batch status check (SR0050.3.2.5)

Representation of the exception:

<Exception text>

(taken from **Batch status check configuration (SR0050.8.7)** process parameter (page 10))

Batch: <batch identifier>,
Expected value: <status>
Actual value: <status>

Example:

The current status of the batch is not appropriate.

Batch: BX127

Expected value: Released Actual value: Quarantined

Failed batch allocation check (SR0050.3.2.6)

Representation during exception handling:

<Exception text>

(taken from **Allocation check configuration (SR0050.8.9)** process parameter (page 11))

Batch: <batch identifier>

Example:

The current batch has not been allocated.

Batch: BX127

Failed expiry date check (SR0050.3.2.7)

Representation of the exception:

<Exception text>

(taken from **Expiry date check configuration (SR0050.8.8)** process parameter (page 11))

Batch: <batch identifier>

Expected value: <number of days>

Actual value: <date>

Example:

The current expiry date is not sufficient anymore.

Batch: BX127

Expected value: 720 days Actual value: 10/12/2011

Multiple exceptions (SR0050.3.2.3)

In case multiple system-triggered exceptions occur, only one combined exception (system-triggered exception) is recorded including information about all exceptions. The highest risk assessment of all related exceptions and its related signature privilege apply.

User-triggered Exceptions (SR0050.3.1+)

A user-triggered exception is represented in the list of available user-triggered exceptions in the Exception Window, as the description of the exception, and in the batch report.

The following user-triggered exceptions are available.

Identify manually (SR0050.3.1.1)

The **Identify manually** exception allows an operator to identify material manually.

Representation during exception handling:

■ Instruction:

To identify manually, enter the sublot identifier.

Box for barcode input.

Confirm button.

Exception text:

<Exception text>

(taken from Identify manually (SR0050.8.10) process parameter (page 12))

Identified sublot: < sublot identifier>

Example:

Manual identification

Identified sublot: SL00005678

Step	#	Description
Operator confirms exception	10	Phase executes the checks of step 30 to 60 of the Identify material (SR0050.2.1) function (page 7).
	20	If all checks have passed successfully, phase records exception according to Identify manually (SR0050.8.10) process parameter (page 12).
	30	Material is identified.

Undo identification (SR0050.3.1.2)

The **Undo identification** exception allows an operator to revoke the identification of a sublot as long as the sublot has not been accounted.

Representation during exception handling:

■ Instruction:

To undo the identification, enter the identifier of the affected sublot. Box for barcode input.

Confirm button.

Exception text:

<Exception text>

 $(taken\ from\ Undo\ identification\ (SR0050.8.11)\ process\ parameter\ (page\ 13))$

Unidentified sublot: <sublot identifier>

Example:

Undo identification

Unidentified sublot: SL00005678

Step	#	Description
Operator confirms exception	10	If the sublot has been accounted, phase records exception according to Undo identification (SR0050.8.11) process parameter (page 13).
	20	Sublot is no longer identified

Multiple exceptions (SR0050.3.1.3)

In case an **Identify manually (SR0050.3.1.1)** user-triggered exception (page 16) coincides with system-triggered exceptions (page 14), only one combined exception (user-triggered exception) is recorded including information about all related exceptions. The highest risk assessment of all related exceptions and its related signature privilege apply.

Post-completion Exceptions (SR0050.3.3+)

A post-completion exception is accessible via the Navigator and represented in the list of available post-completion exceptions in the Exception Window, as the description of the exception, and in the batch report.

The following post-completion exceptions are available.

Identify additionally (SR0050.3.3.1)

The **Identify additionally** exception allows an operator to manually identify an additional sublot from the Navigator after the completion of the phase.

Representation of the exception:

■ Instruction:

To identify an additional sublot, enter the sublot identifier.

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Box for barcode input.

Confirm button.

<Exception text> (taken from Post - Identify additionally (SR0050.8.12) process parameter (page 13))

Additionally identified sublot: <sublot identifier>

Example:

Post additional identification

Additionally identified sublot: SL00005678

Step	#	Description
Operator triggers action	10	Phase displays Exception Window.
	20	Operator enters barcode.
	30	Phase executes the checks of step 30 to 60 of the Identify material (SR0050.2.1) function (page 7).
	40	If all checks have passed successfully, phase records exception according to Post - Identify additionally (SR0050.8.12) process parameter (page 13).
	50	Material is identified.

Undo identification (SR0050.3.3.2)

The **Undo identification** exception allows an operator to revoke the identification of a sublot as long as the sublot has not been accounted from the Navigator after the completion of the phase.

Representation during exception handling:

■ Instruction:

To undo the identification, enter the identifier of the affected sublot.

Box for barcode input.

Confirm button.

Exception text:

<Exception text>

(taken from **Post - Undo identification (SR0050.8.13)** process parameter (page 14))

Unidentified sublot: <sublot identifier>

Example:

Undo identification

Unidentified sublot: SL00005678

Step	#	Description
Operator triggers action	10	If the sublot has not been accounted, phase records exception according to Post - Undo identification (SR0050.8.13) process parameter (page 14).
	20	Sublot is no longer identified

Multiple exceptions (SR0050.3.3.3)

In case an **Identify additionally (SR0050.3.3.1)** post-completion exception (page 17) coincides with system-triggered exceptions (page 14), only one combined exception (post-completion exception) is recorded including information about all related exceptions. The highest risk assessment of all related exceptions and its related signature privilege apply.

Information Messages

There are no information messages available.

Questions

There are no questions available.

Decisions

There are no decisions available.

Error Messages (SR0050.3.6+)

Error messages are represented in an error message dialog containing a message type-specific icon, the error message, and an **OK** button.

The following error messages are available to inform the operator about error conditions.

MFC check failed (SR0050.3.6.1)

UI text	Comment
material, since it does not correspond to the required	Message pack: PhaseProductIdentifyMaterial <version> Message ID: CannotIdentifySublotMaterial Potential error cause: The identified material is not MFC-relevant for this order. It cannot be used at this point.</version>

Wrong order (SR0050.3.6.2)

UI text	Comment
`	Message pack: srv_inventory.checks Message ID: CheckMaterialForIntermediateOSI_0 Potential error cause: The identified material (intra material sublot) has not been produced for the current
	order. It cannot be used at this point.

Sublot already identified (SR0050.3.6.3)

UI text	Comment
Cannot identify the sublot (<sublot id="">), since it has already been identified for another order step. Select another sublot.</sublot>	Message pack: srv_inventory.checks Message ID: CheckSublotBlockedByProcessing_0 Potential error cause: The identified material has already been identified for another order. It cannot be used at this point.

Output Variables

The following output variables are available to reference the phase's output.

Instance count (Framework capability)

Data type: Long

Usage: The output variable provides the count of the number of instances the phase has been processed, for example in a loop. The count is also increased when the phase is skipped from an operator's perspective, since the phase is still executed, but as a hidden phase.

The count variable of a phase that has not been executed provides 0 as output value.

Start time (Framework capability)

Data type: Timestamp

Usage: The output variable provides the start time of the phase.

Completion time (Framework capability)

Data type: Timestamp

■ Usage: The output variable provides the completion time of the phase.

Identifier (Framework capability)

Data type: String

■ Usage: The output variable provides the identifier of the phase.

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Account Material Phase (SR0070+)

The **Account material** phase allows an operator to account identified sublots in terms of consumed, wasted, sampled, and returned quantities.

Example use cases are:

- Consume partial sublots
 - For sublots that were not completely used up during processing, the actual amount of material that has been utilized can be declared as consumed and the remainder can be declared as to be returned.
- Consume sublots completely If several sublots of one material have been identified and consumed completely, the consumption can be declared per material at once.
- Account samples A processing step requires to create samples. The quantity that was used for sampling purposes can be declared separately.
- Account unused sublots One of the identified sublots was not used at all during processing. The entire sublot can be returned.

The number of accounted sublots and their material identifiers are stored in the batch record, thereby becoming available for documentation purposes in the sub-report and batch report (page 27).

After completion the phase displays the accounted material with the following data in the Execution Window:

- batch and/or sublot identifiers
- identified quantity
- consumed quantity
- waster quantity
- sampled quantity
- returned quantity.

The Navigator displays the ratio between accounted quantity and the identified quantity in percent.

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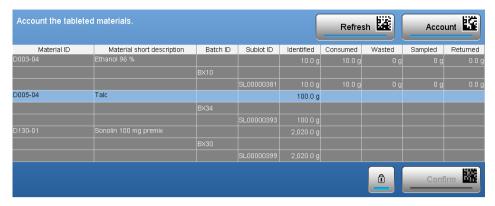


Figure 3: Account material during execution

Layout

The phase provides individual layouts for its representation during execution (page 24), in the Navigator (page 26), and in the sub-report (page 27).

Representation during Execution (SR0070.1+)

The representation during execution depends on the phase mode.

Preview mode (SR0070.1.4)

- 1. <Instruction text> (taken from Instruction (**SR0070.8.1**) process parameter (page 29))
- 2. **Refresh** button (disabled).
- 3. **Account** button (disabled).
- List of materials available for accounting (Table of materials (SR0070.1.2) (page 25))
 (token from material input parameters (SR0070.6.1) (page 20))

(taken from material input parameters (SR0070.6.1) (page 29))

- 5. **Enable** button (disabled).

 The button is not visible in case a phase completion signature was configured during authoring.
- 6. **Confirm** button (disabled).

Active mode (SR0070.1.1)

- <Instruction text>
 (taken from Instruction (SR0070.8.1) process parameter (page 29))
- 2. **Refresh** button.
- 3. **Account** button.

- 4. List of materials available for accounting (Table of materials (SR0070.1.2) (page 25))
 - (taken from material input parameters (SR0070.6.1) (page 29))
- Enable button (unlocks the Confirm button).
 The button is not visible in case a phase completion signature was configured during authoring.
- 6. **Confirm** button.

Table of materials (SR0070.1.2)

Data available per sublot/batch:

- Material ID (taken from material input parameters (SR0070.6.1) (page 29))
- Material short description (taken from material input parameters (SR0070.6.1) (page 29))
- Batch ID
- Sublot ID
- Identified quantity
- Consumed quantity
- Wasted quantity
- Sampled quantity
- Returned quantity

Accounting dialog (SR0070.1.3)

Data available per accounting step:

- **Identified** quantity and **UoM** toggle button (both read-only)
- Consumed quantity and UoM toggle button
- Wasted quantity and UoM toggle button (accessible according to Calculation configuration (SR0070.8.3) process parameter (page 30))
- Sampled quantity and UoM toggle button
- Returned quantity and UoM toggle button (accessible according to Calculation configuration (SR0070.8.3) process parameter (page 30))
- Account button
- Cancel button

Accounting dialog - Single sublot (SR0070.1.3.1)

If, in the Table of materials (SR0070.1.2) (page 25), a single sublot has been selected for accounting, the following data can be provided:

- Consumed quantity
- Sampled quantity
- Wasted quantity or Returned quantity (depends on Calculation configuration (SR0070.8.3) process parameter (page 30))

Accounting dialog - Consume all (SR0070.1.3.2)

If, in the Table of materials (SR0070.1.2) (page 25), a single batch, material item, or multiple sublots have been selected for accounting, the dialog opens in a **Consume all** mode. The **Identified** quantities are taken over as **Consumed** quantities. No quantities can be entered manually.

Completed mode (SR0070.1.5)

- 1. <Instruction text> (taken from Instruction (**SR0070.8.1**) process parameter (page 29))
- 2. **Refresh** button (completed).
- 3. **Account** button (completed.
- List of materials available for accounting (Table of materials (SR0070.1.2) (page 25))
 (taken from material input parameters (SR0070.6.1) (page 29))
- Enable button (disabled).
 The button is not visible in case a phase completion signature was configured during authoring.
- 6. **Confirm** button (completed).

Representation in Navigator (SR0070.4+)

The Navigator provides the following details:

Phase column (Framework capability)

- <Phase name>
 - Example: Account materials

Information column (SR0070.4.1)

- <Ratio between accounted quantity and identified quantity in percent>
 - Example: 98%

Action column

There are no actions available.

Representation in Sub-report (SR0070.5+)

The sub-report contains the following information:

Common sub-report elements (Framework capability)

- Start time>
- <Completion time>
- Unit procedure> / < operation> / < phase>
- Work center> / <station> / <device> <phase completion user>

Sub-report elements (SR0070.5.1)

- Material: <identifier> / <short description>
- Number of accounted sublots per material

Business Logic (SR0070.2+)

The phase implements the following business logic.

Account material (SR0070.2.1)

- Function: Account pre-defined materials
- Trigger: Phase becomes active
- Postcondition: Pre-defined materials are accounted

Step	#	Description
Phase activation	10	Phase displays its user interface according to the Active mode (SR0070.1.1) layout (page 24).
Operator starts accounting	20	Phase displays Accounting dialog (SR0070.1.3) form (page 25) to declare consumed, wasted, sampled, and returned quantities.

Detect unaccounted materials (SR0070.2.2)

■ Function: Detect if there are unaccounted materials

■ Trigger: Operator confirms phase

■ Postcondition: Unaccounted materials are recorded as exception

Step	#	Description
Operator confirms phase	10	According to Accounting configuration (SR0070.8.2) process parameter (page 29), phase checks if there are no unaccounted materials left. If the check fails, phase creates the Unaccounted material (SR0070.3.2.1) system-triggered exception (page 30).

Unit procedure context (SR0070.2.3)

■ Function: Define unit procedure context

■ Trigger: Materials have been accounted

■ Postcondition: Unit procedure context is defined

Step	#	Description
Phase defines unit procedure context	10	Phase assures that accounted materials are only recognized within the given unit procedure.

Phase completion (SR0070.2.4)

■ Function: Completion of phase

■ Trigger: Complete material accounting

■ Postcondition: Phase is completed

Step	#	Description
Operator confirms phase		In order to be completed, the phase requires all system-triggered exceptions to be recorded.

Recipe Parameters

The phase provides material input parameters as process inputs (page 29) and process parameters (page 29).

Process Inputs (SR0070.6+)

Material input parameters (SR00570.6.1)

The default material input parameters are available to define which materials can be accounted during execution.

Process Parameters (SR0070.8+)

The following process parameters define the behavior of the phase.

BASIC PARAMETERS

Instruction (SR0070.8.1)

For recent changes, see revision history (page 47).

Attribute	Туре	Comment
Column 1	HTML text	Instruction text to be displayed. Restriction: Maximum length is 2000 characters (including HTML tags).
Column 2	HTML text	Not used.
Column 3	HTML text	

CONFIGURATION OF SYSTEM-TRIGGERED EXCEPTIONS

Accounting configuration (SR0070.8.2)

Attribute	Туре	Comment
Enabled	Flag	Controls if a check is performed.
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment). Default setting: High.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 2000 characters.

See also Unaccounted material (SR0070.3.2.1) system-triggered exception (page 30).

PROCESSING PARAMETER

Calculation configuration (SR0070.8.3)

Attribute	Туре	Comment
Result	Choice list	Defines whether the returned quantity or the wasted quantity is calculated. Return(ed) qty = Identified qty - Consumed qty - Sampled qty - Wasted qty Waste(d) qty = Identified qty - Consumed qty - Sampled qty - Returned qty Default setting: Return.

Exceptions (SR0070.3+)

The phase supports user-defined, user-triggered (page 31), system-triggered (page 30), and post-completion exceptions (page 31) and their configuration by means of process parameters (page 29).

User-defined exceptions cannot be configured by process parameters since they are provided by the framework and independent of phases.

System-triggered Exceptions (SR0070.3.2+)

For recent changes, see revision history (page 47).

A system-triggered exception is represented in a message dialog along with an **Exception** button, in the Exception Window as the read-only description of the exception, and in the batch report.

The following system-triggered exceptions are available.

Unaccounted material (SR0070.3.2.1)

Representation during exception handling:

<Exception text> (taken from Accounting configuration (SR0070.8.2) process parameter (page 29))

<Number> sublots have not been accounted yet.

Example:

Unaccounted materials.

2 sublots have not been accounted yet.

•
•
•
•

Step	#	Description
Operator triggers exception	10	Phase records exception.

User-triggered Exceptions

There are no user-triggered exceptions available.

Post-completion Exceptions

There are no post-completion exceptions available.

Information Messages

There are no information messages available.

Questions

There are no questions available.

Decisions

There are no decisions available.

Error Messages

There are no error messages available.

Output Variables

The following output variables are available to reference the phase's output.

Instance count (Framework capability)

- Data type: Long
- Usage: The output variable provides the count of the number of instances the phase has been processed, for example in a loop. The count is also increased when the phase is skipped from an operator's perspective, since the phase is still executed, but as a hidden phase.

The count variable of a phase that has not been executed provides 0 as output value.

Start time (Framework capability)

Data type: Timestamp

■ Usage: The output variable provides the start time of the phase.

Completion time (Framework capability)

Data type: Timestamp

■ Usage: The output variable provides the completion time of the phase.

Identifier (Framework capability)

Data type: String

Usage: The output variable provides the identifier of the phase.

Produce Material Phase (SR0060+)

The **Produce material** phase allows an operator to produce intra materials or the final product during recipe execution.

Example use cases are:

- Produce intra materials

 The intra materials produced in a processing step will be used in a subsequent processing step. Create the sublots of the intra materials and print their labels.

 Now, the intra materials are prepared for identification in the next processing step.
- Produce intra materials with defined quality status The quality status of the intra materials must be **Released**. This requirement can be defined and will be assigned to the produced sublots.
- Produce final product
 For final products, the quantity can be declared and labels printed per sublot.
 Then, the product can be delivered to the warehouse.
- Reprint a sublot label
 If there was a problem during label printing that renders the printed labels unusable, the required labels can be printed again.

The number of produced sublots and their material identifiers are stored in the batch record, thereby becoming available for documentation purposes in the sub-report and batch report (page 36).

Anomalies that occur during processing are covered by the phase exception handling (page 41) (e.g. label reprint).

After completion the phase displays the produced material with the following data in the Execution Window:

- batch and/or sublot identifiers
- planned quantity
- produced quantity.

The Navigator displays the overall produced quantity and provides access to the post-completion exception.

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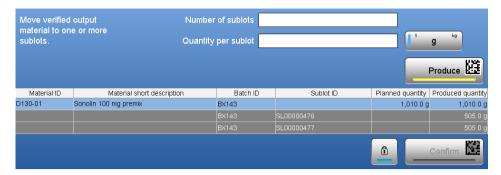


Figure 4: Produce material during execution

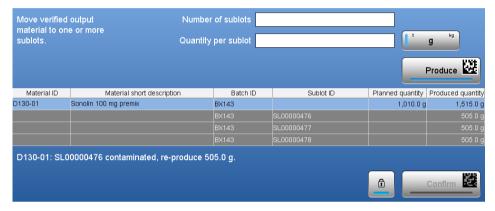


Figure 5: Reactivated Produce material during execution with Comment to execution

Layout

The phase provides individual layouts for its representation during execution (page 34), in the Navigator (page 36), and in the sub-report (page 36).

Representation during Execution (SR0060.1+)

The representation during execution depends on the phase mode.

Preview mode (SR0060.1.3)

- <Instruction text>
 (taken from Instruction (SR0060.8.1) process parameter (page 39))
- 2. Text box for the number of sublots (disabled).
- 3. Text box for the quantity per sublot (disabled).
- 4. **UoM** button (disabled).
- 5. **Produce** button (disabled).

- 6. List of materials available for production (Table of materials (SR0060.1.2) (page 35))
 - (taken from material output parameters (SR0060.7.1) (page 39))
- 7. Material-related comment to execution (only visible if comment is maintained for the order step output)
- 8. **Enable** button (disabled).

The button is not visible in case a phase completion signature was configured during authoring.

9. **Confirm** button (disabled).

Active mode (SR0060.1.1)

- 1. <Instruction text> (taken from **Instruction (SR0060.8.1)** process parameter (page 39))
- 2. Text box for the number of sublots
- 3. Text box for the quantity per sublot
- 4. **UoM** toggle button
- 5. **Produce** button
- 6. List of materials available for production (Table of materials (SR0060.1.2) (page 35))

(taken from material output parameters (SR0060.7.1) (page 39))

- 7. Material-related comment to execution (only visible if comment is maintained for the order step output)
- 8. **Enable** button (unlocks the **Confirm** button).

 The button is not visible in case a phase completion signature was configured during authoring.
- 9. **Confirm** button.

Table of materials (SR0060.1.2)

Data available per sublot:

- Material ID (taken from material output parameters (SR0060.7.1) (page 39))
- Material short description (taken from material output parameters (SR0060.7.1) (page 39))
- Batch ID of material to be produced
- Sublot ID of produced sublots
- Planned quantity (taken from material output parameters (SR0060.7.1) (page 39))

Produced quantity (total and per sublot)

Completed mode (SR0060.1.4)

- 1. <Instruction text> (taken from **Instruction (SR0060.8.1)** process parameter (page 39))
- 2. Text box for the number of sublots (disabled).
- 3. Text box for the quantity per sublot (disabled).
- 4. **UoM** button (disabled).
- 5. **Produce** button (completed).
- 6. List of materials available for production (Table of materials (SR0060.1.2) (page 35))
 - (taken from material output parameters (SR0060.7.1) (page 39))
- 7. Material-related comment to execution (only visible if comment is maintained for the order step output)
- 8. **Enable** button (disabled).

 The button is not visible in case a phase completion signature was configured during authoring.
- 9. **Confirm** button (completed).

Representation in Navigator (SR0060.4+)

The Navigator provides the following details:

Phase column (Framework capability)

- <Phase name>
 - Example: Verify coating output

Information column (SR0060.4.1)

- <Overall produced quantity>
 - Example: 980 kg

Action column (SR0060.4.2)

Reprint, reprints a sublot label.

Representation in Sub-report (SR0060.5+)

The sub-report contains the following information:

Common sub-report elements (Framework capability)

- <Start time>
- <Completion time>
- <Unit procedure> / <operation> / <phase>
- <Work center> / <station> / <device> <phase completion user>

Sub-report elements (SR0060.5.1)

- Material: <identifier> / <short description>
- List of produced sublots including planned and produced quantities
- Material-related comment to execution (only visible if comment was visible during execution, i.e. was maintained for the order step output at that time)

Business Logic (SR0060.2+)

The phase implements the following business logic.

Produce material (SR0060.2.1)

Function: Produce pre-defined material

■ Trigger: Phase becomes active

■ Postcondition: Pre-defined material is produced

Step	#	Description
Phase activation	10	Phase displays its user interface according to the Active mode (SR0060.1.1) layout (page 35).
Operator starts producing	20	The Create sublot (SR0060.2.2) function (page 37) becomes active.
	30	The Assign storage location (SR0060.2.3) function (page 38) becomes active.
	40	The Assign batch status (SR0060.2.5) function (page 38) becomes active.

Create sublot (SR0060.2.2)

■ Function: Creation of sublots

Trigger: Operator starts producing

■ Postcondition: Sublots are created

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Step	#	Description
Operator provides data and starts producing	10	Phase creates sublots and prints a label for each produced sublot.

Assign storage location (SR0060.2.3)

■ Function: Assignment of storage location

■ Trigger: New sublot has been created

Postcondition: Storage location is assigned

Step	#	Description
Sublots have	10	Phase assigns the pre-defined storage location to each sublot, per
been created		configuration on work center level.

Assign batch status (SR0060.2.5)

■ Function: Assignment of batch status

■ Trigger: New batch has been created

Precondition: No order-related batch exists yet for the product material

■ Postcondition: Batch status is assigned

Step	#	Description
Unit procedure context has been defined	10	According to Batch definition (SR0060.8.2) process parameter (page 40), phase assigns a pre-defined batch status to the newly created batch. (Does not apply to already existing batches that have been defined on order level.)
	20	If no status is pre-defined, Quarantined is assigned as the default status.

Unit procedure context (SR0060.2.4)

■ Function: Define unit procedure context

■ Trigger: A new sublot is created

Postcondition: Unit procedure context is defined

Step	#	Description
Phase defines unit procedure	10	Phase assures that produced materials are only recognized within the given unit procedure.
context		unic procedure.

Recipe Parameters

The phase provides material output parameters as process outputs (page 39) and process parameters (page 39).

Process Outputs (SR0060.7+)

Material output parameters (SR0060.7.1)

The default material output parameters are available to define which material can be produced during execution.

Quantity definitions of the material output parameters are populated to the **Table of materials** (**SR0060.1.2**) list (page 35) that is displayed during execution. This includes the reflection of quantity-related calculations during order explosion.

Process Parameters (SR0060.8+)

The following process parameters define the behavior of the phase.

BASIC PARAMETERS

Instruction (SR0060.8.1)

For recent changes, see revision history (page 47).

Attribute	Туре	Comment
Column 1	HTML text	Instruction text to be displayed. Restriction: Maximum length is 2000 characters (including HTML tags).
Column 2	HTML text	Not used.
Column 3	HTML text	

PROCESSING PARAMETER

Batch definition (SR0060.8.2)

Attribute	Туре	Comment
Batch status	Choice list	Defines the batch status of the newly created batch. Default setting: Quarantined. Important: The batch status setting only applies to newly created batches, but not to already existing batches.

CONFIGURATION OF USER-TRIGGERED EXCEPTIONS

Reprint (SR0060.8.3)

Attribute	Туре	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment). Default setting: High.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 2000 characters.

See also Reprint label (SR0600.3.1.1) user-triggered exception (page 41).

CONFIGURATION OF POST-COMPLETION EXCEPTIONS

Post - Reprint (SR0060.8.4)

Attribute	Туре	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment).

Attribute	Туре	Comment
		Default setting: High .
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 2000 characters.

See also Reprint label (SR0060.3.3.1) post-completion exception (page 42).

Exceptions (SR0060.3+)

The phase supports user-defined, user-triggered (page 41), system-triggered (page 41), and post-completion exceptions (page 42) and their configuration by means of process parameters (page 39).

User-defined exceptions cannot be configured by process parameters since they are provided by the framework and independent of phases.

System-triggered Exceptions

There are no system-triggered exceptions available.

User-triggered Exceptions (SR0060.3.1+)

A user-triggered exception is represented in the list of available user-triggered exceptions in the Exception Window, as the description of the exception, and in the batch report.

The following user-triggered exceptions are available.

Reprint label (SR0060.3.1.1)

The **Reprint label** exception allows an operator to reprint a sublot label.

Representation during exception handling:

■ Instruction:

To reprint a sublot label, enter the ID of the produced sublot. Box for barcode input.

Confirm button.

Exception text:

<Exception text>

 $(taken\ from\ \textbf{Reprint}\ (\textbf{SR0060.8.3})\ process\ parameter\ (page\ 40))$

Label of < sublot identifier> sublot reprinted.

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Example:

Label reprinted

Label of SL00008765 sublot reprinted.

Step	#	Description
Operator confirms exception	10	Phase reprints label.

Post-completion Exceptions (SR0060.3.3+)

A post-completion exception is accessible via the Navigator and represented in the list of available post-completion exceptions in the Exception Window, as the description of the exception, and in the batch report.

The following post-completion exceptions are available.

Reprint label (SR0060.3.3.1)

The **Reprint label** exception allows an operator to reprint a sublot label from the Navigator after the completion of the phase.

Representation of the exception:

Instruction:

To reprint a sublot label, enter the ID of the produced sublot.

Box for barcode input.

Confirm button.

<Exception text>

(taken from **Post - Reprint** (**SR0060.8.4**) process parameter (page 40)) Label of < sublot identifier> sublot reprinted.

Example:

Label reprinted

Label of SL00008765 sublot reprinted.

Step	#	Description
Operator triggers action	10	Phase displays Exception Window.
Operator confirms exception	20	Phase reprints label.

Information Messages

There are no information messages available.

Questions

There are no questions available.

Decisions

There are no decisions available.

Error Messages (SR0060.3.6+)

Error messages are represented in an error message dialog containing a message type-specific icon, the error message, and an **OK** button.

The following error messages are available to inform the operator about error conditions.

No sublots identified (SR0060.3.6.1)

UI text	Comment
Cannot proceed, since no sublots of the ingoing material(s) are currently identified.	Message pack: PhaseProductProduceMaterial <version> Message ID: NoOSIMsg</version>

Output Variables

The following output variables are available to reference the phase's output.

Instance count (Framework capability)

- Data type: Long
- Usage: The output variable provides the count of the number of instances the phase has been processed, for example in a loop. The count is also increased when the phase is skipped from an operator's perspective, since the phase is still executed, but as a hidden phase.

The count variable of a phase that has not been executed provides 0 as output value.

Start time (Framework capability)

Data type: Timestamp

■ Usage: The output variable provides the start time of the phase.

Completion time (Framework capability)

Data type: Timestamp

■ Usage: The output variable provides the completion time of the phase.

Identifier (Framework capability)

Data type: String

■ Usage: The output variable provides the identifier of the phase.

Reference Documents

The following documents are available from the Rockwell Automation Download Site.

No.	Document Title	Part Number
A1	PharmaSuite Functional Requirement Specification Execution Framework	PSFRSEF-RM004E-EN-E

TIP

To access the Rockwell Automation Download Site, you need to acquire a user account from Rockwell Automation Sales or Support.

Rockwell Software PharmaSuite® 8.4 - Functional Requirement Specification Material Tracking Phases

Document Information

The document information covers various data related to the document.

Approval

This document has been approved electronically via the Rockwell Automation Document Management System (DMS). The required approvers of this document include the following:

Name	Role
Martin Dittmer	Product Manager
Steffen Landes	Development Manager
Martin Irmisch	Test Manager

In addition, the electronic document approval via DMS is confirmed by a handwritten signature of all approvers in the Quality Document when the release is completed. The Quality Document summarizes the quality-related planning activities and results of a PharmaSuite release.

Version Information

Object	Version
PharmaSuite	8.4
Identify material	5.0 MR4
Account material	5.1
Produce material	5.0 MR4
Functional Requirement Specification	1.0

Revision History

The following table describes the history of this document.

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Rockwell Software PharmaSuite® 8.4 - Functional Requirement Specification Material Tracking Phases

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Changes related to the document:

Object	Description	Document

Changes related to "Identify Material" (page 3):

Object	Description	Document
System-triggered Exceptions (SR0050.3.2+) (page 14)	Update The message dialog of a system-triggered exception no longer provides a Cancel button.	1.0
Instruction (SR0050.8.1) (page 10)	Update The maximum length of the Instruction process parameter is 2000 characters (including HTML tags). No change of code.	1.0

Changes related to "Account Material" (page 23):

Object	Description	Document
System-triggered Exceptions (SR0070.3.2+) (page 30)	Update The message dialog of a system-triggered exception no longer provides a Cancel button.	1.0
Instruction (SR0070.8.1) (page 29)	Update The maximum length of the Instruction process parameter is 2000 characters (including HTML tags). No change of code.	1.0

Changes related to "Produce Material" (page 33):

Object	Description	Document
Instruction (SR0060.8.1) (page 39)	Update The maximum length of the Instruction process parameter is 2000 characters (including HTML tags). No change of code.	1.0
	2000 Characters (including frime tags). No change of code.	

	Sub-report elements (SR0070.5.1) • 27
A	System-triggered exceptions (SR0070.3.2+) • 30
Account material (SR0070+) • 23	Table of materials (SR0070.1.2) • 25
Account material (SR0070.2.1) • 27	Unaccounted material (SR0070.3.2.1) • 30
Accounting configuration (SR0070.8.2) • 29	Unit procedure context (SR0070.2.3) • 28
Accounting dialog - Consume all (SR0070.1.3.2) • 25	User-triggered exceptions • 31
Accounting dialog - Single sublot (SR0070.1.3.1) • 25	
Accounting dialog (SR0070.1.3) • 25	С
Action column • 27	Compliance-related
Active mode (SR0070.1.1) • 24	SR0050.3+ - Exceptions (Identify material) • 14
Business logic (SR0070.2+) • 27	SR0060.3+ - Exceptions (Produce material) • 41
Calculation configuration (SR0070.8.3) • 30	SR0070.3+ - Exceptions (Account material) • 30
Common sub-report elements (Framework capability) •	Conventions (typographical) • 1
27	F
Completed mode (SR0070.1.5) • 26	Г
Completion time (Framework capability) • 32	Framework capability
Decisions • 31	Common sub-report elements (Account material) • 27
Detect unaccounted materials (SR0070.2.2) • 28	Common sub-report elements (Identify material) • 6
Error messages • 31	Common sub-report elements (Produce material) • 37
Exceptions (SR0070.3+) • 30	Completion time (Account material) • 32
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Information column (SR0070.4.1) • 27	Completion time (Produce material) • 44
Information messages • 31	Identifier (Account material) • 32
Instance count (Framework capability) • 31	Identifier (Identify material) • 21
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Material input parameters (SR0070.6.1) • 29	Instance count (Account material) • 31
Output variables • 31	Instance count (Identify material) • 20
Phase column (Framework capability) • 26	Instance count (Produce material) • 43
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