Swedish Match

Quality and Environmental Management System

Document Title
Quantitative Analysis of Ethyl Carbamate with (b) (4)

Part of Process
Assignment Analyses APS

Document Type
Method Description

Valid From
31/03/2017

Approved By
(b) (6)

Document Publisher
(b) (6)



# QUANTITATIVE ANALYSIS OF ETHYL CARBAMATE IN TOBACCO, SMOKELESS TOBACCO PRODUCTS, TOBACCO DERIVED PRODUCTS AND FIBRE-BASED MATRICES WITH (b) (4)

## TABLE OF CONTENTS

## Purpose

To determine the concentration of ethyl carbamate (urethane) in tobacco flour, smokeless tobacco products, tobacco derived products and fibre-based matrices with (b) (4)

## Applies to

APS

## General information

### Principle of the method

After weighing in of the sample, an internal standard (IS) is added followed by extraction with (b) (4). The extract is then filtered using (b) (4) filter vials, whereupon the sample preparation is complete. Separation and quantification are performed with (b) (4) through a microbore (b) (4) column coupled to a (b) (4). Calculations are performed using (b) (4) and (b) (4). The capacity per instrument and person is (b) (4) single samples/week. The chemical structural formula for ethyl carbamate (EC) is shown in **Figure 1**.

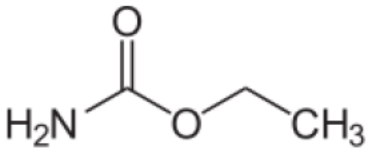



**Figure 1.** Chemical structural formula for ethyl carbamate (EC).

Note: All reference documents and additional information stated "available upon request" are in Swedish. They are available upon request but need to be translated into English first.

### Method scope, measurement range, and measurement uncertainty

Scope

The method is used for the quantitative analysis of ethyl carbamate in tobacco, smokeless tobacco products, tobacco derived products, and fibre-based matrices.

Method's measurement range

The concentration range of calibration solutions is between (b) (4) ng/ml, which corresponds to (b) (4) (ng/g) in the sample.

Measurement uncertainty

The combined relative measurement uncertainty for ethyl carbamate is stated with a coverage factor of 2. The combined relative measurement uncertainty for a single sample is (b) (4) and for duplicate samples (b) (4).
The contribution to measurement uncertainty is greatest from precision, accuracy and the calibration curve. In order to reduce the measurement uncertainty contribution from precision, care must be taken when adding the internal standard solution.

**Literature references**

(b) (4)

**Internal reference documents (available upon request)**

(b) (4)

- 

## Risk assessment and safety instructions

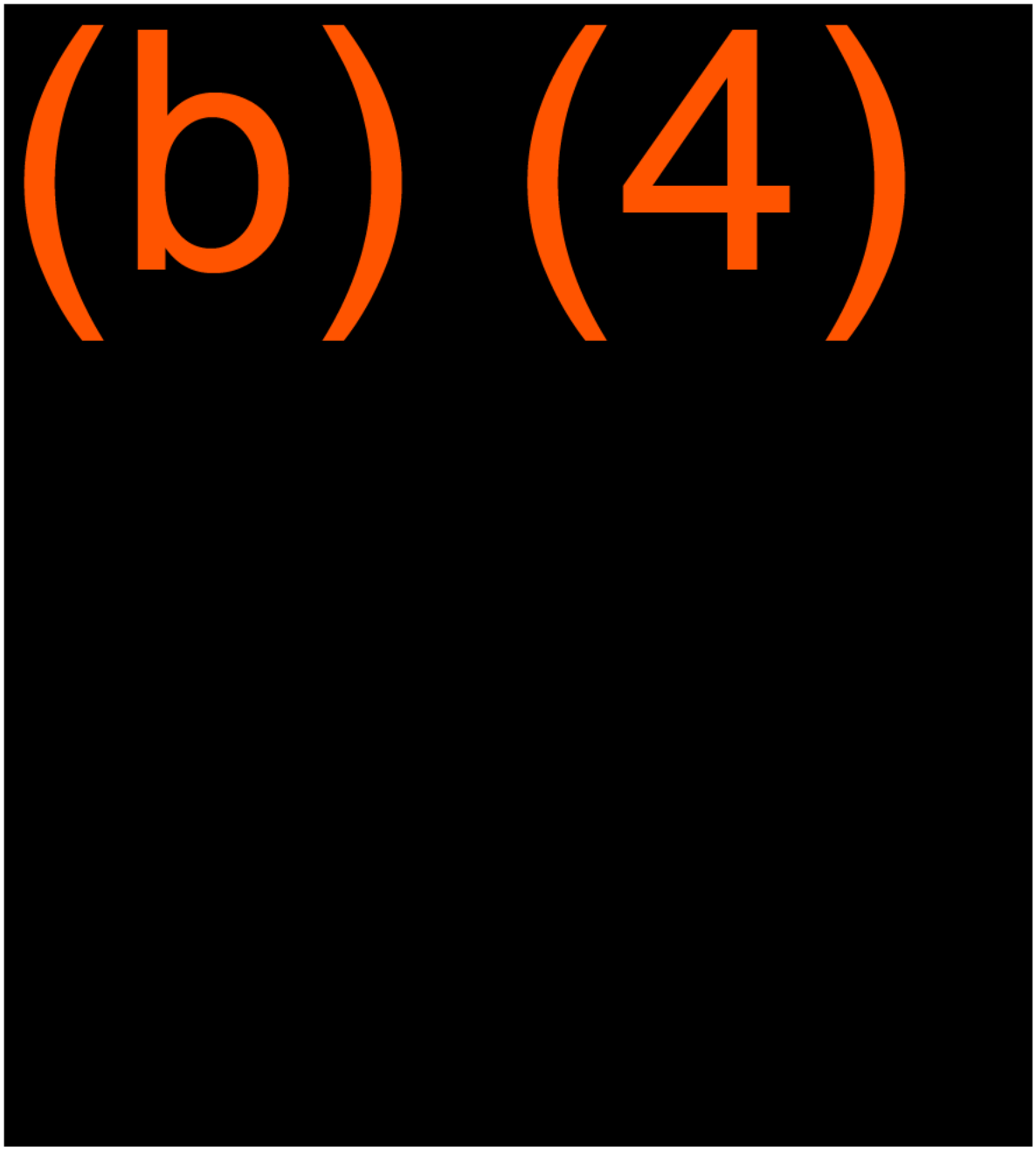
### Summarised risk assessment

Safety data sheet for ethyl carbamate is kept at the back of the method binder.

For the preparation of stock standard of ethyl carbamate, weighing in should be conducted in a (b) (4).

Gloves should be worn for the preparation of stock and interim standard solutions and for the preparation of mobile phase A and strong wash.

**Risk and safety phrases**



(b) (4)

## Equipment

### Apparatus

Four different (b) (4) systems are used for analysis. See the relevant appendix for the system's individual settings.

1. (b) (4)
2.
3.
4.

### Other equipment and laboratory utensils

(b) (4)

### Chemicals, reagents, and solvents

(b) (4)

(b) (4)

**Check samples**

Check samples are analysed at each analysis timepoint. A check sample is prepared and analysed before and another one after the samples, as described under "Control Charts and Check Samples". (b) (4)

**Preparation of standards and internal standards**

General information

All standard and internal standard solutions are stored in a refrigerator. All solutions are brought up to room temperature before use. Certificates of analysis are kept in the binder "Certificates of Analysis for Ethyl carbamate" in (b) (4).

Stock standard solution of ethyl carbamate 0.5 mg/ml in methanol

(b) (4)

Swedish Match

Quality and Environmental Management System

| Document Title | Valid From | Page |
|---|---|---|
| Quantitative Analysis of Ethyl Carbamate with (b) (4) | 31/03/2017 | 9(48) |

Part of Process
Assignment Analyses APS

Approved By
(b) (6)

Document Type
Method Description

Document Publisher
(b) (6)

(b) (4)

Swedish Match

Quality and Environmental Management System

| Document Title | Valid From | Page |
|---|---|---|
| Quantitative Analysis of Ethyl Carbamate with (b) (4) | 31/03/2017 | 10(48) |

Part of Process
Assignment Analyses APS

Approved By
(b) (6)

Document Type
Method Description

Document Publisher
(b) (6)

(b) (4)

**Preparation of other solutions**

(b) (4)

**Sample handling**

(b) (4)

## Analysis

### Calibration and verification of apparatus

The system performance is controlled at start up and at the end of each sequence by the calibration standard (b) (4) being injected and evaluated. (b) (4)

Swedish Match

Quality and Environmental Management System

| Document Title | Valid From | Page |
|---|---|---|
| Quantitative Analysis of Ethyl Carbamate with (b) (4) | 31/03/2017 | 12(48) |

Part of Process
Assignment Analyses APS

Approved By
(b) (6)

Document Type
Method Description

Document Publisher
(b) (6)

(b) (4)

(b) (4)

**Sample stability**

Prepared samples are stable for (b) (4) days in the sample manager (b) (4) or a refrigerator.

**Analytical procedure**

Sample preparation

(b) (4)

**Special instructions**

(b) (4)

## Data

### Collection and storage of data

The samples are weighed in directly to (b) (4). The raw data is collected with (b) (4) . The samples are injected with (b) (4) . In order to control the injector, a sample sequence is built up in which the sample identity is specified along with the methods to be used. The sequence also indicates whether it is a standard or an unknown sample. (b) (4)

t.

### Calculations

(b) (4)

(b) (4)

**Quality assurance**

(b) (4)

(b) (4)

**Assessment of the control charts and actions when exceeding the alarm limit or action limit**

(b) (4)

(b) (4)

**Reporting of analysis results**

(b) (4)

## Revision history

March 2017

(b) (4)

Oct 2016

(b) (4)

Oct 2014

(b) (4)

June 2013:

(b) (4)

## Person responsible

Director APS

## Validation

(b) (4)

Swedish Match

Quality and Environmental Management System

| Document Title | Valid From | Page |
|---|---|---|
| Quantitative Analysis of Ethyl Carbamate with (b) (4) | 31/03/2017 | 19(48) |

Part of Process
Assignment Analyses APS

Approved By
(b) (6)

Document Type
Method Description

Document Publisher
(b) (6)

(b) (4)

Swedish Match

Quality and Environmental Management System

| Document Title | Valid From | Page |
|---|---|---|
| Quantitative Analysis of Ethyl Carbamate with (b) (4) | 31/03/2017 | 20(48) |

Part of Process
Assignment Analyses APS

Approved By
(b) (6)

Document Type
Method Description

Document Publisher
(b) (6)

(b) (4)

Swedish Match

Quality and Environmental Management System

| Document Title | Valid From | Page |
|---|---|---|
| Quantitative Analysis of Ethyl Carbamate with (b) (4) | 31/03/2017 | 21(48) |

Part of Process
Assignment Analyses APS

Approved By
(b) (6)

Document Type
Method Description

Document Publisher
(b) (6)

(b) (4)

Swedish Match

Quality and Environmental Management System

| Document Title | Valid From | Page |
|---|---|---|
| Quantitative Analysis of Ethyl Carbamate with (b) (4) | 31/03/2017 | 22(48) |

Part of Process
Assignment Analyses APS

Approved By
(b) (6)

Document Type
Method Description

Document Publisher
(b) (6)

(b) (4)

Swedish Match

Quality and Environmental Management System

| Document Title | Valid From | Page |
|---|---|---|
| Quantitative Analysis of Ethyl Carbamate with (b) (4) | 31/03/2017 | 23(48) |

Part of Process
Assignment Analyses APS

Approved By
(b) (6)

Document Type
Method Description

Document Publisher
(b) (6)

(b) (4)

Swedish Match

Quality and Environmental Management System

| Document Title | Valid From | Page |
|---|---|---|
| Quantitative Analysis of Ethyl Carbamate with (b) (4) | 31/03/2017 | 24(48) |

Part of Process
Assignment Analyses APS

Approved By
(b) (6)

Document Type
Method Description

Document Publisher
(b) (6)

(b) (4)

Swedish Match

Quality and Environmental Management System

| Document Title | Valid From | Page |
|---|---|---|
| Quantitative Analysis of Ethyl Carbamate with (b) (4) | 31/03/2017 | 25(48) |

Part of Process
Assignment Analyses APS

Approved By
(b) (6)

Document Type
Method Description

Document Publisher
(b) (6)

(b) (4)

(b) (4)

Swedish Match

Quality and Environmental Management System

| Document Title | Valid From | Page |
|---|---|---|
| Quantitative Analysis of Ethyl Carbamate with (b) (4) | 31/03/2017 | 27(48) |

Part of Process
Assignment Analyses APS

Approved By
(b) (6)

Document Type
Method Description

Document Publisher
(b) (6)

(b) (4)

Swedish Match

Quality and Environmental Management System

| Document Title | Valid From | Page |
|---|---|---|
| Quantitative Analysis of Ethyl Carbamate with (b) (4) | 31/03/2017 | 28(48) |

Part of Process
Assignment Analyses APS

Approved By
(b) (6)

Document Type
Method Description

Document Publisher
(b) (6)

(b) (4)

Swedish Match

Quality and Environmental Management System

| Document Title | Valid From | Page |
|---|---|---|
| Quantitative Analysis of Ethyl Carbamate with (b) (4) | 31/03/2017 | 29(48) |

Part of Process
Assignment Analyses APS

Approved By
(b) (6)

Document Type
Method Description

Document Publisher
(b) (6)

(b) (4)

Swedish Match

Quality and Environmental Management System

| Document Title | Valid From | Page |
|---|---|---|
| Quantitative Analysis of Ethyl Carbamate with (b) (4) | 31/03/2017 | 30(48) |

Part of Process
Assignment Analyses APS

Approved By
(b) (6)

Document Type
Method Description

Document Publisher
(b) (6)

(b) (4)

Swedish Match

Quality and Environmental Management System

| Document Title | Valid From | Page |
|---|---|---|
| Quantitative Analysis of Ethyl Carbamate with (b) (4) | 31/03/2017 | 31(48) |

Part of Process
Assignment Analyses APS

Approved By
(b) (6)

Document Type
Method Description

Document Publisher
(b) (6)

**Appendix 1.** (b) (4)

(b) (4)

Swedish Match

Quality and Environmental Management System

| Document Title | Valid From | Page |
|---|---|---|
| Quantitative Analysis of Ethyl Carbamate with (b) (4) | 31/03/2017 | 32(48) |

Part of Process
Assignment Analyses APS

Approved By
(b) (6)

Document Type
Method Description

Document Publisher
(b) (6)

(b) (4)

Swedish Match

Quality and Environmental Management System

| Document Title | Valid From | Page |
|---|---|---|
| Quantitative Analysis of Ethyl Carbamate with (b) (4) | 31/03/2017 | 33(48) |

Part of Process
Assignment Analyses APS

Approved By
(b) (6)

Document Type
Method Description

Document Publisher
(b) (6)

(b) (4)

Swedish Match

Quality and Environmental Management System

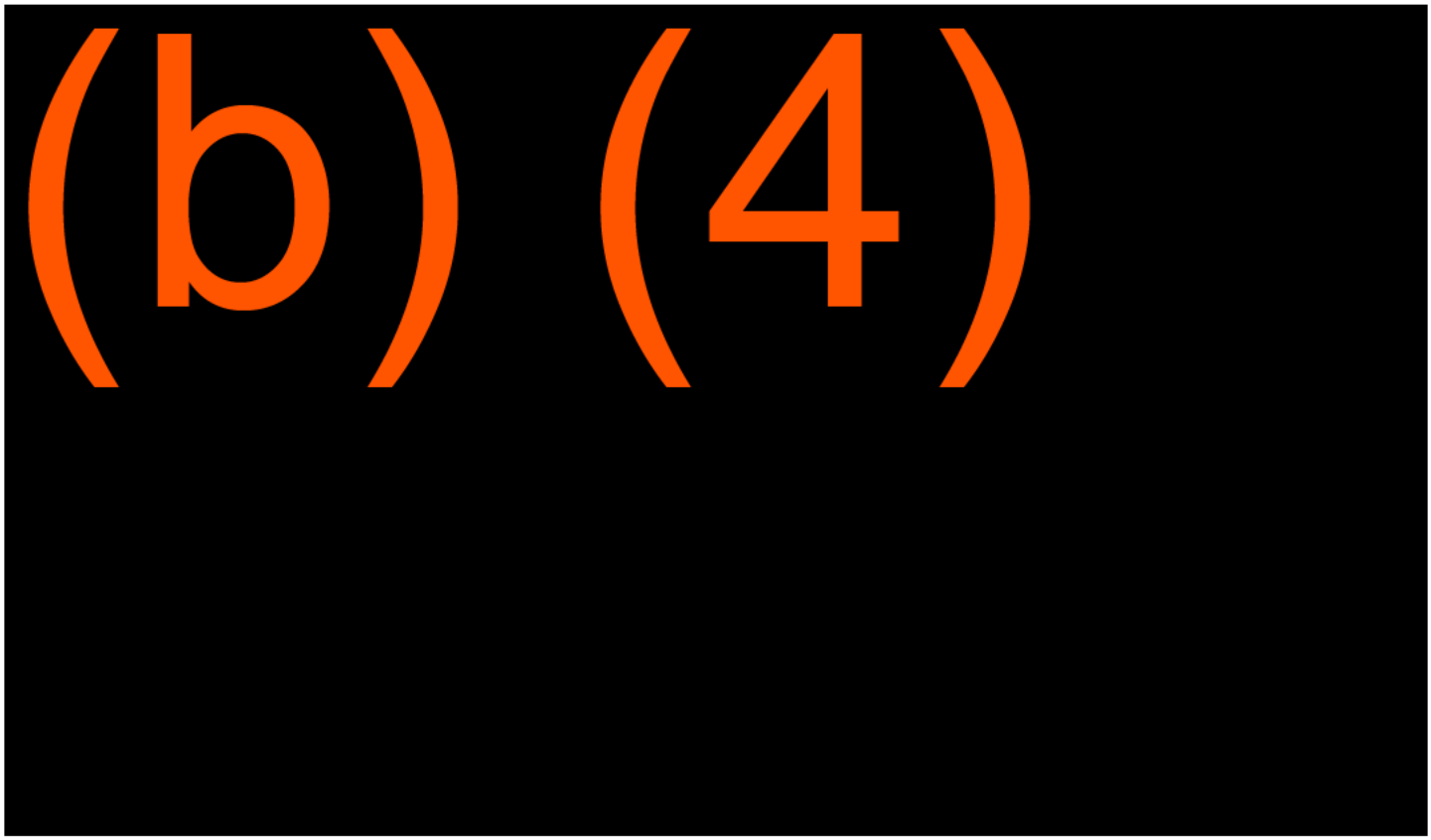
| Document Title | Valid From | Page |
|---|---|---|
| Quantitative Analysis of Ethyl Carbamate with (b) (4) | 31/03/2017 | 34(48) |

Part of Process
Assignment Analyses APS

Approved By
(b) (6)

Document Type
Method Description

Document Publisher
(b) (6)



**Appendix 2.** (b) (4)

(b) (4)

Swedish Match

Quality and Environmental Management System

| Document Title | Valid From | Page |
|---|---|---|
| Quantitative Analysis of Ethyl Carbamate with (b) (4) | 31/03/2017 | 36(48) |

Part of Process
Assignment Analyses APS

Approved By
(b) (6)

Document Type
Method Description

Document Publisher
(b) (6)

(b) (4)

Swedish Match

Quality and Environmental Management System

| Document Title | Valid From | Page |
|---|---|---|
| Quantitative Analysis of Ethyl Carbamate with (b) (4) | 31/03/2017 | 37(48) |

Part of Process
Assignment Analyses APS

Approved By
(b) (6)

Document Type
Method Description

Document Publisher
(b) (6)

(b) (4)

Swedish Match

Quality and Environmental Management System

| Document Title | Valid From | Page |
|---|---|---|
| Quantitative Analysis of Ethyl Carbamate with (b) (4) | 31/03/2017 | 38(48) |

Part of Process
Assignment Analyses APS

Approved By
(b) (6)

Document Type
Method Description

Document Publisher
(b) (6)

(b) (4)

Swedish Match

Quality and Environmental Management System

| Document Title | Valid From | Page |
|---|---|---|
| Quantitative Analysis of Ethyl Carbamate with (b) (4) | 31/03/2017 | 39(48) |

Part of Process
Assignment Analyses APS

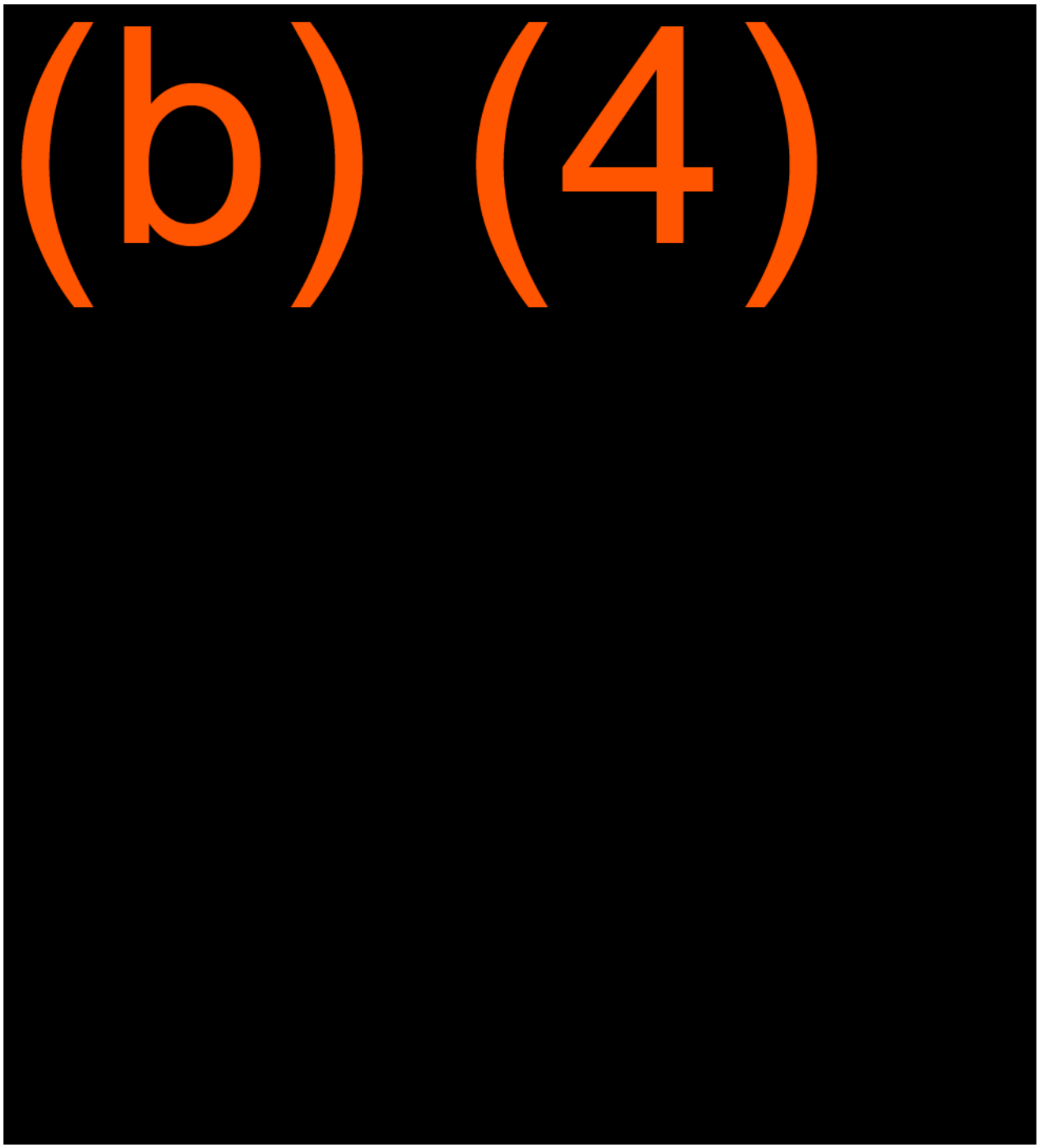
Approved By
(b) (6)

Document Type
Method Description

Document Publisher
(b) (6)

(b) (4)

**Appendix 3.** (b) (4)



Swedish Match

Quality and Environmental Management System

| Document Title | Valid From | Page |
|---|---|---|
| Quantitative Analysis of Ethyl Carbamate with (b) (4) | 31/03/2017 | 41(48) |

Part of Process
Assignment Analyses APS

Approved By
(b) (6)

Document Type
Method Description

Document Publisher
(b) (6)

(b) (4)

Swedish Match

Quality and Environmental Management System

| Document Title | Valid From | Page |
|---|---|---|
| Quantitative Analysis of Ethyl Carbamate with (b) (4) | 31/03/2017 | 42(48) |

Part of Process
Assignment Analyses APS

Approved By
(b) (6)

Document Type
Method Description

Document Publisher
(b) (6)

(b) (4)

(b) (4)

**Appendix 4.** (b) (4)

(b) (4)

Swedish Match

Quality and Environmental Management System

| Document Title | Valid From | Page |
|---|---|---|
| Quantitative Analysis of Ethyl Carbamate with (b) (4) | 31/03/2017 | 44(48) |

Part of Process
Assignment Analyses APS

Approved By
(b) (6)

Document Type
Method Description

Document Publisher
(b) (6)

(b) (4)

(b) (4)

Swedish Match

Quality and Environmental Management System

Document Title
Quantitative Analysis of Ethyl Carbamate with (b) (4)

Part of Process
Assignment Analyses APS

Document Type
Method Description

Valid From
31/03/2017

Approved By
(b) (6)

Document Publisher
(b) (6)



(b) (4)

Swedish Match

Quality and Environmental Management System

| Document Title | Valid From | Page |
|---|---|---|
| Quantitative Analysis of Ethyl Carbamate with (b) (4) | 31/03/2017 | 47(48) |

Part of Process
Assignment Analyses APS

Approved By
(b) (6)

Document Type
Method Description

Document Publisher
(b) (6)

(b) (4)

Swedish Match

Quality and Environmental Management System

| Document Title | Valid From | Page |
|---|---|---|
| Quantitative Analysis of Ethyl Carbamate with (b) (4) | 31/03/2017 | 48(48) |

Part of Process
Assignment Analyses APS

Approved By
(b) (6)

Document Type
Method Description

Document Publisher
(b) (6)

(b) (4)