

Official Journal of the European Union

L 302



English edition

Legislation

Volume 61

28 November 2018

Contents

II Non-legislative acts

REGULATIONS

- ★ **Commission Regulation (EU) 2018/1850 of 21 November 2018 registering a geographical indication for a spirit drink in Annex III to Regulation (EC) No 110/2008 ('Гроздова ракия от Търговище/Grozdova rakya ot Targovishte' (GI))** 1
- ★ **Commission Implementing Regulation (EU) 2018/1851 of 21 November 2018 entering a name in the register of protected designations of origin and protected geographical indications ('Bayrisch Blockmalz'/'Bayrischer Blockmalz'/'Echt Bayrisch Blockmalz'/'Aecht Bayrischer Blockmalz' (PGI))** 5
- ★ **Commission Implementing Regulation (EU) 2018/1852 of 26 November 2018 approving non-minor amendments to the specification for a name entered in the register of protected designations of origin and protected geographical indications ['Mahón-Menorca' (PDO)]** 7
- ★ **Commission Implementing Regulation (EU) 2018/1853 of 27 November 2018 granting a Union authorisation for the biocidal product family Teat disinfectants biocidal product family of CVAS ⁽¹⁾** 8

DECISIONS

- ★ **Commission Implementing Decision (EU) 2018/1854 of 27 November 2018 on recognition of the 'Better Biomass' voluntary scheme for demonstrating compliance with the sustainability criteria under Directives 98/70/EC and 2009/28/EC of the European Parliament and of the Council** 73
- ★ **Commission Implementing Decision (EU) 2018/1855 of 27 November 2018 on greenhouse gas emissions covered by Decision No 406/2009/EC of the European Parliament and of the Council for the year 2016 for each Member State** 75

⁽¹⁾ Text with EEA relevance.

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

★ Commission Implementing Decision (EU) 2018/1856 of 27 November 2018 amending the Annex to Implementing Decision 2014/709/EU concerning animal health control measures relating to African swine fever in certain Member States (notified under document C(2018) 8058) ⁽¹⁾	78
--	----

ACTS ADOPTED BY BODIES CREATED BY INTERNATIONAL AGREEMENTS

★ Regulation No 39 of the Economic Commission for Europe of the United Nations (UN/ECE) — Uniform provisions concerning the approval of vehicles with regard to the speedometer and odometer equipment including its installation [2018/1857]	106
★ Amendments to Regulation No 100 of the Economic Commission for Europe of the United Nations (UN/ECE) — Uniform provisions concerning the approval of vehicles with regard to specific requirements for the electric power train [2018/1858]	114

Corrigenda

★ Corrigendum to Commission Decision (EU) 2018/860 of 7 February 2018 on the Aid Scheme SA.45852 — 2017/C (ex 2017/N) which Germany is planning to implement for Capacity Reserve (OJ L 153, 15.6.2018)	115
---	-----

⁽¹⁾ Text with EEA relevance.

II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) 2018/1850

of 21 November 2018

**registering a geographical indication for a spirit drink in Annex III to Regulation (EC) No 110/2008
(‘Гроздова ракия от Търговище/Grozdova rakya ot Targovishte’ (GI))**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 110/2008 of the European Parliament and of the Council of 15 January 2008 on the definition, description, presentation, labelling and the protection of geographical indications of spirit drinks and repealing Council Regulation (EEC) No 1576/89 ⁽¹⁾, and in particular Article 17(8) thereof,

Whereas:

- (1) The Commission examined Bulgaria's application for registration of the geographical indication ‘Гроздова ракия от Търговище/Grozdova rakya ot Targovishte’ in accordance with Article 17(5) of Regulation (EC) No 110/2008.
- (2) As it concluded that the application complied with Regulation (EC) No 110/2008, the Commission published the main specifications of the technical file in the *Official Journal of the European Union* ⁽²⁾ pursuant to Article 17(6) of that Regulation.
- (3) As no statement of objection has been received by the Commission under Article 17(7) of Regulation (EC) No 110/2008, the indication ‘Гроздова ракия от Търговище/Grozdova rakya ot Targovishte’ should be registered as a geographical indication in Annex III to that Regulation.
- (4) The name, as published in the Official Journal in order to allow objections to be made, contains a transcription error. Following the correction of that error, the corrected version of the main specifications of the technical file should be published for information.
- (5) The measures provided for in this Regulation are in accordance with the opinion of the Committee for Spirit Drinks,

HAS ADOPTED THIS REGULATION:

Article 1

In Annex III to Regulation (EC) No 110/2008, the following entry is added under the product category ‘Wine spirit’:

‘Wine spirit	Гроздова ракия от Търговище/Grozdova rakya ot Targovishte	Bulgaria’
--------------	---	-----------

Article 2

The corrected version of the main specifications of the technical file is included in the Annex to this Regulation.

⁽¹⁾ OJ L 39, 13.2.2008, p. 16.⁽²⁾ OJ C 294, 5.9.2017, p. 15.

Article 3

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 21 November 2018.

*For the Commission,
On behalf of the President,
Phil HOGAN
Member of the Commission*

ANNEX

MAIN SPECIFICATIONS OF THE TECHNICAL FILE

‘ТРОЗДОВА РАКИЯ ОТ ТЪРГОВИЩЕ’/‘GROZDOVA RAKYA OT TARGOVISHTE’

EU No: PGI-BG-01864 – 7.1.2014

1. **Geographical indication to be registered:** ‘Троздова ракия от Търговище’/‘Grozdova rakya ot Targovishte’
2. **Category of the spirit drink:** Wine spirit
3. **Description of the spirit drink:**
 - 3.1. **Physical, chemical and/or organoleptic characteristics**

Wine spirit with the geographical indication ‘Троздова ракия от Търговище’/‘Grozdova rakya ot Targovishte’ has a pale yellow colour, a pleasant aroma of vanilla and a harmonious mild taste. Its specific physico-chemical and organoleptic characteristics are due to the following factors: the raw materials, the geographical area, the method of production and the human factor, which involves applying good manufacturing practices that combine tradition with modern technology.

- 3.2. **Specific characteristics (compared to spirit drinks of the same category)**

Wine spirit with the geographical indication ‘Троздова ракия от Търговище’/‘Grozdova rakya ot Targovishte’ is produced using a traditional Bulgarian method and has the following physico-chemical properties:

- the minimum alcoholic strength of the drink is 40 % vol.;
- a volatile substance content (including higher alcohols, total acids, esters and aldehydes) of 267-365 g/hl of 100 % vol. alcohol;
- a maximum methanol content of 120 g/hl of 100 % vol. alcohol.

The wood from which the barrels used for maturing the distillate are made and the mineral water which, after softening, is used for diluting the wine distillate also contribute to the drink's distinctive taste.

4. **Geographical area concerned:**

Wine spirit with the geographical indication ‘Троздова ракия от Търговище’/‘Grozdova rakya ot Targovishte’ is produced in the province of Targovishte, which is situated in the eastern part of the Danube plain. The vineyards are located in the municipality of Targovishte, in areas belonging to the following six villages: Kralevo, Dalgach, Ovcharovo, Pevets, Strazha and Ruets.

5. **Method for obtaining the spirit drink:**

Wine spirit with the geographical indication ‘Троздова ракия от Търговище’/‘Grozdova rakya ot Targovishte’ is produced from the following grape varieties:

- white — Chardonnay, Rkatsiteli, Muscat Ottonel, Dimyat, Tamyanka, Traminer, Sauvignon Blanc, Aligoté, Riesling Italico;
- red — Cabernet Sauvignon and Pamid.

Production begins with the harvesting of the grapes, which are sorted by variety, general outward appearance and sugar content, then pressed. The resultant pulp is macerated in rotary strainers for 4-12 hours. The grape must is then clarified and the clear fractions are transferred on for fermentation. Alcoholic fermentation takes place over approximately 20 days at temperatures of 14-18 °C. The distillate obtained undergoes single or double distillation in a K-5 distillation column until it reaches 65 % vol. alcohol. The K-5 distillation system is a Bulgarian design. The resulting wine spirit is stored in separate compartments for maturing in oak barrels and blending (coupage).

6. **Link with the geographical environment or origin:**

- 6.1. **Details of the geographical area or origin relevant to the link**

The geographical area is mostly hilly or undulating. The average elevation is 200–520 m above sea-level. It has a mild, temperate continental climate with maritime influences. Autumns are warm, dry and long, which greatly favours the accumulation of sugars in the grapes. The annual average temperature in the area is approximately 10,7 °C. In terms of annual average precipitation, maximum levels mostly occur in late spring and early summer. The soils in the area are sandy-loamy chernozem and grey forest soils.

6.2. Specific characteristics of the spirit drink attributable to the geographical area

Wine spirit with the geographical indication 'Троздова ракия от Търговище'/'Grozdova rakya ot Targovishte' is produced in the province of Targovishte, whose topography, soils and climate combine to create ideal conditions for growing quality grapes that attain optimum technical ripeness. Many of the distinctive qualities of the drink are due to the special oak of the species *Quercus Frainetto* (Blagun oak), from which the barrels used for maturing the distillate are made. Softened mineral water from the Boaza spring, situated 8 km to the south-west of the city of Targovishte, is used for diluting the distillate. Subsequent blending results in a quality product with stable organoleptic characteristics — a pale yellow colour, a pleasant aroma of vanilla and a harmonious mild taste. The aromatic substances contained in the grapes, which bring out the bouquet and the aroma of the drink, are preserved by using both traditional and modern production methods.

7. European Union or national/regional provisions:

In Bulgaria, the procedure for approving spirit drinks with a geographical indication is set out in Section VII, 'Production of spirit drinks with a geographical indication', of Chapter Nine, 'Spirit drinks', of the Wine and Spirit Drinks Act (ZVSN), published in State Gazette No 45 of 15 June 2012.

'Троздова ракия от Търговище'/'Grozdova rakya ot Targovishte' was approved as a wine spirit with a geographical indication by Order No T-RD-27-13 of the Minister for the Economy of 27 November 2013, which has been published on the Ministry of the Economy's website at: <http://www.mi.government.bg/bg/library/zapoved-zautvarjdavane-na-vinena-destilatna-spirtna-napitka-grozdova-rakiya-s-geografsko-ukazanie-t-68-c28-m361-1.html>.

8. Applicant:

Member State, third country or legal/natural person: **Република България, Министерство на икономиката/Republic of Bulgaria, Ministry of the Economy.**

— Full address (street number and name, town/city and postal code, country):

гр. София 1052, ул. 'Славянска' № 8, Република България/8 ul. Slavyanska, 1052 Sofia, Bulgaria

9. Specific labelling rules:

The rules on the labelling of spirit drinks with a geographical indication produced in Bulgaria and intended for the Bulgarian market are laid down in Article 170(1) and Article 172(1) of the Wine and Spirit Drinks Act.

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1851**of 21 November 2018****entering a name in the register of protected designations of origin and protected geographical indications ('Bayrisch Blockmalz'/'Bayrischer Blockmalz'/'Echt Bayrisch Blockmalz'/'Aecht Bayrischer Blockmalz' (PGI))**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs ⁽¹⁾, and in particular Article 15(1) and Article 52(2) thereof,

Whereas:

- (1) Pursuant to Article 50(2)(a) of Regulation (EU) No 1151/2012, Germany's application to register the name 'Bayrisch Blockmalz'/'Bayrischer Blockmalz'/'Echt Bayrisch Blockmalz'/'Aecht Bayrischer Blockmalz' was published in the *Official Journal of the European Union* ⁽²⁾.
- (2) As no statement of opposition under Article 51 of Regulation (EU) No 1151/2012 has been received by the Commission, the name should therefore be entered in the register.
- (3) By emails received on 19 April 2018 and 21 June 2018, the German authorities notified the Commission that during the national opposition procedure it had been argued that registration of the name 'Bayrisch Blockmalz'/'Bayrischer Blockmalz'/'Echt Bayrisch Blockmalz'/'Aecht Bayrischer Blockmalz' would jeopardise the existence of an entirely identical name and that products bearing that name had been legally marketed for more than five years preceding the date of publication of the document referred to in Article 50(2)(a) of Regulation (EU) No 1151/2012. They therefore requested that a transitional period, lasting until 31 December 2020, be granted under Article 15(1) of that Regulation to the producer 'Kalfany Süße Werbung GmbH & Co.KG, D-79336 Herbolzheim', located outside the geographical area defined for the production of 'Bayrisch Blockmalz'/'Bayrischer Blockmalz'/'Echt Bayrisch Blockmalz'/'Aecht Bayrischer Blockmalz', which had been legally marketing the product sold under the name 'Bayrisch Blockmalz'/'Bayrischer Blockmalz'/'Echt Bayrisch Blockmalz'/'Aecht Bayrischer Blockmalz', using this name continuously for more than five years.
- (4) Since the company 'Kalfany Süße Werbung GmbH & Co.KG, D-79336 Herbolzheim' meets the requirements laid down in Article 15(1) of Regulation (EU) No 1151/2012 for the granting of a transitional period in which to make legal use of the sales name after registration, it should be granted a transitional period lasting until 31 December 2020 during which time it may make use of the name 'Bayrisch Blockmalz'/'Bayrischer Blockmalz'/'Echt Bayrisch Blockmalz'/'Aecht Bayrischer Blockmalz'.
- (5) The measures provided for in this Regulation are in accordance with the opinion of the Agricultural Product Quality Policy Committee,

HAS ADOPTED THIS REGULATION:

Article 1

The name 'Bayrisch Blockmalz'/'Bayrischer Blockmalz'/'Echt Bayrisch Blockmalz'/'Aecht Bayrischer Blockmalz' (PGI) is hereby entered in the register.

The name specified in the first paragraph denotes a product in Class 2.3. – bread, pastry, cakes, confectionery, biscuits and other baker's wares, as listed in Annex XI to Commission Implementing Regulation (EU) No 668/2014 ⁽³⁾.

Article 2

The producer 'Kalfany Süße Werbung GmbH & Co.KG, D-79336 Herbolzheim', is hereby authorised to continue to use the registered name 'Bayrisch Blockmalz'/'Bayrischer Blockmalz'/'Echt Bayrisch Blockmalz'/'Aecht Bayrischer Blockmalz' (PGI) until 31 December 2020.

⁽¹⁾ OJ L 343, 14.12.2012, p. 1.

⁽²⁾ OJ C 96, 14.3.2018, p. 38.

⁽³⁾ Commission Implementing Regulation (EU) No 668/2014 of 13 June 2014 laying down rules for the application of Regulation (EU) No 1151/2012 of the European Parliament and of the Council on quality schemes for agricultural products and foodstuffs (OJ L 179, 19.6.2014, p. 36).

Article 3

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 21 November 2018.

*For the Commission,
On behalf of the President,
Phil HOGAN
Member of the Commission*

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1852**of 26 November 2018****approving non-minor amendments to the specification for a name entered in the register of protected designations of origin and protected geographical indications ['Mahón-Menorca' (PDO)]**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs ⁽¹⁾, and in particular Article 52(2) thereof,

Whereas:

- (1) Pursuant to the first subparagraph of Article 53(1) of Regulation (EU) No 1151/2012, the Commission has examined Spain's application for the approval of amendments to the specification for the protected designation of origin 'Mahón-Menorca', registered under Commission Regulation (EC) No 1107/96 ⁽²⁾ as last amended by Commission Regulation (EC) No 913/2001 ⁽³⁾.
- (2) Since the amendments in question are not minor within the meaning of Article 53(2) of Regulation (EU) No 1151/2012, the Commission published the amendment application in the *Official Journal of the European Union* ⁽⁴⁾ as required by Article 50(2)(a) of that Regulation.
- (3) As no statement of opposition under Article 51 of Regulation (EU) No 1151/2012 has been received by the Commission, the amendments to the specification should be approved,

HAS ADOPTED THIS REGULATION:

*Article 1*The amendments to the specification published in the *Official Journal of the European Union* regarding the name 'Mahón-Menorca' (PDO) are hereby approved.*Article 2*This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 26 November 2018.

For the Commission,
On behalf of the President,
Phil HOGAN
Member of the Commission

⁽¹⁾ OJ L 343, 14.12.2012, p. 1.

⁽²⁾ Commission Regulation (EC) No 1107/96 of 12 June 1996 on the registration of geographical indications and designations of origin under the procedure laid down in Article 17 of Council Regulation (EEC) No 2081/92 (OJ L 148, 21.6.1996, p. 1).

⁽³⁾ Commission Regulation (EC) No 913/2001 of 10 May 2001 amending the Annex to Regulation (EC) No 1107/96 on the registration of geographical indications and designations of origin under the procedure laid down in Article 17 of Council Regulation (EEC) No 2081/92 (OJ L 129, 11.5.2001, p. 8).

⁽⁴⁾ OJ C 187, 1.6.2018, p. 13.

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1853**of 27 November 2018****granting a Union authorisation for the biocidal product family Teat disinfectants biocidal product family of CVAS****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ⁽¹⁾, and in particular Article 44(5) thereof,

Whereas:

- (1) On 28 August 2015, the Scientific Consulting Company — SCC GmbH acting on behalf of CVAS Development GmbH submitted an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 for authorisation of a biocidal product family named Teat disinfectants biocidal product family of CVAS ('product family') of product-type 3, as described in Annex V to that Regulation. The competent authority of Netherlands agreed to evaluate the application as referred to in Article 43(1) of Regulation (EU) No 528/2012. The application was recorded under the case number BC-WU019429-99 in the Register for Biocidal Products ('the Register').
- (2) The biocidal product family contains iodine, including polyvinylpyrrolidone iodine, as the active substance, which is included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012. Taking into account the intrinsic properties of the active substance, and following the entry into application of the scientific criteria for the determination of endocrine-disrupting properties set out in Commission Delegated Regulation (EU) 2017/2100 ⁽²⁾, the Commission will consider the need to review the approval of iodine, including polyvinylpyrrolidone iodine, in accordance with Article 15 of Regulation (EU) No 528/2012. Depending on the outcome of that review, the Commission will then consider whether the Union authorisations for products containing the active substance have to be reviewed in accordance with Article 48 of Regulation (EU) No 528/2012.
- (3) On 30 August 2017, the evaluating competent authority submitted, in accordance with Article 44(1) of Regulation (EU) No 528/2012, the assessment report and the conclusions of its evaluation to the European Chemicals Agency ('the Agency').
- (4) On 19 March 2018, the Agency submitted to the Commission an opinion ⁽³⁾, including the draft summary of the biocidal product characteristics ('SPC') of the product family and the final assessment report on the product family in accordance with Article 44(3) of Regulation (EU) No 528/2012. The opinion concludes that the product family falls within the definition of 'biocidal product family' laid down in Article 3(1)(s) of Regulation (EU) No 528/2012, that it is eligible for Union authorisation in accordance with Article 42(1) of that Regulation and that subject to compliance with the draft SPC, the product family meets the conditions laid down in Article 19(1) and (6) of that Regulation.
- (5) On 25 April 2018, the Agency transmitted to the Commission the draft SPC in all the official languages of the Union in accordance with Article 44(4) of Regulation (EU) No 528/2012.
- (6) The Commission concurs with the opinion of the Agency and considers it therefore appropriate to grant a Union authorisation for the biocidal product family.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council (OJ L 301, 17.11.2017, p. 1).

⁽³⁾ ECHA opinion of 7 March 2018 on the Union authorisation of Teat disinfectants biocidal product family of CVAS (ECHA/BPC/193/2018).

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation is granted to CVAS Development GmbH for the biocidal product family Teat disinfectants biocidal product family of CVAS with authorisation number EU-0018724-0000.

The Union authorisation is valid from 18 December 2018 until 30 November 2028.

The Union authorisation is subject to compliance with the SPC set out in the Annex.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 27 November 2018.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Summary of product characteristics for a biocidal product family

TEAT DISINFECTANTS BIOCIDAL PRODUCT FAMILY OF CVAS

Product type 3 — Veterinary hygiene (Disinfectants)

Authorisation number: EU-0018724-0000

R4BP 3 asset number: EU-0018724-0000

PART I

FIRST INFORMATION LEVEL**1. ADMINISTRATIVE INFORMATION****1.1. Family name**

Name	TEAT DISINFECTANTS BIOCIDAL PRODUCT FAMILY OF CVAS

1.2. Product type(s)

Product type(s)	PT03 — Veterinary hygiene (Disinfectants)

1.3. Authorisation holder

Name and address of the authorisation holder	Name	CVAS Development GmbH
	Address	Dr Albert Reimann Str. 16a, 68526 Ladenburg, Germany
Authorisation number	EU-0018724-0000	
R4BP asset number	EU-0018724-0000	
Date of the authorisation	18 December 2018	
Expiry date of the authorisation	30 November 2028	

1.4. Manufacturer(s) of the biocidal products

Name of manufacturer	Calvatis GmbH
Address of manufacturer	Dr Albert Reimann Str. 16a, 68526 Ladenburg, Germany
Location of manufacturing sites	Dr Albert Reimann Str. 16a, 68526 Ladenburg, Germany
Name of manufacturer	Arthur Schopf Hygiene GmbH & Co. KG
Address of manufacturer	Pfaffensteinstr. 1, 83115 Neubuern, Germany
Location of manufacturing sites	Pfaffensteinstr. 1, 83115 Neubuern, Germany

1.5. Manufacturer(s) of the active substance(s)

Active substance	Iodine
Name of manufacturer	Cosayach Nitratos S.A.

Address of manufacturer	Amunategui 178 Santiago Chile
Location of manufacturing sites	S.C.M. Cosayach Cala Cala Pozo Almonte Chile
Active substance	Iodine
Name of manufacturer	ACF Minera S.A.
Address of manufacturer	San Martín No 499 Iquique Chile
Location of manufacturing sites	Lagunas mine Pozo Almonte Chile
Active substance	Iodine
Name of manufacturer	SQM S.A.
Address of manufacturer	Los Militares 4290, Piso 4 Las Condes Chile
Location of manufacturing sites	Nueva Victoria plant Pedro de Valdivia plant Chile
Active substance	Iodine
Name of manufacturer	Nihon Tennen Gas Co., Ltd/Kanto Natural Gas Development Co., Ltd
Address of manufacturer	661 Mobara 297-8550 Mobara City, Chiba Japan
Location of manufacturing sites	Chiba Plant, 2508 Minami-Hinata 299-4205 Shirako-Machi, Chosei-Gun, Chiba Japan
Active substance	Polyvinylpyrrolidone iodine
Name of manufacturer	Norkem Limited (manufacturer of PVP-iodine)
Address of manufacturer	Norkem House, Bexton Lane WA 16 9FB Knutsford, Cheshire United Kingdom
Location of manufacturing sites	Norkem House, Bexton Lane WA 16 9FB Knutsford, Cheshire United Kingdom

2. PRODUCT FAMILY COMPOSITION AND FORMULATION

2.1. Qualitative and quantitative information on the composition of the family

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	0	0,54
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0	4,16
Acetic acid	Acetic acid	Non active substance	64-19-7	200-580-7	0	0,33

2.2. Type(s) of formulation

Formulation(s)	AL — Any other liquid

PART II

SECOND INFORMATION LEVEL — META SPC(S)

META SPC 1

1. META SPC 1 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 1 identifier

Identifier	meta SPC 1
------------	------------

1.2. Suffix to the authorisation number

Number	1-1
--------	-----

1.3. Product type(s)

Product type(s)	PT03 — Veterinary hygiene (Disinfectants)

2. META SPC 1 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	0	0
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		1,16	1,5
Acetic acid	Acetic acid	Non active substance	64-19-7	200-580-7	0	0

2.2. Type(s) of formulation of the meta SPC 1

Formulation	AL — Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1

Hazard statements	
Precautionary statements	If medical advice is needed, have product container or label at hand. Keep out of reach of children.

4. AUTHORISED USE(S) OF THE META SPC 1

4.1. Use description

Table 1. Use # 1 — Teat disinfection of milkable animals: Post-milking teat disinfection by manual dipping

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—

Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Manual dipping using a dip cup
Application rate(s) and frequency	cows: 5 mL per treatment Post-milking application: 2-3×/day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

4.1.1. *Use-specific instructions for use*

The product must be brought to a temperature above 20 °C before use.

The use of a dosing pump for filling the product into the application equipment is recommended.

Fill the reservoir with the RTU product assuming 5 mL product per cow and screw the dip cup on top. Avoid discharge of surplus fluids.

Clean the teats carefully by wiping with a single service paper towel/cloth immediately before milking.

After milking, squeeze the reservoir and put the dip cup over each teat from below making sure that about 3 cm of the teat are immersed into the disinfectant.

Refill the cup of the dipping unit with fresh disinfectant by squeezing the reservoir as needed. Refill the reservoir with fresh disinfectant as needed.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

After disinfection, empty the reservoir and clean reservoir and dip cup by rinsing with water.

4.1.2. *Use-specific risk mitigation measures*

In case a combination of pre- and post-milking disinfection is necessary, using another product not containing iodine has to be considered for pre-milking disinfection.

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use.

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use.

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use.

4.2. **Use description**

Table 2. Use # 2 — Teat disinfection of milkable animals: Post-milking teat disinfection by automated dipping

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—

Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Automated dipping
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2 - 3×/day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

4.2.1. *Use-specific instructions for use*

The product must be brought to a temperature above 20 °C before use.

Open a can containing the RTU product and insert a suction tube of the automated dipping-system. Avoid discharge of surplus fluids.

After milking, the vacuum is shut off and the teat dip is injected into a manifold on the clawpiece. The teats are coated with ca. 5 mL of dip when the teat cup is withdrawn by the Automatic Cluster Removal (ACR). After the removal of the ACR, every liner of the automated dipping-system is thoroughly rinsed with water and blown out with compressed air.

In a final cleaning step after each milking session of the herd, the liners are disinfected (e.g. with a chlorine-based product) and blown out again with compressed air.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

Afterwards, the milking system is ready for the next milking event.

The whole process is automated.

4.2.2. *Use-specific risk mitigation measures*

In case a combination of pre- and post-milking disinfection is necessary, using another product not containing iodine has to be considered for pre-milking disinfection.

4.2.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use.

4.2.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use.

4.2.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use.

5. GENERAL DIRECTIONS FOR USE ⁽¹⁾ OF THE META SPC 1

5.1. **Instructions for use**

See use specific instructions for use.

5.2. **Risk mitigation measures**

See use specific risk mitigation measures.

⁽¹⁾ Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC1.

5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Mentioned in the MSDS

Description of first aid measures

After inhalation: Supply fresh air; consult doctor in case of symptoms.

After skin contact: Instantly wash with water and soap and rinse thoroughly.

After eye contact: Rinse opened eye for several minutes under running water (at least 15 minutes).

After swallowing: Rinse out mouth and then drink plenty of water. Instantly call for doctor.

If medical advice is needed, have product container or label at hand.

Stability and reactivity

Reactivity: No dangerous reactions known.

Chemical stability: The product is chemically stable under normal surroundings terms (ambient temperature).

Possibility of hazardous reactions: By designated use no dangerous reactions are to be expected.

Conditions to avoid: Not determined.

Incompatible materials: Not determined.

Hazardous decomposition products: No dangerous decomposition products known.

Accidental release measures

Personal precautions, protective equipment and emergency procedures: Wear protective clothing.

Ensure adequate ventilation.

Keep ignition sources away — Do not smoke.

Environmental precautions: Do not allow to enter drainage system, surface or ground water.

Methods and material for containment and cleaning up: Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Dispose of the material collected according to regulations.

5.4. Instructions for safe disposal of the product and its packaging

Mentioned in the MSDS

Waste treatment methods: Hazardous waste (AVV). Must not be disposed of together with household garbage. Do not allow product to reach sewage system. Must be specially treated under adherence to official regulations.

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

Recommended cleaning agent: Water, if needed detergent

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

Shelf-life: 18 months

Products need to be protected from frost, stored at temperatures not exceeding 30 °C and away from direct sunlight.

6. OTHER INFORMATION

—

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 1

7.1. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	Dip es barriere Dip es barriere 1.4 Iod Dip F 14 P				
Authorisation number	EU-0018724-0001 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		1,16
Acetic acid	Acetic acid	Non active substance	64-19-7	200-580-7	0

META SPC 2

1. META SPC 2 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 2 identifier

Identifier	meta SPC 2
------------	------------

1.2. Suffix to the authorisation number

Number	1-2
--------	-----

1.3. Product type(s)

Product type(s)	PT03 — Veterinary hygiene (Disinfectants)

2. META SPC 2 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	0	0
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		1,56	2,5
Acetic acid	Acetic acid	Non active substance	64-19-7	200-580-7	0	0

2.2. Type(s) of formulation of the meta SPC 2

Formulation	AL — Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 2

Hazard statements	Harmful to aquatic life with long lasting effects.
Precautionary statements	If medical advice is needed, have product container or label at hand. Keep out of reach of children. Avoid release to the environment. Dispose of contents to local/regional/national/international regulation. Dispose of container to local/regional/national/international regulation.

4. AUTHORISED USE(S) OF THE META SPC 2

4.1. Use description

Table 3. Use # 1 — Teat disinfection of milkable animals: Post-milking teat disinfection by manual dipping

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Manual dipping using a dip cup
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2-3×/day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

4.1.1. Use-specific instructions for use

The product must be brought to a temperature above 20 °C before use.

The use of a dosing pump for filling the product into the application equipment is recommended.

Fill the reservoir with the RTU product assuming 5 mL product per cow and screw the dip cup on top. Avoid discharge of surplus fluids.

Clean the teats carefully by wiping with a single service paper towel/cloth immediately before milking.

After milking, squeeze the reservoir and put the dip cup over each teat from below making sure that about 3 cm of the teat are immersed into the disinfectant.

Refill the cup of the dipping unit with fresh disinfectant by squeezing the reservoir as needed. Refill the reservoir with fresh disinfectant as needed.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

After disinfection, empty the reservoir and clean reservoir and dip cup by rinsing with water.

4.1.2. Use-specific risk mitigation measures

In case a combination of pre- and post-milking disinfection is necessary, using another product not containing iodine has to be considered for pre-milking disinfection.

4.1.3. Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See general directions for use.

4.1.4. Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use.

4.1.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use.

4.2. Use description

Table 4. Use # 2 — Teat disinfection of milkable animals: Post-milking teat disinfection by automated dipping

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Automated dipping
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2 - 3×/day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

4.2.1. Use-specific instructions for use

The product must be brought to a temperature above 20 °C before use.

Open a can containing the RTU product and insert a suction tube of the automated dipping-system. Avoid discharge of surplus fluids.

After milking, the vacuum is shut off and the teat dip is injected into a manifold on the clawpiece. The teats are coated with ca. 5 mL of dip when the teat cup is withdrawn by the Automatic Cluster Removal (ACR). After the removal of the ACR, every liner of the automated dipping-system is thoroughly rinsed with water and blown out with compressed air.

In a final cleaning step after each milking session of the herd, the liners are disinfected (e.g. with a chlorine-based product) and blown out again with compressed air.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

Afterwards, the milking system is ready for the next milking event.

The whole process is automated.

4.2.2. *Use-specific risk mitigation measures*

In case a combination of pre- and post-milking disinfection is necessary, using another product not containing iodine has to be considered for pre-milking disinfection.

4.2.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use.

4.2.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use.

4.2.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use.

5. GENERAL DIRECTIONS FOR USE ⁽¹⁾ OF THE META SPC 2

5.1. **Instructions for use**

See use specific instructions for use.

5.2. **Risk mitigation measures**

See use specific risk mitigation measures.

5.3. **Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment**

Mentioned in the MSDS

Description of first aid measures

After inhalation: Supply fresh air; consult doctor in case of symptoms.

After skin contact: Instantly wash with water and soap and rinse thoroughly.

After eye contact: Rinse opened eye for several minutes under running water (at least 15 minutes).

After swallowing: Rinse out mouth and then drink plenty of water. Instantly call for doctor.

If medical advice is needed, have product container or label at hand.

Stability and reactivity

Reactivity: No dangerous reactions known.

Chemical stability: The product is chemically stable under normal surroundings terms (ambient temperature).

Possibility of hazardous reactions: By designated use no dangerous reactions are to be expected.

Conditions to avoid: Not determined.

Incompatible materials: Not determined.

Hazardous decomposition products: No dangerous decomposition products known.

Accidental release measures

Personal precautions, protective equipment and emergency procedures: Wear protective clothing.

Ensure adequate ventilation.

Keep ignition sources away — Do not smoke.

⁽¹⁾ Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC2.

Environmental precautions: Do not allow to enter drainage system, surface or ground water.

Methods and material for containment and cleaning up: Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Dispose of the material collected according to regulations.

5.4. Instructions for safe disposal of the product and its packaging

Mentioned in the MSDS

Waste treatment methods: Hazardous waste (AVV). Must not be disposed of together with household garbage. Do not allow product to reach sewage system. Must be specially treated under adherence to official regulations.

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

Recommended cleaning agent: Water, if needed detergent.

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

Shelf-life: 18 months

Products need to be protected from frost, stored at temperatures not exceeding 30 °C and away from direct sunlight.

6. OTHER INFORMATION

—

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 2

7.1. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	Dip es Io-film Dip es Io-film 3.0 Iod-Dip Io-film 30				
Authorisation number	EU-0018724-0002 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		2,5
Acetic acid	Acetic acid	Non active substance	64-19-7	200-580-7	0

META SPC 3

1. META SPC 3 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 3 identifier

Identifier	meta SPC 3
------------	------------

1.2. Suffix to the authorisation number

Number	1-3
--------	-----

1.3. **Product type(s)**

Product type(s)	PT03 — Veterinary hygiene (Disinfectants)

2. META SPC 3 COMPOSITION

2.1. **Qualitative and quantitative information on the composition of the meta SPC 3**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	0	0
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		1,56	4,16
Acetic acid	Acetic acid	Non active substance	64-19-7	200-580-7	0	0

2.2. **Type(s) of formulation of the meta SPC 3**

Formulation	AL — Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 3

Hazard statements	Harmful to aquatic life with long lasting effects.
Precautionary statements	If medical advice is needed, have product container or label at hand. Keep out of reach of children. Avoid release to the environment. Dispose of contents to local/regional/national/international regulation. Dispose of container to local/regional/national/international regulation.

4. AUTHORISED USE(S) OF THE META SPC 3

4.1. **Use description****Table 5. Use # 1 — Teat disinfection of milkable animals: Post-milking teat disinfection by manual dipping**

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking

Application method(s)	Manual dipping using a dip cup
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2-3×/day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerry can (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

4.1.1. *Use-specific instructions for use*

The product must be brought to a temperature above 20 °C before use.

The use of a dosing pump for filling the product into the application equipment is recommended.

Fill the reservoir with the RTU product assuming 5 mL product per cow and screw the dip cup on top. Avoid discharge of surplus fluids.

Clean the teats carefully by wiping with a single service paper towel/cloth immediately before milking.

After milking, squeeze the reservoir and put the dip cup over each teat from below making sure that about 3 cm of the teat are immersed into the disinfectant.

Refill the cup of the dipping unit with fresh disinfectant by squeezing the reservoir as needed. Refill the reservoir with fresh disinfectant as needed.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

After disinfection, empty the reservoir and clean reservoir and dip cup by rinsing with water.

4.1.2. *Use-specific risk mitigation measures*

In case a combination of pre- and post-milking disinfection is necessary, using another product not containing iodine has to be considered for pre-milking disinfection.

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use.

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use.

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use.

4.2. **Use description**

Table 6. Use # 2 — Teat disinfection of milkable animals: Post-milking teat disinfection by automated dipping

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts

Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Automated dipping
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2 - 3×/day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

4.2.1. *Use-specific instructions for use*

The product must be brought to a temperature above 20 °C before use.

Open a can containing the RTU product and insert a suction tube of the automated dipping-system. Avoid discharge of surplus fluids.

After milking, the vacuum is shut off and the teat dip is injected into a manifold on the clawpiece. The teats are coated with ca. 5 mL of dip when the teat cup is withdrawn by the Automatic Cluster Removal (ACR). After the removal of the ACR, every liner of the automated dipping-system is thoroughly rinsed with water and blown out with compressed air.

In a final cleaning step after each milking session of the herd, the liners are disinfected (e.g. with a chlorine-based product) and blown out again with compressed air.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

Afterwards, the milking system is ready for the next milking event.

The whole process is automated.

4.2.2. *Use-specific risk mitigation measures*

In case a combination of pre- and post-milking disinfection is necessary, using another product not containing iodine has to be considered for pre-milking disinfection.

4.2.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use.

4.2.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use.

4.2.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use.

5. GENERAL DIRECTIONS FOR USE ⁽¹⁾ OF THE META SPC 3

5.1. **Instructions for use**

See use specific instructions for use.

⁽¹⁾ Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC3.

5.2. Risk mitigation measures

See use specific risk mitigation measures.

5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Mentioned in the MSDS

Description of first aid measures

After inhalation: Supply fresh air; consult doctor in case of symptoms.

After skin contact: Instantly wash with water and soap and rinse thoroughly.

After eye contact: Rinse opened eye for several minutes under running water (at least 15 minutes).

After swallowing: Rinse out mouth and then drink plenty of water. Instantly call for doctor.

If medical advice is needed, have product container or label at hand.

Stability and reactivity

Reactivity: No dangerous reactions known.

Chemical stability: The product is chemically stable under normal surroundings terms (ambient temperature).

Possibility of hazardous reactions: By designated use no dangerous reactions are to be expected.

Conditions to avoid: Not determined.

Incompatible materials: Not determined.

Hazardous decomposition products: No dangerous decomposition products known.

Accidental release measures

Personal precautions, protective equipment and emergency procedures: Wear protective clothing.

Ensure adequate ventilation.

Keep ignition sources away — Do not smoke.

Environmental precautions: Do not allow to enter drainage system, surface or ground water.

Methods and material for containment and cleaning up: Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Dispose of the material collected according to regulations.

5.4. Instructions for safe disposal of the product and its packaging

Mentioned in the MSDS

Waste treatment methods: Hazardous waste (AVV). Must not be disposed of together with household garbage. Do not allow product to reach sewage system. Must be specially treated under adherence to official regulations.

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

Recommended cleaning agent: Water, if needed detergent.

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

Shelf-life: 18 months

Products need to be protected from frost, stored at temperatures not exceeding 30 °C and away from direct sunlight.

6. OTHER INFORMATION

—

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 3

7.1. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	Dip es barriere S Dip es barriere 3.0 Iod-Dip F 30 P Baktostop Barrier color				
Authorisation number	EU-0018724-0003 1-3				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		2,5
Acetic acid	Acetic acid	Non active substance	64-19-7	200-580-7	0

7.2. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	Dip es barriere RS Dip es barriere 5.0 Iod-Dip F 50 P BaktoStop barrier				
Authorisation number	EU-0018724-0004 1-3				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		4,16
Acetic acid	Acetic acid	Non active substance	64-19-7	200-580-7	0

META SPC 4

1. META SPC 4 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 4 identifier

Identifier	meta SPC 4
------------	------------

1.2. Suffix to the authorisation number

Number	1-4
--------	-----

1.3. **Product type(s)**

Product type(s)	PT03 — Veterinary hygiene (Disinfectants)

2. META SPC 4 COMPOSITION

2.1. **Qualitative and quantitative information on the composition of the meta SPC 4**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	0	0
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		1,56	2,5
Acetic acid	Acetic acid	Non active substance	64-19-7	200-580-7	0	0

2.2. **Type(s) of formulation of the meta SPC 4**

Formulation	AL — Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 4

Hazard statements	Harmful to aquatic life with long lasting effects.
Precautionary statements	If medical advice is needed, have product container or label at hand. Keep out of reach of children. Avoid release to the environment. Dispose of contents to local/regional/national/international regulation. Dispose of container to local/regional/national/international regulation.

4. AUTHORISED USE(S) OF THE META SPC 4

4.1. **Use description****Table 7. Use # 1 — Teat disinfection of milkable animals: Post-milking teat disinfection by manual dipping**

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking

Application method(s)	Manual dipping using a dip cup
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2-3×/day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerry can (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

4.1.1. *Use-specific instructions for use*

The product must be brought to a temperature above 20 °C before use.

The use of a dosing pump for filling the product into the application equipment is recommended.

Fill the reservoir with the RTU product assuming 5 mL product per cow and screw the dip cup on top. Avoid discharge of surplus fluids.

Clean the teats carefully by wiping with a single service paper towel/cloth immediately before milking.

After milking, squeeze the reservoir and put the dip cup over each teat from below making sure that about 3 cm of the teat are immersed into the disinfectant.

Refill the cup of the dipping unit with fresh disinfectant by squeezing the reservoir as needed. Refill the reservoir with fresh disinfectant as needed.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

After disinfection, empty the reservoir and clean reservoir and dip cup by rinsing with water.

4.1.2. *Use-specific risk mitigation measures*

In case a combination of pre- and post-milking disinfection is necessary, using another product not containing iodine has to be considered for pre-milking disinfection.

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use.

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use.

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use.

4.2. **Use description**

Table 8. Use # 2 — Teat disinfection of milkable animals: Post-milking teat disinfection by manual spraying using a trigger sprayer

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts

Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Manual spraying using a trigger sprayer
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2 - 3×/day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

4.2.1. *Use-specific instructions for use*

The product must be brought to a temperature above 20 °C before use.

The use of a dosing pump for filling the product into the application equipment is recommended.

Fill the reservoir with the RTU product assuming 5 mL product per cow and screw the top of the trigger sprayer on it. Avoid discharge of surplus fluids.

Clean the teats carefully by wiping with a single service paper towel/cloth immediately before milking.

After milking, spray the disinfectant on the teats using the trigger sprayer making sure that about 3 cm of the teat around the streak canal are covered with the disinfectant.

Refill the reservoir of the trigger sprayer with fresh disinfectant as needed.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

After disinfection, empty the reservoir and clean reservoir and trigger sprayer by rinsing with water.

4.2.2. *Use-specific risk mitigation measures*

Use chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) during postmilking teat disinfection by manual spraying using a trigger sprayer.

Avoid working in a spray mist.

In case a combination of pre- and post-milking disinfection is necessary, using another product not containing iodine has to be considered for pre-milking disinfection.

4.2.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use.

4.2.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use.

4.2.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use.

4.3. Use description

Table 9. Use # 3 — Teat disinfection of milkable animals: Post-milking teat disinfection by manual spraying using an electronic sprayer

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Manual spraying using an electronic sprayer
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2 - 3×/day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

4.3.1. Use-specific instructions for use

The product must be brought to a temperature above 20 °C before use.

Open a can containing the RTU product assuming 5 mL product per cow and insert a sucking lance of the electronic sprayer. Avoid discharge of surplus fluids.

Clean carefully the teats by wiping with a single service paper towel/cloth before milking.

After milking, spray the disinfectant on the teats using the electronic sprayer making sure that about 3 cm of the teat around the streak canal are covered with the disinfectant.

Replace the empty can by a new can containing the RTU product as needed.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

After disinfection, put the sucking lance system into a bucket of water and rinse the sprayer by pumping the water through the sprayer.

4.3.2. Use-specific risk mitigation measures

Use chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) during postmilking teat disinfection by manual spraying using an electronic sprayer.

Avoid working in spray mist.

In case a combination of pre- and post-milking disinfection is necessary, using another product not containing iodine has to be considered for pre-milking disinfection.

4.3.3. Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See general directions for use.

4.3.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use.

4.3.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use.

4.4. **Use description**

Table 10. Use # 4 — Teat disinfection of milkable animals: Post-milking teat disinfection by automated dipping

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Automated dipping
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2 - 3×/day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

4.4.1. *Use-specific instructions for use*

The product must be brought to a temperature above 20 °C before use.

Open a can containing the RTU product and insert a suction tube of the automated dipping-system. Avoid discharge of surplus fluids.

After milking, the vacuum is shut off and the teat dip is injected into a manifold on the clawpiece. The teats are coated with ca. 5 mL of dip when the teat cup is withdrawn by the Automatic Cluster Removal (ACR). After the removal of the ACR, every liner of the automated dipping-system is thoroughly rinsed with water and blown out with compressed air.

In a final cleaning step after each milking session of the herd, the liners are disinfected (e.g. with a chlorine-based product) and blown out again with compressed air.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

Afterwards, the milking system is ready for the next milking event.

The whole process is automated.

4.4.2. *Use-specific risk mitigation measures*

In case a combination of pre- and post-milking disinfection is necessary, using another product not containing iodine has to be considered for pre-milking disinfection.

4.4.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use.

4.4.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use.

4.4.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use.

4.5. **Use description**

Table 11. Use # 5 — Teat disinfection of milkable animals: Post-milking teat disinfection by automated spraying by robot

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Automated spraying by robot
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2 - 3×/day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

4.5.1. *Use-specific instructions for use*

The product must be brought to a temperature above 20 °C before use.

Open a can containing the RTU product and insert a suction tube of the robotic milking device. Avoid discharge of surplus fluids.

The teats are cleaned by robot with automatic brushes.

After robotic milking, the disinfectant is sprayed automatically onto teats from a cluster arm.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

Rinsing of the sprayer is automatic.

4.5.2. *Use-specific risk mitigation measures*

In case a combination of pre- and post-milking disinfection is necessary, using another product not containing iodine has to be considered for pre-milking disinfection.

4.5.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use.

4.5.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use.

4.5.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use.

5. GENERAL DIRECTIONS FOR USE ⁽¹⁾ OF THE META SPC 4

5.1. **Instructions for use**

See use specific instructions for use.

5.2. **Risk mitigation measures**

See use specific risk mitigation measures.

5.3. **Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment**

Mentioned in the MSDS

Description of first aid measures

After inhalation: Supply fresh air; consult doctor in case of symptoms.

After skin contact: Instantly wash with water and soap and rinse thoroughly.

After eye contact: Rinse opened eye for several minutes under running water (at least 15 minutes).

After swallowing: Rinse out mouth and then drink plenty of water. Instantly call for doctor.

If medical advice is needed, have product container or label at hand.

Stability and reactivity

Reactivity: No dangerous reactions known.

Chemical stability: The product is chemically stable under normal surroundings terms (ambient temperature).

Possibility of hazardous reactions: By designated use no dangerous reactions are to be expected.

Conditions to avoid: Not determined.

Incompatible materials: Not determined.

Hazardous decomposition products: No dangerous decomposition products known.

Accidental release measures

Personal precautions, protective equipment and emergency procedures:

Wear protective clothing.

Ensure adequate ventilation.

Keep ignition sources away — Do not smoke.

⁽¹⁾ Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC4.

Environmental precautions: Do not allow to enter drainage system, surface or ground water.

Methods and material for containment and cleaning up: Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Dispose of the material collected according to regulations.

5.4. Instructions for safe disposal of the product and its packaging

Mentioned in the MSDS

Waste treatment methods: Hazardous waste (AVV). Must not be disposed of together with household garbage. Do not allow product to reach sewage system. Must be specially treated under adherence to official regulations.

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

Recommended cleaning agent: Water, if needed detergent.

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

Shelf-life: 18 months

Products need to be protected from frost, stored at temperatures not exceeding 30 °C and away from direct sunlight.

6. OTHER INFORMATION

—

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 4

7.1. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	Dip es silver				
Authorisation number	EU-0018724-0005 1-4				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		2,5
Acetic acid	Acetic acid	Non active substance	64-19-7	200-580-7	0

META SPC 5

1. META SPC 5 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 5 identifier

Identifier	meta SPC 5
------------	------------

1.2. Suffix to the authorisation number

Number	1-5
--------	-----

1.3. **Product type(s)**

Product type(s)	PT03 — Veterinary hygiene (Disinfectants)

2. META SPC 5 COMPOSITION

2.1. **Qualitative and quantitative information on the composition of the meta SPC 5**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	0	0
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		1,16	1,16
Acetic acid	Acetic acid	Non active substance	64-19-7	200-580-7	0	0

2.2. **Type(s) of formulation of the meta SPC 5**

Formulation	AL — Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 5

Hazard statements	
Precautionary statements	If medical advice is needed, have product container or label at hand. Keep out of reach of children.

4. AUTHORISED USE(S) OF THE META SPC 5

4.1. **Use description****Table 12. Use # 1 — Teat disinfection of milkable animals: Post-milking teat disinfection by manual dipping**

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Manual dipping using a dip cup
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2-3×/day (after each milking)

Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

4.1.1. *Use-specific instructions for use*

The product must be brought to a temperature above 20 °C before use.

The use of a dosing pump for filling the product into the application equipment is recommended.

Fill the reservoir with the RTU product assuming 5 mL product per cow and screw the dip cup on top. Avoid discharge of surplus fluids.

Clean the teats carefully by wiping with a single service paper towel/cloth immediately before milking.

After milking, squeeze the reservoir and put the dip cup over each teat from below making sure that about 3 cm of the teat are immersed into the disinfectant.

Refill the cup of the dipping unit with fresh disinfectant by squeezing the reservoir as needed. Refill the reservoir with fresh disinfectant as needed.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

After disinfection, empty the reservoir and clean reservoir and dip cup by rinsing with water.

4.1.2. *Use-specific risk mitigation measures*

In case a combination of pre- and post-milking disinfection is necessary, using another product not containing iodine has to be considered for pre-milking disinfection.

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use.

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use.

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use.

4.2. **Use description**

Table 13. Use # 2 — Teat disinfection of milkable animals: Post-milking teat disinfection by manual spraying using a trigger sprayer

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking

Application method(s)	Manual spraying using a trigger sprayer
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2 - 3×/day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerry can (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

4.2.1. Use-specific instructions for use

The product must be brought to a temperature above 20 °C before use.

The use of a dosing pump for filling the product into the application equipment is recommended.

Fill the reservoir with the RTU product assuming 5 mL product per cow and screw the top of the trigger sprayer on it. Avoid discharge of surplus fluids.

Clean the teats carefully by wiping with a single service paper towel/cloth immediately before milking.

After milking, spray the disinfectant on the teats using the trigger sprayer making sure that about 3 cm of the teat around the streak canal are covered with the disinfectant.

Refill the reservoir of the trigger sprayer with fresh disinfectant as needed.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

After disinfection, empty the reservoir and clean reservoir and trigger sprayer by rinsing with water.

4.2.2. Use-specific risk mitigation measures

Avoid working in a spray mist.

In case a combination of pre- and post-milking disinfection is necessary, using another product not containing iodine has to be considered for pre-milking disinfection.

4.2.3. Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See general directions for use.

4.2.4. Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use.

4.2.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use.

4.3. Use description

Table 14. Use # 3 — Teat disinfection of milkable animals: Post-milking teat disinfection by manual spraying using an electronic sprayer

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts

Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Manual spraying using an electronic sprayer
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2 - 3×/day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

4.3.1. *Use-specific instructions for use*

The product must be brought to a temperature above 20 °C before use.

Open a can containing the RTU product assuming 5 mL product per cow and insert a sucking lance of the electronic sprayer. Avoid discharge of surplus fluids.

Clean carefully the teats by wiping with a single service paper towel/cloth before milking.

After milking, spray the disinfectant on the teats using the electronic sprayer making sure that about 3 cm of the teat around the streak canal are covered with the disinfectant.

Replace the empty can by a new can containing the RTU product as needed.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

After disinfection, put the sucking lance system into a bucket of water and rinse the sprayer by pumping the water through the sprayer.

4.3.2. *Use-specific risk mitigation measures*

Avoid working in a spray mist.

In case a combination of pre- and post-milking disinfection is necessary, using another product not containing iodine has to be considered for pre-milking disinfection.

4.3.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use.

4.3.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use.

4.3.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use.

4.4. **Use description**

Table 15. Use # 4 — Teat disinfection of milkable animals: Post-milking teat disinfection by automated dipping

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—

Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Automated dipping
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2 - 3×/day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

4.4.1. Use-specific instructions for use

The product must be brought to a temperature above 20 °C before use.

Open a can containing the RTU product and insert a suction tube of the automated dipping-system. Avoid discharge of surplus fluids.

After milking, the vacuum is shut off and the teat dip is injected into a manifold on the clawpiece. The teats are coated with ca. 5 mL of dip when the teat cup is withdrawn by the Automatic Cluster Removal (ACR). After the removal of the ACR, every liner of the automated dipping-system is thoroughly rinsed with water and blown out with compressed air.

In a final cleaning step after each milking session of the herd, the liners are disinfected (e.g. with a chlorine-based product) and blown out again with compressed air.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

Afterwards, the milking system is ready for the next milking event.

The whole process is automated.

4.4.2. Use-specific risk mitigation measures

In case a combination of pre- and post-milking disinfection is necessary, using another product not containing iodine has to be considered for pre-milking disinfection.

4.4.3. Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See general directions for use.

4.4.4. Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use.

4.4.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use.

4.5. Use description

Table 16. Use # 5 — Teat disinfection of milkable animals: Post-milking teat disinfection by automated spraying by robot

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Automated spraying by robot
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2 - 3×/day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

4.5.1. Use-specific instructions for use

The product must be brought to a temperature above 20 °C before use.

Open a can containing the RTU product and insert a suction tube of the robotic milking device. Avoid discharge of surplus fluids.

The teats are cleaned by robot with automatic brushes.

After robotic milking, the disinfectant is sprayed automatically onto teats from a cluster arm.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

Rinsing of the sprayer is automatic.

4.5.2. Use-specific risk mitigation measures

In case a combination of pre- and post-milking disinfection is necessary, using another product not containing iodine has to be considered for pre-milking disinfection.

4.5.3. Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See general directions for use.

4.5.4. Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use.

4.5.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use.

5. GENERAL DIRECTIONS FOR USE ⁽¹⁾ OF THE META SPC 5

5.1. **Instructions for use**

See use specific instructions for use.

5.2. **Risk mitigation measures**

See use specific risk mitigation measures.

5.3. **Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment**

Mentioned in the MSDS

Description of first aid measures

After inhalation: Supply fresh air; consult doctor in case of symptoms.

After skin contact: Instantly wash with water and soap and rinse thoroughly.

After eye contact: Rinse opened eye for several minutes under running water (at least 15 minutes).

After swallowing: Rinse out mouth and then drink plenty of water. Instantly call for doctor.

If medical advice is needed, have product container or label at hand.

Stability and reactivity

Reactivity: No dangerous reactions known.

Chemical stability: The product is chemically stable under normal surroundings terms (ambient temperature).

Possibility of hazardous reactions: By designated use no dangerous reactions are to be expected.

Conditions to avoid: Not determined.

Incompatible materials: Not determined.

Hazardous decomposition products: No dangerous decomposition products known.

Accidental release measures

Personal precautions, protective equipment and emergency procedures: Wear protective clothing.

Ensure adequate ventilation.

Keep ignition sources away — Do not smoke.

Environmental precautions: Do not allow to enter drainage system, surface or ground water.

Methods and material for containment and cleaning up: Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Dispose of the material collected according to regulations.

5.4. **Instructions for safe disposal of the product and its packaging**

Mentioned in the MSDS

Waste treatment methods: Hazardous waste (AVV). Must not be disposed of together with household garbage. Do not allow product to reach sewage system. Must be specially treated under adherence to official regulations.

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

Recommended cleaning agent: Water, if needed detergent.

⁽¹⁾ Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC5.

5.5. **Conditions of storage and shelf-life of the product under normal conditions of storage**

Shelf-life: 18 months

Products need to be protected from frost, stored at temperatures not exceeding 30 °C and away from direct sunlight.

6. OTHER INFORMATION

—

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 5

7.1. **Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	Dip es SF Dip es SF 3.0 Iod Dip S 30 P Dip es SF 1.4 Iod-Dip S 14 P EUTADIPP				
Authorisation number	EU-0018724-0006 1-5				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		1,16
Acetic acid	Acetic acid	Non active substance	64-19-7	200-580-7	0

META SPC 6

1. META SPC 6 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 6 identifier**

Identifier	meta SPC 6
------------	------------

1.2. **Suffix to the authorisation number**

Number	1-6
--------	-----

1.3. **Product type(s)**

Product type(s)	PT03 — Veterinary hygiene (Disinfectants)

2. META SPC 6 COMPOSITION

2.1. **Qualitative and quantitative information on the composition of the meta SPC 6**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	0	0

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		1,16	1,16
Acetic acid	Acetic acid	Non active substance	64-19-7	200-580-7	0	0

2.2. Type(s) of formulation of the meta SPC 6

Formulation	AL — Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 6

Hazard statements	
Precautionary statements	If medical advice is needed, have product container or label at hand. Keep out of reach of children.

4. AUTHORISED USE(S) OF THE META SPC 6

4.1. Use description

Table 17. Use # 1 — Teat disinfection of milkable animals: Pre-milking teat disinfection by manual foaming

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use before milking
Application method(s)	Manual foaming using a foam cup
Application rate(s) and frequency	Cows: 5 mL per treatment Pre-milking application: 2-3×/day (before each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerry can (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

4.1.1. Use-specific instructions for use

The product must be brought to a temperature above 20 °C before use.

The use of a dosing pump for filling the product into the application equipment is recommended.

Fill the reservoir with the RTU product assuming 5 mL product per cow and screw the foam cup on top. Avoid discharge of surplus fluids.

Clean the teats carefully by wiping with a single service paper towel/cloth before pre-milking disinfection.

Before milking, squeeze the reservoir and put the foam cup over each teat from below making sure that about 3 cm of the teat are immersed into the disinfectant.

Leave the product on the teats for at least 60 seconds.

Refill the cup of the foaming unit with fresh disinfectant by squeezing the reservoir as needed. Refill the reservoir with fresh disinfectant as needed.

Clean the teats carefully by wiping with a single service paper towel/cloth immediately before milking.

After disinfection, empty the reservoir and clean reservoir and foam cup by rinsing with water.

4.1.2. Use-specific risk mitigation measures

This product can be used for pre- and post-milking disinfection in combination. However, it should not be used in combination with a different iodine-based product

4.1.3. Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See general directions for use.

4.1.4. Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use.

4.1.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use.

4.2. Use description

Table 18. Use # 2 — Teat disinfection of milkable animals: Post-milking teat disinfection by manual foaming

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Manual foaming using a foam cup
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2 - 3×/day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

4.2.1. Use-specific instructions for use

The product must be brought to a temperature above 20 °C before use.

The use of a dosing pump for filling the product into the application equipment is recommended.

Fill the reservoir with the RTU product assuming 5 mL product per cow and screw the foam cup on top. Avoid discharge of surplus fluids.

Clean the teats carefully by wiping with a single service paper towel/cloth immediately before milking.

After milking, squeeze the reservoir and put the foam cup over each teat from below making sure that about 3 cm of the teat are immersed into the disinfectant.

Refill the cup of the foaming unit with fresh disinfectant by squeezing the reservoir as needed. Refill the reservoir with fresh disinfectant as needed.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

After disinfection, empty the reservoir and clean reservoir and foam cup by rinsing with water.

4.2.2. Use-specific risk mitigation measures

This product can be used for pre- and post-milking disinfection in combination. However, it should not be used in combination with a different iodine-based product

4.2.3. Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See general directions for use.

4.2.4. Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use.

4.2.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use.

4.3. Use description

Table 19. Use # 3 — Teat disinfection of milkable animals: Post-milking teat disinfection by automated foaming

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria- Yeasts-
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Automated foaming
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2 - 3×/day (after each milking)

Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

4.3.1. *Use-specific instructions for use*

The product must be brought to a temperature above 20 °C before use.

Open a can containing the RTU product and insert a suction tube of the automated foaming-system. Avoid discharge of surplus fluids.

After milking, the vacuum is shut off and the teat disinfectant is injected into a manifold on the clawpiece. The teats are coated with ca. 5 mL of foam when the teat foam cup is withdrawn by the Automatic Cluster Removal (ACR). After the removal of the ACR, every liner of the automated foaming-system is thoroughly rinsed with water and blown out with compressed air.

In a final cleaning step after each milking session of the herd, the liners are disinfected (e.g. with a chlorine-based product) and blown out again with compressed air.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

Afterwards, the milking system is ready for the next milking event.

The whole process is automated.

4.3.2. *Use-specific risk mitigation measures*

This product can be used for pre- and post-milking disinfection in combination. However, it should not be used in combination with a different iodine-based product

4.3.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use.

4.3.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use.

4.3.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use.

4.4. **Use description**

Table 20. Use # 4 — Teat disinfection of milkable animals: Pre- and post-milking teat disinfection by manual foaming

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use before and after milking
Application method(s)	Manual foaming using a foam cup

Application rate(s) and frequency	Cows: 5 mL per treatment Pre- and post-milking application: 4-6 times per day (before and after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

4.4.1. *Use-specific instructions for use*

The product must be brought to a temperature above 20 °C before use.

The use of a dosing pump for filling the product into the application equipment is recommended.

Fill the reservoir with the RTU product assuming 5 mL product per cow and screw the foam cup on top. Avoid discharge of surplus fluids.

Clean the teats carefully by wiping with a single service paper towel/cloth before pre-milking disinfection.

Before milking, squeeze the reservoir and put the foam cup over each teat from below making sure that about 3 cm of the teat are immersed into the disinfectant.

Leave the product on the teats for at least 60 seconds.

Clean the teats carefully by wiping with a cloth immediately before milking. After milking, repeat the disinfection by foaming as described above.

Refill the cup of the foaming unit with fresh disinfectant by squeezing the reservoir as needed. Refill the reservoir with fresh disinfectant as needed.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

After disinfection, empty the reservoir and clean reservoir and foam cup by rinsing with water.

4.4.2. *Use-specific risk mitigation measures*

This product can be used for pre- and post-milking disinfection in combination. However, it should not be used in combination with a different iodine-based product

4.4.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use.

4.4.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use.

4.4.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use.

5. GENERAL DIRECTIONS FOR USE ⁽¹⁾ OF THE META SPC 6

5.1. **Instructions for use**

See use specific instructions for use.

⁽¹⁾ Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC6.

5.2. Risk mitigation measures

See use specific risk mitigation measures.

5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Mentioned in the MSDS

Description of first aid measures

After inhalation: Supply fresh air; consult doctor in case of symptoms.

After skin contact: Instantly wash with water and soap and rinse thoroughly.

After eye contact: Rinse opened eye for several minutes under running water (at least 15 minutes).

After swallowing: Rinse out mouth and then drink plenty of water. Instantly call for doctor.

If medical advice is needed, have product container or label at hand.

Stability and reactivity

Reactivity: No dangerous reactions known.

Chemical stability: The product is chemically stable under normal surroundings terms (ambient temperature).

Possibility of hazardous reactions: By designated use no dangerous reactions are to be expected.

Conditions to avoid: Not determined.

Incompatible materials: Not determined.

Hazardous decomposition products: No dangerous decomposition products known.

Accidental release measures

Personal precautions, protective equipment and emergency procedures:

Wear protective clothing.

Ensure adequate ventilation.

Keep ignition sources away — Do not smoke.

Environmental precautions: Do not allow to enter drainage system, surface or ground water.

Methods and material for containment and cleaning up: Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Dispose of the material collected according to regulations.

5.4. Instructions for safe disposal of the product and its packaging

Mentioned in the MSDS

Waste treatment methods: Hazardous waste (AVV). Must not be disposed of together with household garbage. Do not allow product to reach sewage system. Must be specially treated under adherence to official regulations.

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

Recommended cleaning agent: Water, if needed detergent.

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

Shelf-life: 18 months

Products need to be protected from frost, stored at temperatures not exceeding 30 °C and away from direct sunlight.

6. OTHER INFORMATION

—

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 6

7.1. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	Dip es Io-foam Dip es Io-foam 1.4 Iod-Dip Io-foam BaktoStop foam				
Authorisation number	EU-0018724-0007 1-6				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		1,16
Acetic acid	Acetic acid	Non active substance	64-19-7	200-580-7	0

META SPC 7

1. META SPC 7 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 7 identifier

Identifier	meta SPC 7
------------	------------

1.2. Suffix to the authorisation number

Number	1-7
--------	-----

1.3. Product type(s)

Product type(s)	PT03 — Veterinary hygiene (Disinfectants)

2. META SPC 7 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 7

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	0,14	0,14
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0	0
Acetic acid	Acetic acid	Non active substance	64-19-7	200-580-7	0,11	0,33

2.2. **Type(s) of formulation of the meta SPC 7**

Formulation	AL — Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 7

Hazard statements	Harmful to aquatic life with long lasting effects.
Precautionary statements	Avoid release to the environment. Dispose of contents to local/regional/national/international regulation. Dispose of container to local/regional/national/international regulation.

4. AUTHORISED USE(S) OF THE META SPC 7

4.1. **Use description****Table 21. Use # 1 — Teat disinfection of milkable animals: Post-milking teat disinfection by manual dipping**

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Manual dipping using a dip cup
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2-3×/day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

4.1.1. *Use-specific instructions for use*

The product must be brought to a temperature above 20 °C before use.

The use of a dosing pump for filling the product into the application equipment is recommended.

Fill the reservoir with the RTU product assuming 5 mL product per cow and screw the dip cup on top. Avoid discharge of surplus fluids.

Clean the teats carefully by wiping with a single service paper towel/cloth immediately before milking.

After milking, squeeze the reservoir and put the dip cup over each teat from below making sure that about 3 cm of the teat are immersed into the disinfectant.

Refill the cup of the dipping unit with fresh disinfectant by squeezing the reservoir as needed. Refill the reservoir with fresh disinfectant as needed.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

After disinfection, empty the reservoir and clean reservoir and dip cup by rinsing with water.

4.1.2. *Use-specific risk mitigation measures*

In case a combination of pre- and post-milking disinfection is necessary, using another product not containing iodine has to be considered for pre-milking disinfection.

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use.

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use.

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use.

4.2. **Use description**

Table 22. Use # 2 — Teat disinfection of milkable animals: Post-milking teat disinfection by manual foaming

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Manual foaming using a foam cup
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2-3×/day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

4.2.1. *Use-specific instructions for use*

The product must be brought to a temperature above 20 °C before use.

The use of a dosing pump for filling the product into the application equipment is recommended.

Fill the reservoir with the RTU product assuming 5 mL product per cow and screw the foam cup on top. Avoid discharge of surplus fluids.

Clean the teats carefully by wiping with a single service paper towel/cloth immediately before milking.

After milking, squeeze the reservoir and put the foam cup over each teat from below making sure that about 3 cm of the teat are immersed into the disinfectant.

Refill the cup of the foaming unit with fresh disinfectant by squeezing the reservoir as needed. Refill the reservoir with fresh disinfectant as needed.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

After disinfection, empty the reservoir and clean reservoir and foam cup by rinsing with water.

4.2.2. *Use-specific risk mitigation measures*

In case a combination of pre- and post-milking disinfection is necessary, using another product not containing iodine has to be considered for pre-milking disinfection.

4.2.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use.

4.2.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use.

4.2.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use.

4.3. **Use description**

Table 23. Use # 3 — Teat disinfection of milkable animals: Post-milking teat disinfection by manual spraying using a trigger sprayer

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Manual spraying using a trigger sprayer
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2-3×/day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

4.3.1. *Use-specific instructions for use*

The product must be brought to a temperature above 20 °C before use.

The use of a dosing pump for filling the product into the application equipment is recommended.

Fill the reservoir with the RTU product assuming 5 mL product per cow and screw the top of the trigger sprayer on it. Avoid discharge of surplus fluids.

Clean the teats carefully by wiping with a single service paper towel/cloth immediately before milking.

After milking, spray the disinfectant on the teats using the trigger sprayer making sure that about 3 cm of the teat around the streak canal are covered with the disinfectant.

Refill the reservoir of the trigger sprayer with fresh disinfectant as needed.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

After disinfection, empty the reservoir and clean reservoir and trigger sprayer by rinsing with water.

4.3.2. Use-specific risk mitigation measures

Use chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) during postmilking teat disinfection by manual spraying using a trigger sprayer.

Avoid working in spray mist.

In case a combination of pre- and post-milking disinfection is necessary, using another product not containing iodine has to be considered for pre-milking disinfection.

4.3.3. Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See general directions for use.

4.3.4. Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use.

4.3.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use.

4.4. Use description

Table 24. Use # 4 — Teat disinfection of milkable animals: Post-milking teat disinfection by manual spraying using an electronic sprayer

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Manual spraying using an electronic sprayer
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2-3×/day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

4.4.1. *Use-specific instructions for use*

The product must be brought to a temperature above 20 °C before use.

Open a can containing the RTU product assuming 5 mL product per cow and insert a sucking lance of the electronic sprayer. Avoid discharge of surplus fluids.

Clean carefully the teats by wiping with a single service paper towel/cloth before milking.

After milking, spray the disinfectant on the teats using the electronic sprayer making sure that about 3 cm of the teat around the streak canal are covered with the disinfectant.

Replace the empty can by a new can containing the RTU product as needed.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

After disinfection, put the sucking lance system into a bucket of water and rinse the sprayer by pumping the water through the sprayer.

4.4.2. *Use-specific risk mitigation measures*

Use chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) during post/milking teat disinfection by manual spraying using an electronic sprayer.

Avoid working in spray mist.

In case a combination of pre- and post-milking disinfection is necessary, using another product not containing iodine has to be considered for pre-milking disinfection.

4.4.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use.

4.4.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use.

4.4.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use.

4.5. **Use description**

Table 25. Use # 5 — Teat disinfection of milkable animals: Post-milking teat disinfection by automated dipping

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Automated dipping
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2-3×/day (after each milking)

Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

4.5.1. *Use-specific instructions for use*

The product must be brought to a temperature above 20 °C before use.

Open a can containing the RTU product and insert a suction tube of the automated dipping-system. Avoid discharge of surplus fluids.

After milking, the vacuum is shut off and the teat dip is injected into a manifold on the clawpiece. The teats are coated with ca. 5 mL of dip when the teat cup is withdrawn by the Automatic Cluster Removal (ACR). After the removal of the ACR, every liner of the automated dipping-system is thoroughly rinsed with water and blown out with compressed air.

In a final cleaning step after each milking session of the herd, the liners are disinfected (e.g. with a chlorine-based product) and blown out again with compressed air.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

Afterwards, the milking system is ready for the next milking event.

The whole process is automated.

4.5.2. *Use-specific risk mitigation measures*

In case a combination of pre- and post-milking disinfection is necessary, using another product not containing iodine has to be considered for pre-milking disinfection.

4.5.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use.

4.5.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use.

4.5.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use.

4.6. **Use description**

Table 26. Use # 6 — Teat disinfection of milkable animals: Post-milking teat disinfection by automated foaming

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking

Application method(s)	Automated foaming
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2-3×/day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerry can (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

4.6.1. Use-specific instructions for use

The product must be brought to a temperature above 20 °C before use.

Open a can containing the RTU product and insert a suction tube of the automated foaming-system. Avoid discharge of surplus fluids.

After milking, the vacuum is shut off and the teat disinfectant is injected into a manifold on the clawpiece. The teats are coated with ca. 5 mL of foam when the teat foam cup is withdrawn by the Automatic Cluster Removal (ACR). After the removal of the ACR, every liner of the automated foaming-system is thoroughly rinsed with water and blown out with compressed air.

In a final cleaning step after each milking session of the herd, the liners are disinfected (e.g. with a chlorine-based product) and blown out again with compressed air.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

Afterwards, the milking system is ready for the next milking event.

The whole process is automated.

4.6.2. Use-specific risk mitigation measures

In case a combination of pre- and post-milking disinfection is necessary, using another product not containing iodine has to be considered for pre-milking disinfection.

4.6.3. Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See general directions for use.

4.6.4. Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use.

4.6.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use.

4.7. Use description

Table 27. Use # 7 — Teat disinfection of milkable animals: Post-milking teat disinfection by automated spraying by robot

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts

Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Automated spraying by robot
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2-3×/day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

4.7.1. *Use-specific instructions for use*

The product must be brought to a temperature above 20 °C before use.

Open a can containing the RTU product and insert a suction tube of the robotic milking device. Avoid discharge of surplus fluids.

The teats are cleaned by robot with automatic brushes.

After robotic milking, the disinfectant is sprayed automatically onto teats from a cluster arm.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

Rinsing of the sprayer is automatic.

4.7.2. *Use-specific risk mitigation measures*

In case a combination of pre- and post-milking disinfection is necessary, using another product not containing iodine has to be considered for pre-milking disinfection.

4.7.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use.

4.7.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use.

4.7.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use.

5. GENERAL DIRECTIONS FOR USE ⁽¹⁾ OF THE META SPC 7

5.1. **Instructions for use**

See use specific instructions for use.

5.2. **Risk mitigation measures**

See use specific risk mitigation measures.

⁽¹⁾ Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC7.

5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Mentioned in the MSDS

Description of first aid measures

After inhalation: Supply fresh air; consult doctor in case of symptoms.

After skin contact: Wash with water and soap.

After eye contact: Rinse opened eye for several minutes under running water. Then consult doctor.

After swallowing: Rinse out mouth and then drink plenty of water. Seek immediate medical advice.

Stability and reactivity

Possibility of hazardous reactions: Reaction with oxidant- and reducing agent.

Conditions to avoid: No further relevant information available.

Incompatible materials: No further relevant information available.

Hazardous decomposition products: iodine (when warming up).

Accidental release measures

Personal precautions, protective equipment and emergency procedures: No special measures required.

Environmental precautions: Do not allow product to reach sewage systems or water bodies in great quantities.

Methods and material for containment and cleaning up: Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Dispose of the material collected according to regulations.

5.4. Instructions for safe disposal of the product and its packaging

Mentioned in the MSDS

Waste treatment methods

Recommendation: Must be specially treated with regard to official regulations.

Waste disposal key number: Corresponding to the regulation of the European Waste catalogue the relation of the waste key numbers has to be made specific to industry and process.

European waste catalogue: Corresponding to the regulation of the EWC the relation of the waste key numbers has to be made specific to industry and process.

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

Recommended cleaning agent: Water, if necessary with cleaning agent.

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

Shelf-life: 24 months

Products need to be protected from frost, stored at temperatures not exceeding 30 °C and away from direct sunlight.

6. OTHER INFORMATION

—

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 7

7.1. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	calgodip D 1200 Jod-Dip S 12 Dip es SF 1200				
Authorisation number	EU-0018724-0008 1-7				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,14
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0
Acetic acid	Acetic acid	Non active substance	64-19-7	200-580-7	0,15

META SPC 8

1. META SPC 8 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 8 identifier

Identifier	meta SPC 8
------------	------------

1.2. Suffix to the authorisation number

Number	1-8
--------	-----

1.3. Product type(s)

Product type(s)	PT03 — Veterinary hygiene (Disinfectants)

2. META SPC 8 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 8

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	0,14	0,54
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0	0
Acetic acid	Acetic acid	Non active substance	64-19-7	200-580-7	0,11	0,33

2.2. **Type(s) of formulation of the meta SPC 8**

Formulation	AL — Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 8

Hazard statements	Harmful to aquatic life with long lasting effects.
Precautionary statements	Avoid release to the environment. Dispose of contents to local/regional/national/international regulation. Dispose of container to local/regional/national/international regulation.

4. AUTHORISED USE(S) OF THE META SPC 8

4.1. **Use description****Table 28. Use # 1 — Teat disinfection of milkable animals: Post-milking teat disinfection by manual dipping**

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Manual dipping using a dip cup
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2-3×/day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

4.1.1. *Use-specific instructions for use*

The product must be brought to a temperature above 20 °C before use.

The use of a dosing pump for filling the product into the application equipment is recommended.

Fill the reservoir with the RTU product assuming 5 mL product per cow and screw the dip cup on top. Avoid discharge of surplus fluids.

Clean the teats carefully by wiping with a single service paper towel/cloth immediately before milking.

After milking, squeeze the reservoir and put the dip cup over each teat from below making sure that about 3 cm of the teat are immersed into the disinfectant.

Refill the cup of the dipping unit with fresh disinfectant by squeezing the reservoir as needed. Refill the reservoir with fresh disinfectant as needed.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

After disinfection, empty the reservoir and clean reservoir and dip cup by rinsing with water.

4.1.2. *Use-specific risk mitigation measures*

In case a combination of pre- and post-milking disinfection is necessary, using another product not containing iodine has to be considered for pre-milking disinfection.

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use.

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use.

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use.

4.2. **Use description**

Table 29. Use # 2 — Teat disinfection of milkable animals: Post-milking teat disinfection by automated dipping

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Automated dipping
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2-3×/day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerry can (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

4.2.1. *Use-specific instructions for use*

The product must be brought to a temperature above 20 °C before use.

Open a can containing the RTU product and insert a suction tube of the automated dipping-system. Avoid discharge of surplus fluids.

After milking, the vacuum is shut off and the teat dip is injected into a manifold on the clawpiece. The teats are coated with ca. 5 mL of dip when the teat cup is withdrawn by the Automatic Cluster Removal (ACR). After the removal of the ACR, every liner of the automated dipping-system is thoroughly rinsed with water and blown out with compressed air.

In a final cleaning step after each milking session of the herd, the liners are disinfected (e.g. with a chlorine-based product) and blown out again with compressed air.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

Afterwards, the milking system is ready for the next milking event.

The whole process is automated.

4.2.2. *Use-specific risk mitigation measures*

In case a combination of pre- and post-milking disinfection is necessary, using another product not containing iodine has to be considered for pre-milking disinfection.

4.2.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use.

4.2.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use.

4.2.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use.

5. GENERAL DIRECTIONS FOR USE ⁽¹⁾ OF THE META SPC 8

5.1. **Instructions for use**

See use specific instructions for use.

5.2. **Risk mitigation measures**

See use specific risk mitigation measures.

5.3. **Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment**

Mentioned in the MSDS

Description of first aid measures

After inhalation: Supply fresh air; consult doctor in case of symptoms.

After skin contact: Wash with water and soap. If skin irritation continues, consult a doctor.

After eye contact: Rinse opened eye for several minutes under running water. If symptoms persist, consult doctor.

After swallowing: Rinse out mouth and then drink plenty of water. Seek medical treatment.

Stability and reactivity

Reactivity: No further relevant information available.

Chemical stability/thermal decomposition/conditions to be avoided: No decomposition if used according to specifications.

Possibility of hazardous reactions: No dangerous reactions known.

Conditions to avoid: No further relevant information available.

Incompatible materials: No further relevant information available.

⁽¹⁾ Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC8.

Hazardous decomposition products: iodine (when warming up).

Accidental release measures

Personal precautions, protective equipment and emergency procedures: No special measures required.

Environmental precautions: Do not allow product to reach sewage systems or water bodies in great quantities.

Methods and material for containment and cleaning up: Absorb with liquid-binding material (sand, diatomite, acid binders, universal binder). Do not use combustible material like sawdust. Dispose of the material collected according to regulations.

5.4. Instructions for safe disposal of the product and its packaging

Mentioned in the MSDS

Waste treatment methods

Recommendation: Must be specially treated with regard to official regulations.

Waste disposal key number: Corresponding to the regulation of the European Waste catalogue the relation of the waste key numbers has to be made specific to industry and process.

European waste catalogue: Corresponding to the regulation of the EWC the relation of the waste key numbers has to be made specific to industry and process.

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

Shelf-life: 24 months

Products need to be protected from frost, stored at temperatures not exceeding 30 °C and away from direct sunlight.

6. OTHER INFORMATION

—

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 8

7.1. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	calgodip D 3000 Film Jod-Dip F 30 Jod Dipp 30 Film (Technolit) Jod 30 Film (Iwetec) Dip es barriere 3000 Lerapur Dip Jod 30 BaktoStop barrier color 3.0				
Authorisation number	EU-0018724-0009 1-8				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,34
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0
Acetic acid	Acetic acid	Non active substance	64-19-7	200-580-7	0,26

7.2. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	calgodip D 5000 Jod Dip F 50 Jod Dipp 50 (Iwetec) Jod-Dipp 50 (Technolit) Dip es barriere 5000 BaktoStop barrier 5.0				
Authorisation number	EU-0018724-0010 1-8				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,54
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0
Acetic acid	Acetic acid	Non active substance	64-19-7	200-580-7	0,26

META SPC 9

1. META SPC 9 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 9 identifier

Identifier	meta SPC 9
------------	------------

1.2. Suffix to the authorisation number

Number	1-9
--------	-----

1.3. Product type(s)

Product type(s)	PT03 — Veterinary hygiene (Disinfectants)

2. META SPC 9 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 9

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	0,34	0,34
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0	0
Acetic acid	Acetic acid	Non active substance	64-19-7	200-580-7	0,11	0,33

2.2. **Type(s) of formulation of the meta SPC 9**

Formulation	AL — Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 9

Hazard statements	Harmful to aquatic life with long lasting effects.
Precautionary statements	Avoid release to the environment. Dispose of contents to local/regional/national/international regulation. Dispose of container to local/regional/national/international regulation.

4. AUTHORISED USE(S) OF THE META SPC 9

4.1. **Use description****Table 30. Use # 1 — Teat disinfection of milkable animals: Post-milking teat disinfection by manual dipping**

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Manual dipping using a dip cup
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2-3×/day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

4.1.1. *Use-specific instructions for use*

The product must be brought to a temperature above 20 °C before use.

The use of a dosing pump for filling the product into the application equipment is recommended.

Fill the reservoir with the RTU product assuming 5 mL product per cow and screw the dip cup on top. Avoid discharge of surplus fluids.

Clean the teats carefully by wiping with a single service paper towel/cloth immediately before milking. After milking, squeeze the reservoir and put the dip cup over each teat from below making sure that about 3 cm of the teat are immersed into the disinfectant.

Refill the cup of the dipping unit with fresh disinfectant by squeezing the reservoir as needed. Refill the reservoir with fresh disinfectant as needed.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

After disinfection, empty the reservoir and clean reservoir and dip cup by rinsing with water.

4.1.2. Use-specific risk mitigation measures

In case a combination of pre- and post-milking disinfection is necessary, using another product not containing iodine has to be considered for pre-milking disinfection.

4.1.3. Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See general directions for use.

4.1.4. Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use.

4.1.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use.

4.2. Use description

Table 31. Use # 2 — Teat disinfection of milkable animals: Post-milking teat disinfection by manual foaming

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Manual foaming using a foam cup
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2-3×/day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

4.2.1. Use-specific instructions for use

The product must be brought to a temperature above 20 °C before use.

The use of a dosing pump for filling the product into the application equipment is recommended.

Fill the reservoir with the RTU product assuming 5 mL product per cow and screw the foam cup on top. Avoid discharge of surplus fluids.

Clean the teats carefully by wiping with a single service paper towel/cloth immediately before milking.

After milking, squeeze the reservoir and put the foam cup over each teat from below making sure that about 3 cm of the teat are immersed into the disinfectant.

Refill the cup of the foaming unit with fresh disinfectant by squeezing the reservoir as needed. Refill the reservoir with fresh disinfectant as needed.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

After disinfection, empty the reservoir and clean reservoir and foam cup by rinsing with water.

4.2.2. Use-specific risk mitigation measures

In case a combination of pre- and post-milking disinfection is necessary, using another product not containing iodine has to be considered for pre-milking disinfection.

4.2.3. Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See general directions for use.

4.2.4. Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use.

4.2.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use.

4.3. Use description

Table 32. Use # 3 — Teat disinfection of milkable animals: Post-milking teat disinfection by manual spraying using a trigger sprayer

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Manual spraying using a trigger sprayer
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2-3×/day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

4.3.1. Use-specific instructions for use

The product must be brought to a temperature above 20 °C before use.

The use of a dosing pump for filling the product into the application equipment is recommended.

Fill the reservoir with the RTU product assuming 5 mL product per cow and screw the top of the trigger sprayer on it. Avoid discharge of surplus fluids.

Clean the teats carefully by wiping with a single service paper towel/cloth immediately before milking.

After milking, spray the disinfectant on the teats using the trigger sprayer making sure that about 3 cm of the teat around the streak canal are covered with the disinfectant.

Refill the reservoir of the trigger sprayer with fresh disinfectant as needed.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

After disinfection, empty the reservoir and clean reservoir and trigger sprayer by rinsing with water.

4.3.2. *Use-specific risk mitigation measures*

Use chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), coveralls and chemical resistant boots during post-milking teat disinfection by manual spraying using a trigger sprayer.

Avoid working in spray mist.

In case a combination of pre- and post-milking disinfection is necessary, using another product not containing iodine has to be considered for pre-milking disinfection.

4.3.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use.

4.3.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use.

4.3.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use.

4.4. **Use description**

Table 33. Use # 4 — Teat disinfection of milkable animals: Post-milking teat disinfection by manual spraying using an electronic sprayer

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Manual spraying using an electronic sprayer
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2-3×/day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

4.4.1. *Use-specific instructions for use*

The product must be brought to a temperature above 20 °C before use.

Open a can containing the RTU product assuming 5 mL product per cow and insert a sucking lance of the electronic sprayer. Avoid discharge of surplus fluids.

Clean carefully the teats by wiping with a single service paper towel/cloth before milking.

After milking, spray the disinfectant on the teats using the electronic sprayer making sure that about 3 cm of the teat around the streak canal are covered with the disinfectant.

Replace the empty can by a new can containing the RTU product as needed.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

After disinfection, put the sucking lance system into a bucket of water and rinse the sprayer by pumping the water through the sprayer.

4.4.2. *Use-specific risk mitigation measures*

Use chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) during post-milking teat disinfection by manual spraying using an electronic sprayer.

Avoid working in spray mist.

In case a combination of pre- and post-milking disinfection is necessary, using another product not containing iodine has to be considered for pre-milking disinfection.

4.4.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use.

4.4.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use.

4.4.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use.

4.5. **Use description**

Table 34. Use # 5 — Teat disinfection of milkable animals: Post-milking teat disinfection by automated dipping

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Automated dipping
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2-3×/day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

4.5.1. *Use-specific instructions for use*

The product must be brought to a temperature above 20 °C before use.

Open a can containing the RTU product and insert a suction tube of the automated dipping-system. Avoid discharge of surplus fluids.

After milking, the vacuum is shut off and the teat dip is injected into a manifold on the clawpiece. The teats are coated with ca. 5 mL of dip when the teat cup is withdrawn by the Automatic Cluster Removal (ACR). After the removal of the ACR, every liner of the automated dipping-system is thoroughly rinsed with water and blown out with compressed air.

In a final cleaning step after each milking session of the herd, the liners are disinfected (e.g. with a chlorine-based product) and blown out again with compressed air.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

Afterwards, the milking system is ready for the next milking event.

The whole process is automated.

4.5.2. *Use-specific risk mitigation measures*

In case a combination of pre- and post-milking disinfection is necessary, using another product not containing iodine has to be considered for pre-milking disinfection.

4.5.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use.

4.5.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use.

4.5.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use.

4.6. **Use description**

Table 35. Use # 6 — Teat disinfection of milkable animals: Post-milking teat disinfection by automated foaming

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Automated foaming
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2-3×/day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

4.6.1. Use-specific instructions for use

The product must be brought to a temperature above 20 °C before use.

Open a can containing the RTU product and insert a suction tube of the automated foaming-system. Avoid discharge of surplus fluids.

After milking, the vacuum is shut off and the teat disinfectant is injected into a manifold on the clawpiece. The teats are coated with ca. 5 mL of foam when the teat foam cup is withdrawn by the Automatic Cluster Removal (ACR). After the removal of the ACR, every liner of the automated foaming-system is thoroughly rinsed with water and blown out with compressed air.

In a final cleaning step after each milking session of the herd, the liners are disinfected (e.g. with a chlorine-based product) and blown out again with compressed air.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

Afterwards, the milking system is ready for the next milking event.

The whole process is automated.

4.6.2. Use-specific risk mitigation measures

In case a combination of pre- and post-milking disinfection is necessary, using another product not containing iodine has to be considered for pre-milking disinfection.

4.6.3. Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See general directions for use.

4.6.4. Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use.

4.6.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use.

4.7. Use description

Table 36. Use # 7 — Teat disinfection of milkable animals: Post-milking teat disinfection by automated spraying by robot

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Automated spraying by robot
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2-3×/day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

4.7.1. *Use-specific instructions for use*

The product must be brought to a temperature above 20 °C before use.

Open a can containing the RTU product and insert a suction tube of the robotic milking device. Avoid discharge of surplus fluids.

The teats are cleaned by robot with automatic brushes.

After robotic milking, the disinfectant is sprayed automatically onto teats from a cluster arm.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

Rinsing of the sprayer is automatic.

4.7.2. *Use-specific risk mitigation measures*

In case a combination of pre- and post-milking disinfection is necessary, using another product not containing iodine has to be considered for pre-milking disinfection.

4.7.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use.

4.7.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use.

4.7.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use.

5. GENERAL DIRECTIONS FOR USE ⁽¹⁾ OF THE META SPC 9

5.1. **Instructions for use**

See use specific instructions for use.

5.2. **Risk mitigation measures**

See use specific risk mitigation measures.

5.3. **Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment**

Mentioned in the MSDS

Description of first aid measures

After inhalation: Supply fresh air; consult doctor in case of symptoms.

After skin contact: Wash with water and soap.

After eye contact: Rinse opened eye for several minutes under running water. Then consult doctor.

After swallowing: Rinse out mouth and then drink plenty of water. Seek immediate medical advice.

Stability and reactivity

Possibility of hazardous reactions: Reaction with oxidant- and reducing agent.

Conditions to avoid: No further relevant information available.

Incompatible materials: No further relevant information available.

Hazardous decomposition products: iodine (when warming up).

⁽¹⁾ Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC9.

Accidental release measures

Personal precautions, protective equipment and emergency procedures: No special measures required.

Environmental precautions: Do not allow product to reach sewage systems or water bodies in great quantities.

Methods and material for containment and cleaning up: Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Dispose of the material collected according to regulations.

5.4. Instructions for safe disposal of the product and its packaging

Mentioned in the MSDS

Waste treatment methods

Recommendation: Must be specially treated with regard to official regulations.

Waste disposal key number: Corresponding to the regulation of the European Waste catalogue the relation of the waste key numbers has to be made specific to industry and process.

European waste catalogue: Corresponding to the regulation of the EWC the relation of the waste key numbers has to be made specific to industry and process.

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

Recommended cleaning agent: Water, if necessary with cleaning agent.

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

Shelf-life: 24 months

Products need to be protected from frost, stored at temperatures not exceeding 30 °C and away from direct sunlight.

6. OTHER INFORMATION

—

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 9

7.1. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	calgodip D 3000 Jod-Dip S 30 Bestfarm Dip Premium Jod 30 Universal (Iwetec) Jod-Dipp 30 (Technolit) Dip es SF 3000 Lerapur Jod SP 30				
Authorisation number	EU-0018724-0011 1-9				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,34
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0
Acetic acid	Acetic acid	Non active substance	64-19-7	200-580-7	0,26

DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2018/1854

of 27 November 2018

on recognition of the ‘Better Biomass’ voluntary scheme for demonstrating compliance with the sustainability criteria under Directives 98/70/EC and 2009/28/EC of the European Parliament and of the Council

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 98/70/EC of the European Parliament and of the Council of 13 October 1998 relating to the quality of petrol and diesel fuels and amending Council Directive 93/12/EEC ⁽¹⁾, and in particular the second subparagraph of Article 7c(4) thereof,

Having regard to Directive 2009/28/EC of the European Parliament and of the Council of 23 April 2009 on the promotion of the use of energy from renewable sources and amending and subsequently repealing Directives 2001/77/EC and 2003/30/EC ⁽²⁾, and in particular the second subparagraph of Article 18(4) thereof,

Whereas:

- (1) Articles 7b and 7c of, and Annex IV to, Directive 98/70/EC and Articles 17 and 18 of, and Annex V to, Directive 2009/28/EC lay down similar sustainability criteria for biofuels and bioliquids, and similar procedures for verifying that biofuels and bioliquids comply with those criteria.
- (2) Where biofuels and bioliquids are to be taken into account for the purposes referred to in Article 17(1)(a), (b) and (c) of Directive 2009/28/EC, Member States should require economic operators to show that biofuels and bioliquids comply with the sustainability criteria set out in Article 17(2) to (5) of that Directive.
- (3) The Commission may decide that voluntary national or international schemes setting standards for the production of biomass products contain accurate data for the purposes of Article 17(2) of Directive 2009/28/EC, and/or demonstrate that consignments of biofuel or bioliquid comply with the sustainability criteria set out in Article 17(3), (4) and (5), and/or that no materials have been intentionally modified or discarded so that the consignment or part thereof would fall under Annex IX. Where an economic operator provides proof or data obtained in accordance with a voluntary scheme that has been recognised by the Commission, to the extent covered by the recognition decision, a Member State should not require the supplier to provide further evidence of compliance with the sustainability criteria.
- (4) The request for recognition that the ‘Better Biomass’ voluntary scheme demonstrates that consignments of biofuel comply with the sustainability criteria set out in Directives 98/70/EC and 2009/28/EC was submitted to the Commission on 20 February 2018. The scheme that is based in Vlinderweg 6, NL-2623 AX Delft, The Netherlands, covers a wide range of feedstocks including wastes and residues and the entire chain of custody. The recognised scheme documents should be made available at the transparency platform established under Directive 2009/28/EC.
- (5) In assessing the ‘Better Biomass’ voluntary scheme, the Commission found that it covers adequately the sustainability criteria set out in Directives 98/70/EC and 2009/28/EC, as well as applies a mass balance methodology in accordance with the requirements of Article 7c(1) of Directive 98/70/EC and Article 18(1) of Directive 2009/28/EC.
- (6) The assessment of the ‘Better Biomass’ voluntary scheme found that it meets adequate standards of reliability, transparency and independent auditing and also complies with the methodological requirements set out in Annex IV to Directive 98/70/EC and in Annex V to Directive 2009/28/EC.
- (7) The measures provided for in this Decision are in accordance with the opinion of the Committee on the Sustainability of Biofuels and Bioliquids,

⁽¹⁾ OJ L 350, 28.12.1998, p. 58.

⁽²⁾ OJ L 140, 5.6.2009, p. 16.

HAS ADOPTED THIS DECISION:

Article 1

The 'Better Biomass' voluntary scheme ('the scheme'), submitted for recognition to the Commission on 20 February 2018, demonstrates that consignments of biofuels and bioliquids produced in accordance with the standards for the production of biofuels and bioliquids set in the scheme comply with the sustainability criteria laid down in Article 7b(3), (4) and (5) of Directive 98/70/EC and Article 17(3), (4) and (5) of Directive 2009/28/EC.

The scheme also contains accurate data for the purposes of Article 17(2) of Directive 2009/28/EC and Article 7b(2) of Directive 98/70/EC.

Article 2

In the event that the contents of the scheme, as submitted for recognition to the Commission on 20 February 2018, change in a way that might affect the basis of this Decision, such changes shall be notified to the Commission without delay. The Commission shall assess the notified changes with a view to establishing whether the scheme still adequately covers the sustainability criteria for which it is recognised.

Article 3

The Commission may repeal this Decision *inter alia* under the following circumstances:

- (a) if it has been clearly demonstrated that the scheme has not implemented elements considered to be decisive for this Decision or if severe and structural breach of those elements has taken place;
- (b) if the scheme fails to submit annual reports to the Commission pursuant to Article 7c(6) of Directive 98/70/EC and Article 18(6) of Directive 2009/28/EC;
- (c) if the scheme fails to implement standards of independent auditing specified in implementing acts referred to in the third subparagraph of Article 7c(5) of Directive 98/70/EC and the third subparagraph of Article 18(5) of Directive 2009/28/EC or improvements to other elements of the scheme considered to be decisive for a continued recognition.

Article 4

This Decision shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply until 18 December 2023.

Done at Brussels, 27 November 2018.

For the Commission

The President

Jean-Claude JUNCKER

COMMISSION IMPLEMENTING DECISION (EU) 2018/1855**of 27 November 2018****on greenhouse gas emissions covered by Decision No 406/2009/EC of the European Parliament and of the Council for the year 2016 for each Member State**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 525/2013 of the European Parliament and of the Council of 21 May 2013 on a mechanism for monitoring and reporting greenhouse gas emissions and for reporting other information at national and Union level relevant to climate change and repealing Decision No 280/2004/EC ⁽¹⁾, and in particular Article 19(6) thereof,

Whereas:

- (1) Decision No 406/2009/EC of the European Parliament and of the Council ⁽²⁾ lays down annual emission allocations for each Member State for each year of the period 2013 to 2020 and a mechanism to annually assess compliance with those limits. Member States' annual emission allocations expressed in tonnes of CO₂ equivalent are contained in Commission Decision 2013/162/EU ⁽³⁾. The adjustments to the annual emission allocations for each Member State are set in Commission Implementing Decision 2013/634/EU ⁽⁴⁾.
- (2) Article 19 of Regulation (EU) No 525/2013 provides for a procedure for the review of Member States' greenhouse gas (GHG) emissions inventories for the purpose of assessing compliance with Decision No 406/2009/EC. The annual review referred to in Article 19(2) of Regulation (EU) No 525/2013 was carried out on the basis of the 2016 emissions data reported to the Commission in March 2018 in accordance with the procedures laid down in Chapter III of Commission Implementing Regulation (EU) No 749/2014 ⁽⁵⁾ and Annex XVI to that Regulation.
- (3) The total amount of GHG emissions covered by Decision No 406/2009/EC for the year 2016 for each Member State should take into consideration the technical corrections and revised estimates calculated during the annual review as contained in the final review reports drawn up pursuant to Article 35(2) of Regulation (EU) No 749/2014.
- (4) This Decision should enter into force on the day of its publication in order to be aligned with the provisions of Article 19(7) of Regulation (EU) No 525/2013 which sets the date of publication of this Decision as the starting point for the four-month period when Member States are allowed to use the flexibility mechanisms under Decision No 406/2009/EC,

HAS ADOPTED THIS DECISION:

Article 1

The total sum of greenhouse gas emissions covered by Decision No 406/2009/EC for each Member State for the year 2016 arising from the corrected inventory data upon completion of the annual review referred to in Article 19(2) of Regulation (EU) No 525/2013 is set out in the Annex to this Decision.

⁽¹⁾ OJ L 165, 18.6.2013, p. 13.

⁽²⁾ Decision No 406/2009/EC of the European Parliament and of the Council of 23 April 2009 on the effort of Member States to reduce their greenhouse gas emissions to meet the Community's greenhouse gas emission reduction commitments up to 2020 (OJ L 140, 5.6.2009, p. 136).

⁽³⁾ Commission Decision 2013/162/EU of 26 March 2013 on determining Member States' annual emission allocations for the period from 2013 to 2020 pursuant to Decision No 406/2009/EC of the European Parliament and of the Council (OJ L 90, 28.3.2013, p. 106).

⁽⁴⁾ Commission Implementing Decision 2013/634/EU of 31 October 2013 on the adjustments to Member States' annual emission allocations for the period from 2013 to 2020 pursuant to Decision No 406/2009/EC of the European Parliament and of the Council (OJ L 292, 1.11.2013, p. 19).

⁽⁵⁾ Commission Implementing Regulation (EU) No 749/2014 of 30 June 2014 on structure, format, submission processes and review of information reported by Member States pursuant to Regulation (EU) No 525/2013 of the European Parliament and of the Council (OJ L 203, 11.7.2014, p. 23).

Article 2

This Decision shall enter into force on the day of its publication in the *Official Journal of the European Union*.

Done at Brussels, 27 November 2018.

For the Commission

The President

Jean-Claude JUNCKER

ANNEX

Member State	Greenhouse gas emissions for the year 2016 covered by Decision No 406/2009/EC (tonnes of carbon dioxide equivalent)
Belgium	74 063 149
Bulgaria	25 587 947
Czech Republic	62 816 957
Denmark	33 124 678
Germany	454 157 411
Estonia	6 218 046
Ireland	43 798 177
Greece	44 897 200
Spain	198 472 205
France	351 924 668
Croatia	16 006 813
Italy	270 685 435
Cyprus	4 111 441
Latvia	9 107 440
Lithuania	13 921 700
Luxembourg	8 524 455
Hungary	42 059 940
Malta	1 329 995
Netherlands	101 333 437
Austria	50 618 898
Poland	198 664 758
Portugal	41 572 594
Romania	73 123 042
Slovenia	11 236 888
Slovakia	19 758 694
Finland	31 358 144
Sweden	32 612 247
United Kingdom	333 899 779

COMMISSION IMPLEMENTING DECISION (EU) 2018/1856**of 27 November 2018****amending the Annex to Implementing Decision 2014/709/EU concerning animal health control measures relating to African swine fever in certain Member States***(notified under document C(2018) 8058)***(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market ⁽¹⁾, and in particular Article 9(4) thereof,

Having regard to Council Directive 90/425/EEC of 26 June 1990 concerning veterinary checks applicable in intra-Union trade in certain live animals and products with a view to the completion of the internal market ⁽²⁾, and in particular Article 10(4) thereof,

Having regard to Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption ⁽³⁾, and in particular Article 4(3) thereof,

Whereas:

- (1) Commission Implementing Decision 2014/709/EU ⁽⁴⁾ lays down animal health control measures in relation to African swine fever in certain Member States, where there have been confirmed cases of that disease in domestic or feral pigs (the Member States concerned). The Annex to that Implementing Decision demarcates and lists certain areas of the Member States concerned in Parts I to IV thereof, differentiated by the level of risk based on the epidemiological situation as regards that disease. The Annex to Implementing Decision 2014/709/EU has been amended several times to take account of changes in the epidemiological situation in the Union as regards African swine fever that need to be reflected in that Annex. The Annex to Implementing Decision 2014/709/EU was last amended by Commission Implementing Decision (EU) 2018/1689 ⁽⁵⁾, following recent instances of African swine fever in Poland and Romania.
- (2) The risk of the spread of African swine fever in wildlife is linked to the natural slow spread of that disease among feral pig populations, and also the risks linked to human activity, as demonstrated by the recent epidemiological evolution of that disease in the Union, and as documented by the European Food Safety Authority (EFSA) in the Scientific Opinion of the Panel on Animal Health and Welfare, published on 14 July 2015; in the Scientific Report of EFSA on Epidemiological analyses on African swine fever in the Baltic countries and Poland, published on 23 March 2017; and in the Scientific Report of EFSA on Epidemiological analyses of African swine fever in the Baltic States and Poland, published on 8 November 2017 ⁽⁶⁾.
- (3) Council Directive 2002/60/EC ⁽⁷⁾ lays down the minimum Union measures to be taken for the control of African swine fever. In particular, Article 9 of Directive 2002/60/EC provides for the establishment of a protection and a surveillance zone when African swine fever has been officially confirmed in pigs on a holding, and Articles 10 and 11 of that Directive lay down the measures to be taken in the protection and surveillance zones in order to

⁽¹⁾ OJ L 395, 30.12.1989, p. 13.

⁽²⁾ OJ L 224, 18.8.1990, p. 29.

⁽³⁾ OJ L 18, 23.1.2003, p. 11.

⁽⁴⁾ Commission Implementing Decision 2014/709/EU of 9 October 2014 concerning animal health control measures relating to African swine fever in certain Member States and repealing Implementing Decision 2014/178/EU (OJ L 295, 11.10.2014, p. 63).

⁽⁵⁾ Commission Implementing Decision (EU) 2018/1689 of 8 November 2018 amending the Annex to Implementing Decision 2014/709/EU concerning animal health control measures relating to African swine fever in certain Member States (OJ L 279, 9.11.2018, p. 39).

⁽⁶⁾ EFSA Journal 2015;13(7):4163; EFSA Journal 2017;15(3):4732; EFSA Journal 2017;15(11):5068.

⁽⁷⁾ Council Directive 2002/60/EC of 27 June 2002 laying down specific provisions for the control of African swine fever and amending Directive 92/119/EEC as regards Teschen disease and African swine fever (OJ L 192, 20.7.2002, p. 27).

prevent the spread of that disease. In addition, Article 15 of Directive 2002/60/EC provides for the measures to be taken where African swine fever is confirmed in feral pigs, including the placing under official surveillance of pig holdings in the defined infected area. Recent experience has shown that the measures laid down in Directive 2002/60/EC are effective in controlling the spread of that disease, and in particular the measures providing for the cleaning and disinfecting of infected holdings.

- (4) Taking into account the effectiveness of the measures being applied in the Member States in accordance with Directive 2002/60/EC, and in particular those laid down in Article 10(4)(b), Article 10(5) and Article 15 thereof, and in line with the risk mitigation measures for African swine fever set out in the Terrestrial Animal Health Code of the World Organization for Animal Health, certain areas in Latvia, Lithuania and Poland currently listed in Part III of the Annex to Implementing Decision 2014/709/EU should now be listed in Part II of that Annex, in view of the expiry of the period of three months from the date of the final cleaning and disinfection of the infected holdings. Given that Part III of the Annex to Implementing Decision 2014/709/EU lists the areas where the epidemiological situation is still evolving and very dynamic, when any amendments are made to areas listed in that Part, particular consideration must always be given to the effect on the surrounding areas.
- (5) In September 2018, a number of cases of African swine fever in wild boar were observed in Belgium. Commission Implementing Decisions (EU) 2018/1242 ⁽¹⁾ and (EU) 2018/1281 ⁽²⁾ were adopted in response to those cases. Implementing Decision (EU) 2018/1281 repealed and replaced Implementing Decision (EU) 2018/1242 and it applies until 30 November 2018. Implementing Decision (EU) 2018/1281 provides that the infected area established by Belgium, where the measures provided for in Article 15 of Directive 2002/60/EC apply, are to comprise at least the areas listed in the Annex to that Implementing Decision.
- (6) These recent cases of African swine fever in Belgium constitute an increased level of risk which should be reflected in the Annex to Implementing Decision 2014/709/EU. Accordingly, this area of Belgium in the Ardennes region affected by African swine fever should now be listed in Part II of that Annex.
- (7) In addition, since the date of adoption of Implementing Decision (EU) 2018/1689, there have been further instances of African swine fever in other Member States that also need to be reflected in the Annex to Implementing Decision 2014/709/EU.
- (8) In October 2018, one case of African swine fever in a feral pig was observed in the county of Marijampolė in Lithuania. This case of African swine fever in a feral pig constitutes an increased level of risk which should be reflected in the Annex to Implementing Decision 2014/709/EU. Accordingly, this area of Lithuania affected by African swine fever should now be listed in Part II of that Annex instead of in Part I thereof.
- (9) In October and November 2018, a few cases of African swine fever in feral pigs were observed in the county of Liepāja in Latvia in close proximity to an area listed in Part I of the Annex to Implementing Decision 2014/709/EU. These cases of African swine fever in feral pigs constitute an increased level of risk which should be reflected in that Annex. Accordingly, these areas of Latvia affected by African swine fever should be listed in Part II of the Annex to Implementing Decision 2014/709/EU instead of in Part I thereof.
- (10) In October and November 2018, a few cases of African swine fever in feral pigs were observed in the counties of Krasnystaw and Garwolin in Poland in close proximity to areas listed in Part I of the Annex to Implementing Decision 2014/709/EU. These cases of African swine fever in feral pigs constitute an increased level of risk which should be reflected in that Annex. Accordingly, these areas of Poland affected by African swine fever should be listed in Part II of the Annex to Implementing Decision 2014/709/EU instead of in Part I thereof.
- (11) In October and November 2018, a few cases of African swine fever in feral pigs were observed in the county of Borsod-Abaúj-Zemplén in Hungary in close proximity to an area listed in Part I of the Annex to Implementing Decision 2014/709/EU. These cases of African swine fever in feral pigs constitute an increased level of risk which should be reflected in that Annex. Accordingly, these areas of Hungary affected by African swine fever should now be listed in Part II of the Annex to Implementing Decision 2014/709/EU instead of in Part I thereof.

⁽¹⁾ Commission Implementing Decision (EU) 2018/1242 of 14 September 2018 concerning certain interim protective measures relating to African swine fever in Belgium (OJ L 231I, 14.9.2018, p. 1).

⁽²⁾ Commission Implementing Decision (EU) 2018/1281 of 21 September 2018 concerning certain protective measures relating to African swine fever in Belgium (OJ L 239, 24.9.2018, p. 18).

- (12) In order to take account of recent developments in the epidemiological evolution of African swine fever in the Union, and in order to combat the risks associated with the spread of that disease in a proactive manner, new high-risk areas of a sufficient size should be demarcated for Belgium, Lithuania, Latvia, Poland and Hungary and duly listed in Parts I, II and III of the Annex to Implementing Decision 2014/709/EU. The Annex to Implementing Decision 2014/709/EU should therefore be amended accordingly.
- (13) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS DECISION:

Article 1

The Annex to Implementing Decision 2014/709/EU is replaced by the text set out in the Annex to this Decision.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 27 November 2018.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

ANNEX

The Annex to Implementing Decision 2014/709/EU is replaced by the following:

‘ANNEX

PART I

1. Belgium

The following areas in Belgium:

in Luxembourg province:

- the area is delimited at the outside clockwise by:
 - the border with France,
 - N85: Rue de Carignan, Rue de France, Rue des Généraux Cuvelier, Rue de la Station, Rue de Neufchâteau,
 - N894: Rue de Chiny, Rue de la Fontenelle, Rue du Millénaire, Rue de la Goulette, Pont saint Nicolas, Rue des Combattants, Rue du Pré au bois,
 - N801: Rue Notre-Dame,
 - N894: Rue des Combattants, Rue des Tilleuls, Naleumont, Rue de Rindchay, Rue de la Distillerie,
 - N40: Rue de Luxembourg, Rue Ranci, Rue de la Chapelle,
 - Rue du Tombois,
 - Rue Du Pierroy,
 - Rue Saint-Orban,
 - Rue Saint-Aubain,
 - Rue des Cottages,
 - Rue de Relune,
 - Rue de Rulune,
 - Route de l’Ermitage,
 - N87: Route de Habay,
 - Chemin des Ecoliers,
 - Le Routy,
 - Rue Burgknapp,
 - Rue de la Halte,
 - Rue du Centre,
 - Rue de l’Eglise,
 - Rue du Marquisat,
 - Rue de la Carrière,
 - Rue de la Lorraine,
 - Rue du Beynert,
 - Millewée,
 - Rue du Tram,
 - Millewée,
 - N4: Route de Bastogne, Avenue de Longwy, Route de Luxembourg,
 - the border with the Grand Duchy of Luxembourg,
- the area is delimited at the outside clockwise by:
 - La N88, depuis son intersection avec la N883 au niveau d’Aubange jusque son intersection avec la N891 au niveau de Géroville,
 - La N891 jusque son intersection avec la N83 au niveau de Jamoigne,

- La N83 jusque son intersection avec la N891,
- La N891 jusque son intersection avec la N879 au niveau de Marbehan,
- La N879 jusque son intersection avec la N897 au niveau de Marbehan,
- La N897 jusque son intersection avec la E25 - E411,
- La E25 - E411 jusque son intersection avec la N81 au niveau de Weyler,
- La N81 jusque son intersection avec la N883 au niveau d'Aubange,
- La N883 jusque son intersection avec la N88.

2. Bulgaria

The following areas in Bulgaria:

in Silistra region:

- within municipality of Alfatar:
 - Bistra,
 - Alekovo,
- within municipality of Dulovo:
 - Kolobar,
 - Varbina,
 - Kozyak,
 - Mezhden,
 - Chukovetz,
 - Tzar Asen,
 - Cherkovna,
 - Dulovo,
 - Chernik,
 - Poroyno,
 - Vodno,
 - Chernolik,
- within municipality of Sitovo:
 - Sitovo,
 - Yastrebno,
 - Slatina,
- within municipality of Silistra:
 - Bradvari,
 - Zlatoklas,
 - Yordanovo,
 - Profesor Ishirkovo,
 - Kazimir,
 - Babuk,
 - Sarpovo,
 - Smiletz,
 - Tzenovich,
 - Polkovnik Lambrinovo,
 - Srebarna,
 - Aydemir,
 - Silistra,
 - Kalipetrovo,

in Dobrich region:

— within municipality of General Toshevo:

- Rosen,
- Krasen,
- Zhiten,
- Snop,
- Gradini,

— within municipality of Krushari:

- Severnyak,
- Abrit,
- Dobrin,
- Alexandria,
- Polkovnik Dyakovo,
- Zagortzi,
- Krushartzi,
- Bistretz,
- Telerig,
- Lozenetz,

— within municipality of Tervel:

- Onogur,
- Balik,
- Angelariy,
- Sarnetz,
- Bozhan,
- Popgruevo,
- Kochmar,
- Guslar,
- Mali Izvor,
- Tervel,
- Bonevo,
- Voynikovo,
- Bezmer,
- Chestimensko,
- Profesor Zlatarski,
- Kableschkovo,
- Glavantzi,
- Nova kamena,
- Kladentzi,
- Gradnitza,

— within municipality of Dobrich:

- Kragulevo,
- Dobrevo,
- Cherna,
- Pchelnik,
- Zhitnitza,

- Polkovnik Ivanovo,
- Hitovo,
- Vodnyantzi,
- Feldfebel Denkovo (Dyankovo),
- Podslon,
- Geshanovo.

3. The Czech Republic

The following areas in the Czech Republic:

- okres Uherské Hradiště,
- okres Kroměříž,
- okres Vsetín,
- katastrální území obcí v okrese Zlín:
 - Bělov,
 - Biskupice u Luhačovic,
 - Bohuslavice nad Vláří,
 - Brumov,
 - Bylnice,
 - Divnice,
 - Dobrkovice,
 - Dolní Lhota u Luhačovic,
 - Drnovice u Valašských Klobouk,
 - Halenkovice,
 - Haluzice,
 - Hrádek na Vlárské dráze,
 - Hřivínův Újezd,
 - Jestřabí nad Vláří,
 - Kaňovice u Luhačovic,
 - Kelníky,
 - Kladná-Žilín,
 - Kochavec,
 - Komárov u Napajedel,
 - Křekov,
 - Lipina,
 - Lipová u Slavičína,
 - Ludkovice,
 - Luhačovice,
 - Machová,
 - Mirošov u Valašských Klobouk,
 - Mysločovice,
 - Napajedla,
 - Návojná,
 - Nedašov,
 - Nedašova Lhota,
 - Nevšová,
 - Otrokovice,

- Petrůvka u Slavičina,
- Pohořelice u Napajedel,
- Polichno,
- Popov nad Vlárí,
- Poteč,
- Pozlovice,
- Rokytnice u Slavičina,
- Rudimov,
- Řetechov,
- Sazovice,
- Sidonie,
- Slavičín,
- Smolina,
- Sptyihněv,
- Svatý Štěpán,
- Šanov,
- Šarovy,
- Štítná nad Vlárí,
- Tichov,
- Tlumačov na Moravě,
- Valašské Klobouky,
- Velký Ořechov,
- Vlachova Lhota,
- Vlachovice,
- Vrbětice,
- Žlutava.

4. Estonia

The following areas in Estonia:

- Hiiu maakond.

5. Hungary

The following areas in Hungary:

- Borsod-Abaúj-Zemplén megye 650100, 650200, 650300, 650400, 650500, 650600, 650700, 650800, 650900, 651000, 651100, 651200, 651300, 651400, 651500, 651610, 651700, 651801, 651802, 651803, 651900, 652000, 652100, 652200, 652300, 652400, 652500, 652601, 652602, 652603, 652700, 652800, 652900, 653000, 653100, 653200, 653300, 653401, 653403, 653500, 653600, 653700, 653800, 653900, 654000, 654201, 654202, 654301, 654302, 654400, 654501, 654502, 654600, 654700, 654800, 654900, 655000, 655100, 655200, 655300, 655400, 655500, 655600, 655700, 655800, 655901, 655902, 656000, 656100, 656200, 656300, 656400, 656600, 657300, 657400, 657500, 657600, 657700, 657800, 657900, 658000, 658100, 658201, 658202, 658403, 659210, 659220, 659300, 659400, 659500, 659601, 659602, 659901, 660000, 660100, 660200, 660400, 660501, 660502, és 660600 kódszámú vadgazdálkodási egységeinek teljes területe,
- Hajdú-Bihar megye 900150, 900250, 900350, 900450, 900550, 900650, 900660, 900670, 900750, 900850, 900860, 900930, 900950, 901050, 901150, 901250, 901260, 901270, 901350, 901450, 901551, 901560, 901570, 901580, 901590, 901650, 901660, 901850, 901950, 902050, 902850, 902860, 902950, 902960, 903050, 903150, 903250, 903350, 903360, 903370, 903450, 903550, 904450, 904460, 904550, 904650, 904750, 904760, 905450 és 905550 kódszámú vadgazdálkodási egységeinek teljes területe,
- Heves megye 700150, 700250, 700260, 700350, 700450, 700460, 700550, 700650, 700750, 700850, 702350, 702450, 702550, 702750, 702850, 703350, 703360, 703450, 703550, 703610, 703750, 703850, 703950, 704050, 704150, 704250, 704350, 704450, 704550, 704650, 704750, 704850, 704950, 705050, 705250, 705350, 705510 és 705610 kódszámú vadgazdálkodási egységeinek teljes területe,

- Jász-Nagykun-Szolnok megye 750150, 750160, 750250, 750260, 750350, 750450, 750460, 750550, 750650, 750750, 750850, 750950 és 750960 kódszámú vadgazdálkodási egységeinek teljes területe,
- Nógrád megye 550120, 550130, 550210, 550710, 550810, 551450, 551460, 551550, 551650, 551710, 552010, 552150, 552250, 552350, 552360, 552450, 552460, 552520, 552550, 552610, 552620, 552710, 552850, 552860, 552950, 552960, 552970, 553050, 553110, 553250, 553260, 553350, 553650, 553750, 553850, 553910 és 554050 kódszámú vadgazdálkodási egységeinek teljes területe,
- Pest megye 571250, 571350, 571550, 571610, 571750, 571760, 572250, 572350, 572550, 572850, 572950, 573360, 573450, 580050 és 580450 kódszámú vadgazdálkodási egységeinek teljes területe,
- Szabolcs-Szatmár-Bereg megye 850650, 850850, 851851, 851852, 851950, 852350, 852450, 852550, 852750, 853560, 853650, 853751, 853850, 853950, 853960, 854050, 854150, 854250, 854350, 855250, 855350, 855450, 855460, 855550, 855650, 855660, 855750, 855850, 855950, 855960, 856012, 856050, 856150, 856260, 857050, 857150, 857350 és 857450 kódszámú vadgazdálkodási egységeinek teljes területe.

6. Latvia

The following areas in Latvia:

- Aizputes novads,
- Alsungas novads,
- Kuldīgas novada Gudenieku, Turlavas un Laidu pagasts,
- Pāvilostas novada Sakas pagasts un Pāvilostas pilsēta,
- Priekules novada Bunkas, Virgas un Kalētu pagasts,
- Skrundas novada Rudbāržu pagasts,
- Stopiņu novada daļa, kas atrodas uz rietumiem no autoceļa V36, P4 un P5, Acones ielas, Daugulupes ielas un Daugulupītes,
- Ventspils novada Jūrkalnes pagasts,
- Grobiņas novada Bārtas un Gaviezes pagasts,
- Rucavas novada Dunikas pagasts.

7. Lithuania

The following areas in Lithuania:

- Jurbarko rajono savivaldybė: Smalininkų ir Viešvilės seniūnijos,
- Kelmės rajono savivaldybė: Kelmės, Kelmės apylinkių, Kražių, Kukečių, Liolių, Pakražančio seniūnijos, Tytuvėnų seniūnijos dalis į vakarus ir šiaurę nuo kelio Nr. 157 ir į vakarus nuo kelio Nr. 2105 ir Tytuvėnų apylinkių seniūnijos dalis į šiaurę nuo kelio Nr. 157 ir į vakarus nuo kelio Nr. 2105, ir Vaiguvo seniūnijos,
- Mažeikių rajono savivaldybė: Sedos, Šerkšnėnų ir Židikų seniūnijos,
- Pagėgių savivaldybė,
- Plungės rajono savivaldybė,
- Raseinių rajono savivaldybė: Girkalnio ir Kalnųjų seniūnijos dalis į šiaurę nuo kelio Nr. A1, Nemakščių, Paliepių, Raseinių, Raseinių miesto ir Viduklės seniūnijos,
- Rietavo savivaldybė,
- Šakių rajono savivaldybė: Barzdų, Griškabūdžio, Kriukų, Kudirkos Naumiesčio, Lekėčių, Sintautų, Slavikų, Sudargo ir Žvirgždaičių seniūnijos,
- Šilalės rajono savivaldybė,
- Šilutės rajono savivaldybė: Juknaičių, Kintų, Šilutės ir Usėnų seniūnijos,
- Tauragės rajono savivaldybė: Lauksargių, Skaudvilės, Tauragės, Mažonų, Tauragės miesto ir Žygaičių seniūnijos.

8. Poland

The following areas in Poland:

w województwie warmińsko-mazurskim:

- gmina Stare Juchy w powiecie elckim,
- gmina Dubeninki w powiecie gołdapskim,

- gmina Ruciane – Nida i część gminy Pisz położona na południe od linii wyznaczonej przez drogę nr 58 oraz miasto Pisz w powiecie piskim,
 - powiat giżycki,
 - gminy Mikołajki, Piecki, część gminy Sorkwity położona na południe od drogi nr 16 i część gminy wiejskiej Mrągowo położona na południe od linii wyznaczonej przez drogę nr 16 biegnącą od zachodniej granicy gminy do granicy miasta Mrągowo oraz na południe od linii wyznaczonej przez drogę nr 59 biegnącą od wschodniej granicy gminy do granicy miasta Mrągowo w powiecie mrągowskim,
 - gmina Bisztynek w powiecie bartoszyckim,
 - gminy Dźwierzuty i Świętajno w powiecie szczycieńskim.
 - gminy Lubomino, część gminy Orneta położona na zachód od linii wyznaczonej przez linię kolejową łączącą miejscowości Lubomino i Pieniężno, część gminy wiejskiej Lidzbark Warmiński położona na południe od linii wyznaczonej przez drogę nr 513 biegnącą od wschodniej granicy gminy do wschodniej granicy miasta Lidzbark Warmiński oraz na południowy wschód od linii wyznaczonej przez drogę nr 51 i część gminy Kiwity położona na południe od linii wyznaczonej przez drogę nr 513 w powiecie lidzbarskim,
 - gminy Elbląg, Godkowo, Gronowo Elbląskie, Markusy, Pasłęk i część gminy Tolkmicko niewymieniona w części II załącznika w powiecie elbląskim oraz strefa wód przybrzeżnych Zalewu Wiślanego i Zatoki Elbląskiej,
 - powiat miejski Elbląg,
 - gminy Biskupiec, Dobre Miasto, Jeziorany, Kolno i Świątki w powiecie olsztyńskim,
 - gmina Miłakowo w powiecie ostródzkim,
- w województwie podlaskim:
- gminy Brańsk z miastem Brańsk, Rudka i Wyszki w powiecie bielskim,
 - gmina Perlejewo w powiecie siemiatyckim,
 - gminy Kolno z miastem Kolno, Mały Płock i Turośl w powiecie kolneńskim,
 - gmina Poświętne w powiecie białostockim,
 - gminy Kołaki Kościelne, Rutki, Szumowo, część gminy Zambrów położona na południe od linii wyznaczonej przez drogę nr 58 i miasto Zambrów w powiecie zambrowskim,
 - gminy Wiżajny i Przerośl w powiecie suwalskim,
 - gminy Kulesze Kościelne, Nowe Piekuty, Szepietowo, Klukowo, Ciechanowiec, Wysokie Mazowieckie z miastem Wysokie Mazowieckie, Czyżew w powiecie wysokomazowieckim,
 - gminy Miastkowo, Nowogród i Zbójna w powiecie łomżyńskim.
- w województwie mazowieckim:
- gminy Cerańów, Kosów Lacki, Sabnie, Sterdyń, część gminy Bielany położona na zachód od linii wyznaczonej przez drogę nr 63 i część gminy wiejskiej Sokołów Podlaski położona na zachód od linii wyznaczonej przez drogę nr 63 w powiecie sokołowskim,
 - gminy Grębków, Korytnica, Liw, Łochów, Miedzna, Sadowne, Stoczek, Wierzbno i miasto Węgrów w powiecie węgrowskim,
 - część gminy Kotuń położona na zachód od linii wyznaczonej przez drogę łączącą miejscowości Nowa Dąbrówka, Pieróg, Kotuń wzdłuż ulicy Gorzkowskiego i Kolejowej do przejazdu kolejowego łączącego się z ulicą Siedlecką, Broszków, Żuków w powiecie siedleckim,
 - gminy Rzekuń, Troszyn, Lelis, Czerwin i Goworowo w powiecie ostrołęckim,
 - powiat miejski Ostrołęka,
 - powiat ostrowski,
 - gminy Karniewo, Maków Mazowiecki, Rzewnie i Szelków w powiecie makowskim,
 - gmina Krasne w powiecie przasnyskim,
 - gminy Mała Wieś i Wyszogród w powiecie płockim,
 - gminy Ciechanów z miastem Ciechanów, Głinojeck, Gołymin – Ośrodek, Ojrzeń, Opinogóra Górna i Sońsk w powiecie ciechanowskim,

- gminy Baboszewo, Czerwińsk nad Wisłą, Naruszewo, Płońsk z miastem Płońsk, Sochocin i Załuski w powiecie płońskim,
 - gminy Gzy, Obryte, Zatory, Pułtusk i część gminy Winnica położona na wschód od linii wyznaczonej przez drogę łączącą miejscowości Bielany, Winnica i Pokrzywnica w powiecie pułtuskim,
 - gminy Brańszczyk, Długosiodło, Rząśnik, Wyszów, Zabrodzie i część gminy Somianka położona na północ od linii wyznaczonej przez drogę nr 62 w powiecie wyszkowskim,
 - gminy Jadów, Klembów, Poświętne, Strachówka i Tłuszcz w powiecie wołomińskim,
 - gminy Dobrze, Jakubów, Mrozy, Kałuszyn, Stanisławów, część gminy Cegłów położona na północ od linii wyznaczonej przez drogę biegnącą od zachodniej granicy gminy łączącą miejscowości Wiciejów, Mienia, Cegłów i na wschód od linii wyznaczonej przez drogę łączącą miejscowości Cegłów, Skwarne i Podskwarne biegnącą do wschodniej granicy gminy i część gminy Mińsk Mazowiecki położona na północ od linii wyznaczonej przez drogę nr 92 biegnącą od zachodniej granicy gminy do granicy miasta Mińsk Mazowiecki i na północ od linii wyznaczonej przez drogę biegnącą od wschodniej granicy miasta Mińsk Mazowiecki łączącą miejscowości Targówka, Budy Barczackie do wschodniej granicy gminy w powiecie mińskim,
 - gminy Górzno, Łaskarzew z miastem Łaskarzew, Sobolew, Trojanów, Żelechów i część gminy Miastków Kościelny położona na południe od rzeki Wilga w powiecie garwolińskim,
 - gminy Garbatka Letnisko, Gniewosów i Sieciechów w powiecie kozienickim,
 - gminy Baranów i Jaktorów w powiecie grodziskim,
 - powiat żyrardowski,
 - gminy Belsk Duży, Błędów, Goszczyn i Mogielnica w powiecie grójeckim,
 - gminy Białobrzegi, Promna, Stara Błotnica, Wyśmierzyce i część gminy Stomiec położona na południe od linii wyznaczonej przez drogę nr 48 w powiecie białobrzeskim,
 - gminy Jedlińsk, Jastrzębia i Pionki z miastem Pionki w powiecie radomskim,
 - gminy Iłów, Młodzieszyn, Nowa Sucha, Rybno, Sochaczew z miastem Sochaczew i Teresin w powiecie sochaczewskim,
 - gmina Policzna w powiecie zwoleńskim,
 - gmina Solec nad Wisłą w powiecie lipskim.
- w województwie lubelskim:
- gminy Bełżyce, Borzechów, Niedrzwica Duża, Jabłonna, Krzczonów, Jastków, Konopnica, Wólka, Głusk, Strzyżewice i Wojciechów w powiecie lubelskim,
 - gminy Miączyn, Nielisz, Sitno, Stary Zamość, Komarów-Osada i część gminy wiejskiej Zamość położona na północ od linii wyznaczonej przez drogę nr 74 w powiecie zamojskim,
 - powiat miejski Zamość,
 - gminy Trzeszczany i Werbkowice w powiecie hrubieszowskim,
 - gminy Jeziorzany i Kock w powiecie lubartowskim,
 - gminy Adamów i Serokomla w powiecie łukowskim,
 - powiat rycki,
 - gminy Janowiec, i część gminy wiejskiej Puławy położona na zachód od rzeki Wisły w powiecie puławskim,
 - gminy Chodel, Karczmiska, Łaziska, Opole Lubelskie, Poniatowa i Wilków w powiecie opolskim,
 - gminy Mełgiew, Rybczewice, miasto Świdnik i część gminy Piaski położona na południe od linii wyznaczonej przez drogę nr 17 biegnącą od wschodniej granicy gminy Piaski do skrzyżowania z drogą nr S12 i na zachód od linii wyznaczonej przez drogę biegnącą od skrzyżowania dróg nr 17 i nr S12 przez miejscowość Majdan Brzezicki do północnej granicy gminy w powiecie świdnickim;
 - gminy Gorzków, Rudnik i Żółkiewka w powiecie krasnostawskim,
 - gminy Bełzec, Jarczów, Lubycza Królewska, Łaszczów, Susiec, Tyszowce i Ulhówek w powiecie tomaszowskim,
 - gminy Łukowa i Obsza w powiecie biłgorajskim,
 - powiat miejski Lublin,
 - gminy Kraśnik z miastem Kraśnik, Szastarka, Trzydnik Duży, Urzędów, Wilkołaz i Zakrzówek w powiecie kraśnickim,
 - gminy Modliborzyce i Potok Wielki w powiecie janowskim.

w województwie podkarpackim:

- gminy Horyniec-Zdrój, Narol, Stary Dzików, Wielkie Oczy i część gminy Oleszyce położona na południe od linii wyznaczonej przez drogę biegnącą od wschodniej granicy gminy przez miejscowość Borchów do skrzyżowania z drogą nr 865 w miejscowości Oleszyce, a następnie na zachód od linii wyznaczonej przez drogę nr 865 biegnącą w kierunku północno-wschodnim do skrzyżowania z drogą biegnącą w kierunku północno-zachodnim przez miejscowość Lubomierz - na południe od linii wyznaczonej przez tę drogę do skrzyżowania z drogą łączącą miejscowości Uszkowce i Nowy Dzików – na zachód od tej drogi w powiecie lubaczowskim,
- gminy Laszki i Wiązownica w powiecie jarosławskim,
- gminy Pysznica, Zaleszany i miasto Stalowa Wola w powiecie stalowowolskim,
- gmina Gorzyce w powiecie tarnobrzeskim.

w województwie świętokrzyskim:

- gminy Tarłów i Ożarów w powiecie opatowskim,
- gminy Dwikozy, Zawichost i miasto Sandomierz w powiecie sandomierskim.

9. Romania

The following areas in Romania:

- Județul Alba cu următoarea delimitare:
 - La nord de drumul național nr. 7,
- Județul Arad cu următoarea delimitare:
 - La nord de linia descrisă de următoarele localități:
 - Macea,
 - Șiria,
 - Bârzava,
 - Toc, care se află la joncțiunea cu drumul național nr. 7,
 - La nord de drumul național nr. 7,
- Restul județului Argeș care nu a fost inclus în partea III,
- Județul Bistrița,
- Județul Brașov,
- Județul Cluj,
- Județul Covasna,
- Județul Harghita,
- Județul Hunedoara cu următoarea delimitare:
 - La nord de linia descrisă de următoarele localități:
 - Brănișca,
 - Municipiul Deva,
 - Turdaș,
 - Localitățile Zam și Aurel Vlaicu, care se află la joncțiunea cu drumul național nr. 7,
 - La nord de drumul național nr. 7,
- Județul Iași,
- Județul Neamț,
- Județul Vâlcea,
- Județul Bistrița Nasaud,
- Restul județului Maramureș care nu a fost inclus în Partea III cu următoarele comune:
 - Comuna Vișeu de Sus,
 - Comuna Borșa,
 - Comuna Oarța de Jos,

- Comuna Suciu de Sus,
- Comuna Moisei,
- Comuna Coroieni,
- Comuna Târgu Lăpuș,
- Comuna Vima Mică,
- Comuna Boiu Mare,
- Comuna Valea Chioarului,
- Comuna Ulmeni,
- Comuna Băsești,
- Comuna Baia Mare,
- Comuna Tăuții Magherăuș,
- Comuna Cicărlău,
- Comuna Seini,
- Comuna Ardușat,
- Comuna Farcasa,
- Comuna Salsig,
- Comuna Asuaju de Sus,
- Comuna Băița de sub Codru,
- Comuna Bicaz,
- Comuna Grosi,
- Comuna Recea,
- Comuna Baia Sprie,
- Comuna Sisesti,
- Comuna Cernesti,
- Copalnic Mănăstur,
- Comuna Dumbrăvița,
- Comuna Cupseni,
- Comuna Șomcuța Mare,
- Comuna Sacaleșeni,
- Comuna Remetea Chioarului,
- Comuna Mireșu Mare,
- Comuna Ariniș.
- Restul județului Mehedinți care nu a fost inclus în Partea III cu următoarele comune:
 - Comuna Garla Mare,
 - Hinova,
 - Burila Mare,
 - Gruia,
 - Pristol,
 - Dubova,
 - Municipiul Drobeta Turnu Severin,
 - Eselnița,
 - Salcia,
 - Devesel,
 - Svinița,
 - Gogoșu,
 - Simian,

- Orșova,
- Obârșia Cîlosani,
- Baia de Aramă,
- Bala,
- Florești,
- Broșteni,
- Corcova,
- Isverna,
- Balta,
- Podeni,
- Cireșu,
- Ilovița,
- Ponoarele,
- Ilovăț,
- Patulele,
- Jiana,
- Iyvoru Bârzii,
- Malovat,
- Bălvănești,
- Breznița Ocol,
- Godeanu,
- Padina Mare,
- Corlățel,
- Vânju Mare,
- Vânjuleț,
- Obârșia de Câmp,
- Vânători,
- Vladaia,
- Pungghina,
- Cujmir,
- Oprișor,
- Dârvari,
- Căzănești,
- Husnicioara,
- Poroina Mare,
- Prunișor,
- Tămna,
- Livezile,
- Rogova,
- Voloiaș,
- Sisești,
- Sovarna,
- Bălăcița,
- Județul Gorj.

PART II

1. Belgium

The following areas in Belgium:

in Luxembourg province:

- the area is delimited clockwise by:
 - La N88, depuis son intersection avec la N883 au niveau d'Aubange jusque son intersection avec la N891 au niveau de Gérouville,
 - La N891 jusque son intersection avec la N83 au niveau de Jamoigne,
 - La N83 jusque son intersection avec la N891,
 - La N891 jusque son intersection avec la N879 au niveau de Marbehan,
 - La N879 jusque son intersection avec la N897 au niveau de Marbehan,
 - La N897 jusque son intersection avec la E25 - E411,
 - La E25 - E411 jusque son intersection avec la N81 au niveau de Weyler,
 - La N81 jusque son intersection avec la N883 au niveau d'Aubange,
 - La N883 jusque son intersection avec la N88.

2. Bulgaria

The following areas in Bulgaria:

in Silistra region:

- within municipality of Kaynardzha:
 - Voynovo,
 - Kaynardzha,
 - Kranovo,
 - Zarnik,
 - Dobrudzhanka,
 - Golesh,
 - Svetoslav,
 - Polk. Cholakovo,
 - Kamentzi,
 - Gospodinovo,
 - Sredishte,
 - Strelkovo,
 - Poprusanovo,
 - Posev,
- within municipality of Alfatar:
 - Alfatar,
 - Kutlovitza,
 - Vasil Levski,
- within municipality of Silistra:
 - Glavan,
 - Popkralevo,
 - Bogorovo,
 - Sratzimir,
 - Bulgarka,

in Dobrich region:

- within municipality of Krushari:
 - Kapitan Dimitrovo,
 - Ognyanovo,
 - Zimnitsa,
- within municipality of Tervel:
 - Brestnitsa,
 - Kolartzi.

3. The Czech Republic

The following areas in the Czech Republic:

- katastrální území obcí v okrese Zlín:
 - Bohuslavice u Zlína,
 - Bratřejov u Vizovic,
 - Březnice u Zlína,
 - Březová u Zlína,
 - Březůvky,
 - Dešná u Zlína,
 - Dolní Ves,
 - Doubravy,
 - Držková,
 - Fryšták,
 - Horní Lhota u Luhačovic,
 - Horní Ves u Fryštáku,
 - Hostišová,
 - Hrobice na Moravě,
 - Hvozdná,
 - Chrástěšov,
 - Jaroslavice u Zlína,
 - Jasenná na Moravě,
 - Karlovice u Zlína,
 - Kašava,
 - Klečůvka,
 - Kostelec u Zlína,
 - Kudlov,
 - Kvítkovice u Otrokovic,
 - Lhota u Zlína,
 - Lhotka u Zlína,
 - Lhotsko,
 - Lípa nad Dřevnicí,
 - Loučka I,
 - Loučka II,
 - Louky nad Dřevnicí,
 - Lukov u Zlína,
 - Lukoveček,
 - Lutonina,

- Lužkovice,
- Malenovice u Zlína,
- Mladcová,
- Neubuz,
- Oldřichovice u Napajedel,
- Ostrata,
- Podhradí u Luhačovic,
- Podkopná Lhota,
- Provodov na Moravě,
- Prštné,
- Příluky u Zlína,
- Racková,
- Raková,
- Salaš u Zlína,
- Sehradice,
- Slopné,
- Slušovice,
- Štípa,
- Tečovice,
- Trnava u Zlína,
- Ublo,
- Újezd u Valašských Klobouk,
- Velíková,
- Veselá u Zlína,
- Vítová,
- Vizovice,
- Vlčková,
- Všemina,
- Vysoké Pole,
- Zádveřice,
- Zlín,
- Želechovice nad Dřevnicí.

4. Estonia

The following areas in Estonia:

- Eesti Vabariik (välja arvatud Hiiu maakond).

5. Hungary

The following areas in Hungary:

- Heves megye 700860, 700950, 701050, 701111, 701150, 701250, 701350, 701550, 701560, 701650, 701750, 701850, 701950, 702050, 702150, 702250, 702260, 702950, 703050, 703150, 703250, 703370, 705150 és 705450 kódszámú vadgazdálkodási egységeinek teljes területe,
- Szabolcs-Szatmár-Bereg megye 850950, 851050, 851150, 851250, 851350, 851450, 851550, 851560, 851650, 851660, 851751, 851752, 852850, 852860, 852950, 852960, 853050, 853150, 853160, 853250, 853260, 853350, 853360, 853450, 853550, 854450, 854550, 854560, 854650, 854660, 854750, 854850, 854860, 854870, 854950, 855050, 855150, 856250, 856350, 856360, 856450, 856550, 856650, 856750, 856760, 856850, 856950, 857650, valamint 850150, 850250, 850260, 850350, 850450, 850550, 852050, 852150, 852250 és 857550 kódszámú vadgazdálkodási egységeinek teljes területe,
- Nógrád megye 550110, 550310, 550320, 550450, 550460, 550510, 550610, 550950, 551010, 551150, 551160, 551250, 551350, 551360, 551810 és 551821 kódszámú vadgazdálkodási egységeinek teljes területe,

- Borsod-Abaúj-Zemplén megye 656701, 656702, 656800, 656900, 657010, 657100, 658310, 658401, 658402, 658404, 658500, 658600, 658700, 658801, 658802, 658901, 658902, 659000, 659100, 659701, 659800 és 660800 kódszámú vadgazdálkodási egységeinek teljes területe.

6. Latvia

The following areas in Latvia:

- Ādažu novads,
- Aglonas novads,
- Aizkraukles novads,
- Aknīstes novads,
- Alojas novads,
- Alūksnes novads,
- Amatas novads,
- Apes novads,
- Auces novads,
- Babītes novads,
- Baldones novads,
- Baltnavas novads,
- Balvu novads,
- Bauskas novads,
- Beverīnas novads,
- Brocēnu novada Blīdenes pagasts, Remtes pagasta daļa uz austrumiem no autoceļa 1154 un P109,
- Burtnieku novads,
- Carnikavas novads,
- Cēsu novads,
- Cesvaines novads,
- Ciblas novads,
- Dagdas novads,
- Daugavpils novads,
- Dobeles novads,
- Dundagas novads,
- Engures novads,
- Ērgļu novads,
- Garkalnes novads,
- Gulbenes novads,
- Iecavas novads,
- Ikšķiles novads,
- Ilūkstes novads,
- Inčukalna novads,
- Jaunjelgavas novads,
- Jaunpiebalgas novads,
- Jaunpils novads,
- Jēkabpils novads,
- Jelgavas novads,
- Kandavas novads,
- Kārsavas novads,
- Ķeguma novads,

- Ķekavas novads,
- Kocēnu novads,
- Kokneses novads,
- Krāslavas novads,
- Krimuldas novads,
- Krustpils novads,
- Kuldīgas novada Ēdoles, Īvandes, Padures, Rendas, Kabiles, Rumbas, Kurmāles, Pelču, Snēpeles un Vārmes pagasts, Kuldīgas pilsēta,
- Lielvārdes novads,
- Līgatnes novads,
- Limbažu novads,
- Līvānu novads,
- Lubānas novads,
- Ludzas novads,
- Madonas novads,
- Mālpils novads,
- Mārupes novads,
- Mazsalacas novads,
- Mērsraga novads,
- Naukšēnu novads,
- Neretas novads,
- Ogres novads,
- Olaines novads,
- Ozolnieku novads,
- Pārgaujas novads,
- Pļaviņu novads,
- Preiļu novads,
- Priekules novada Priekules un Gramzdas pagasts, Priekules pilsēta,
- Priekuļu novads,
- Raunas novads,
- republikas pilsēta Daugavpils,
- republikas pilsēta Jelgava,
- republikas pilsēta Jēkabpils,
- republikas pilsēta Jūrmala,
- republikas pilsēta Rēzekne,
- republikas pilsēta Valmiera,
- Rēzeknes novads,
- Riebiņu novads,
- Rojas novads,
- Ropažu novads,
- Rugāju novads,
- Rundāles novads,
- Rūjienas novads,
- Salacgrīvas novads,
- Salas novads,
- Salaspils novads,

- Saldus novada Novadnieku, Kursīšu, Zvārdes, Pampāļu, Šķēdes, Nīgrandes, Zaņas, Ezeres, Rubas, Jaunaucē un Vadakstes pagasts,
- Saulkrastu novads,
- Sējas novads,
- Siguldas novads,
- Skrīveru novads,
- Skrundas novada Nīkrāces, Skrundas un Raņķu pagasts, Skrundas pilsēta,
- Smiltenes novads,
- Stopiņu novada daļa, kas atrodas uz austrumiem no autoceļa V36, P4 un P5, Acones ielas, Dauguļupes ielas un Dauguļupītes,
- Strenču novads,
- Talsu novads,
- Tērvetes novads,
- Tukuma novads,
- Vaiņodes novads,
- Valkas novads,
- Varakļānu novads,
- Vārkavas novads,
- Vecpiebalgas novads,
- Vecumnieku novads,
- Ventspils novada Ances, Tārgales, Popes, Vārves, Užavas, Piltenes, Puzes, Ziru, Ugāles, Usmas un Zlēku pagasts, Piltenes pilsēta,
- Viesītes novads,
- Viļakas novads,
- Viļānu novads,
- Zilupes novads.

7. Lithuania

The following areas in Lithuania:

- Alytaus rajono savivaldybė: Alovės, Butrimonių, Daugų, Krokialaukio, Miroslavo, Nemunaičio, Pivašiūnų Simno ir Raitininkų seniūnijos,
- Anykščių rajono savivaldybė,
- Biržų miesto savivaldybė,
- Biržų rajono savivaldybė,
- Druskininkų savivaldybė,
- Elektrėnų savivaldybė,
- Ignalinos rajono savivaldybė,
- Jonavos rajono savivaldybė,
- Jurbarko rajono savivaldybė: Eržvilko, Jurbarko miesto ir Jurbarkų seniūnijos,
- Kaišiadorių miesto savivaldybė,
- Kaišiadorių rajono savivaldybė,
- Kalvarijos savivaldybė,
- Kauno miesto savivaldybė,
- Kauno rajono savivaldybė,
- Kazlų Rūdos savivaldybė,

- Kelmės rajono savivaldybė: Tytuvėnų seniūnijos dalis į rytus ir pietus nuo kelio Nr. 157 ir į rytus nuo kelio Nr. 2105 ir Tytuvėnų apylinkių seniūnijos dalis į pietus nuo kelio Nr. 157 ir į rytus nuo kelio Nr. 2105,
- Kėdainių rajono savivaldybė,
- Kupiškio rajono savivaldybė,
- Lazdijų rajono savivaldybė: Būdveičių, Kapčiamiesčio, Krosnos, Kūčiūnų ir Noragėlių seniūnijos,
- Marijampolės savivaldybė: Igliaukos, Gudelių, Liudvinavo, Sasnavos, Šunskų seniūnijos,
- Molėtų rajono savivaldybė: Alantos, Balninkų, Čiulėnų, Inturkės, Joniško, Luokesos, Mindūnų, Suginėčių, Videniškių seniūnijos,
- Pakruojo rajono savivaldybė,
- Panevėžio rajono savivaldybė,
- Pasvalio rajono savivaldybė,
- Radviliškio rajono savivaldybė: Aukštelkų seniūnija, Baisogalos seniūnijos dalis į vakarus nuo kelio Nr. 144, Radviliškio, Radviliškio miesto seniūnija, Šeduvos miesto seniūnijos dalis į pietus nuo kelio Nr. A9 ir į vakarus nuo kelio Nr. 3417, Tyrulių, Pakalniškių, Sidabravo, Skėmių, Šeduvos miesto seniūnijos dalis į šiaurę nuo kelio Nr. A9 ir į rytus nuo kelio Nr. 3417, ir Šiaulėnų seniūnijos,
- Prienų miesto savivaldybė,
- Prienų rajono savivaldybė: Ašmintos, Balbieriškio, Išlaužo, Naujosios Ūtos, Pakuonio, Šilavoto ir Veiverių seniūnijos,
- Raseinių rajono savivaldybė: Ariogalos, Betygalos, Pajūkų, Šiluvos, Kalnų seniūnijos ir Girkalnio seniūnijos dalis į pietus nuo kelio Nr. A1,
- Rokiškio rajono savivaldybė,
- Šakių rajono savivaldybė: Gelgaudiškio, Kidulių, Lukšių, Plokščių ir Šakių seniūnijos,
- Šalčininkų rajono savivaldybė,
- Šilutės rajono savivaldybė: Rusnės seniūnija,
- Širvintų rajono savivaldybės: Čiobiškio, Gelvonų, Jauniūnų, Karnavės, Musninkų, Širvintų, Zibalų seniūnijos,
- Švenčionių rajono savivaldybė,
- Tauragės rajono savivaldybė: Batakių ir Gaurės seniūnijos,
- Telšių rajono savivaldybė: Degaičių, Gadūnavo, Luokės, Nevarėnų, Ryškėnų, Telšių miesto, Upynos, Varnių, Viešvėnų ir Žarėnų seniūnijos,
- Trakų rajono savivaldybė,
- Ukmergės rajono savivaldybė,
- Utenos rajono savivaldybė,
- Varėnos rajono savivaldybė,
- Vilniaus miesto savivaldybė,
- Vilniaus rajono savivaldybė: Avižienių, Bezdonių, Buivydžių, Dūkštų, Juodšilių, Kalvelių, Lavoriškių, Maišiagalos, Marijampolio, Medininkų, Mickūnų, Nemenčinės, Nemenčinės miesto, Nemėžio, Pagirių, Riešės, Rudaminos, Rukainių, Sudervės, Sužionių, Šatrininkų, Žujūnų seniūnijos,
- Vilkaviškio rajono savivaldybė,
- Visagino savivaldybė,
- Zarasų rajono savivaldybė.

8. Poland

The following areas in Poland:

w województwie warmińsko-mazurskim:

- Gminy Kalinowo, Prostki i gmina wiejska Elk w powiecie elckim,
- gminy Milejewo, Młynary i część obszaru lądowego gminy Tolkmicko położona na południe od linii brzegowej Zalewu Wiślanego i Zatoki Elbląskiej do granicy z gminą wiejską Elbląg w powiecie elbląskim,

- gmina Gołdap i część gminy Banie Mazurskie położona na południe od linii wyznaczonej przez drogę nr 650 w powiecie gołdapskim,
- gmina Pozezdrze i część gminy Węgorzewo położona na zachód od linii wyznaczonej przez drogę nr 63 biegnącą od południowo-wschodniej granicy gminy do skrzyżowania z drogą nr 650, a następnie na południe od linii wyznaczonej przez drogę nr 650 biegnącą od skrzyżowania z drogą nr 63 do skrzyżowania z drogą biegnącą do miejscowości Przysań i na wschód od linii wyznaczonej przez drogę łączącą miejscowości Przysań, Pniewo, Kamionek Wielki, Radzieje, Dłużec w powiecie węgorzewskim,
- powiat olecki,
- gminy Orzysz, Biała Piska i część gminy Pisz położona na północ od linii wyznaczonej przez drogę nr 58 w powiecie piskim,
- gmina Górowo Iławeckie z miastem Górowo Iławeckie, część gminy wiejskiej Bartoszyce położona na zachód od linii wyznaczonej przez drogę nr 51 biegnącą od północnej granicy gminy do skrzyżowania z drogą nr 57 i na zachód od linii wyznaczonej przez drogę nr 57 biegnącą od skrzyżowania z drogą nr 51 do południowej granicy gminy i miasto Bartoszyce w powiecie bartoszyckim,
- powiat braniewski,
- gminy Kętrzyn z miastem Kętrzyn, Reszel i część gminy Korsze położona na południe od linii wyznaczonej przez drogę biegnącą od wschodniej granicy łączącą miejscowości Krelikiejmy i Sątoczno i na wschód od linii wyznaczonej przez drogę łączącą miejscowości Sątoczno, Sajna Wielka biegnącą do skrzyżowania z drogą nr 590 w miejscowości Glitajny, a następnie na wschód od drogi nr 590 do skrzyżowania z drogą nr 592 i na południe od linii wyznaczonej przez drogę nr 592 biegnącą od zachodniej granicy gminy do skrzyżowania z drogą nr 590 w powiecie kętrzyńskim,
- część gminy Kiwity położona na północ od linii wyznaczonej przez drogę nr 513, część gminy Orneta położona na wschód od linii wyznaczonej przez linię kolejową łączącą miejscowości Lubomino i Pieniężno, część gminy wiejskiej Lidzbark Warmiński położona na północ od linii wyznaczonej przez drogę nr 51 biegnącą od południowo - zachodniej granicy gminy do południowo - zachodniej granicy miasta Lidzbark Warmiński i na północ od granic miasta Lidzbark Warmiński oraz linii wyznaczonej przez drogę nr 513 biegnącą od wschodniej granicy gminy do wschodniej granicy miasta Lidzbark Warmiński w powiecie lidzbarskim,
- część gminy Sorkwity położona na północ od drogi nr 16 i część gminy wiejskiej Mrągowo położona na północ od linii wyznaczonej przez drogę nr 16 biegnącą od zachodniej granicy gminy do granicy miasta Mrągowo oraz na północ od linii wyznaczonej przez drogę nr 59 biegnącą od wschodniej granicy gminy do granicy miasta Mrągowo w powiecie mrągowskim;

w województwie podlaskim:

- powiat grajewski,
- powiat moniecki,
- powiat sejneński,
- gminy Łomża, Piątnica, Śniadowo, Jedwabne, Przytuły i Wizna w powiecie łomżyńskim,
- powiat miejski Łomża,
- gminy Mielnik, Nurzec – Stacja, Grodzisk, Drohiczyn, Dziadkowice, Milejczyce i Siemiatycze z miastem Siemiatycze w powiecie siemiatyckim,
- powiat hajnowski,
- gminy Kobylin-Borzymy i Sokoły w powiecie wysokomazowieckim,
- część gminy Zambrów położona na północ od linii wyznaczonej przez drogę nr S8 w powiecie zambrowskim,
- gminy Grabowo i Stawiski w powiecie kolneńskim,
- gminy Czarna Białostocka, Dobrzyniewo Duże, Gródek, Juchnowiec Kościelny, Łapy, Michałowo, Supraśl, Suraż, Turośń Kościelna, Tykocin, Wasilków, Zabłudów, Zawady i Choroszcz w powiecie białostockim,
- gminy Boćki, Orla i Bielsk Podlaski z miastem Bielsk Podlaski w powiecie bielskim,
- gminy Bakałarzewo, Filipów, Jeleniewo, Raczki, Rutka-Tartak, Suwałki i Szypliszki w powiecie suwalskim,
- powiat miejski Suwałki,
- powiat augustowski,
- powiat sokółski,
- powiat miejski Białystok.

w województwie mazowieckim:

- gminy Przesmyki, Wodynie, Skórzec, Mokobody, Mordy, Siedlce, Suchożebry, Zbuczyn i część gminy Kotuń położona na wschód od linii wyznaczonej przez drogę łączącą miejscowości Nowa Dąbrówka, Pieróg, Kotuń wzdłuż ulicy Gorzkowskiego i Kolejowej do przejazdu kolejowego łączącego się z ulicą Siedlecką, Broszków, Żuków w powiecie siedleckim,
- powiat miejski Siedlce,
- gminy Repki, Jabłonna Lacka, część gminy Bielany położona na wschód od linii wyznaczonej przez drogę nr 63 i część gminy wiejskiej Sokołów Podlaski położona na wschód od linii wyznaczonej przez drogę nr 63 w powiecie sokołowskim,
- powiat łosicki,
- gmina Brochów w powiecie sochaczewskim,
- powiat nowodworski,
- gminy Joniec i Nowe Miasto w powiecie płońskim,
- gminy Pokrzywnica, Świercze i część gminy Winnica położona na zachód od linii wyznaczonej przez drogę łączącą miejscowości Bielany, Winnica i Pokrzywnica w powiecie pułuskim,
- gminy Dąbrówka, Kobyłka, Marki, Radzymin, Wołomin, Zielonka i Ząbki w powiecie wołomińskim,
- część gminy Somianka położona na południe od linii wyznaczonej przez drogę nr 62 w powiecie wyszkowskim,
- gminy Dębe Wielkie, Halinów, Latowicz, Siennica, Sulejówek, część gminy Ceglów położona na południe od linii wyznaczonej przez drogę biegnącą od zachodniej granicy gminy łączącą miejscowości Wiciejów, Mienia, Ceglów i na zachód od linii wyznaczonej przez drogę łączącą miejscowości Ceglów, Skwarne i Podskwarne biegnącą do wschodniej granicy gminy, część gminy Mińsk Mazowiecki położona na południe od linii wyznaczonej przez drogę nr 92 biegnącą od zachodniej granicy gminy do granicy miasta Mińsk Mazowiecki i na południe od linii wyznaczonej przez drogę biegnącą od wschodniej granicy miasta Mińsk Mazowiecki łączącą miejscowości Targówka, Budy Barczackie do wschodniej granicy gminy i miasto Mińsk Mazowiecki w powiecie mińskim,
- gminy Borowie, Wilga, Garwolin z miastem Garwolin, Maciejowice, Parysów, Pilawa i część gminy Miastków Kościelny położona na północ od rzeki Wilga w powiecie garwolińskim,
- powiat otwocki,
- powiat warszawski zachodni,
- powiat legionowski,
- powiat piaseczyński,
- powiat pruszkowski,
- gminy Chynów, Grójec, Jasieniec, Pniewy i Warka w powiecie grójeckim,
- gminy Milanówek, Grodzisk Mazowiecki, Podkowa Leśna i Żabia Wola w powiecie grodziskim,
- gminy Grabów nad Pilicą, Magnuszew, Głowaczów, Kozienice w powiecie kozienickim,
- część gminy Stromiec położona na północ od linii wyznaczonej przez drogę nr 48 w powiecie białobrzeskim,
- powiat miejski Warszawa.

w województwie lubelskim:

- gminy Borki, Czemierniki, Kąkolewnica, Komarówka Podlaska, Wohyń i Radzyń Podlaski z miastem Radzyń Podlaski w powiecie radzyńskim,
- gminy Stoczek Łukowski z miastem Stoczek Łukowski, Wola Mysłowska, Trzebieszów, Krzywda, część gminy Stanin położona na zachód od linii wyznaczonej przez drogę nr 807, część gminy wiejskiej Łuków położona na wschód od linii wyznaczonej przez drogę biegnącą od północnej granicy gminy przez miejscowość Wólka Świątkowa do północnej granicy miasta Łuków i na północ od linii wyznaczonej przez drogę nr 806 biegnącą od wschodniej granicy miasta Łuków do wschodniej granicy gminy wiejskiej Łuków i miasto Łuków w powiecie łukowskim,
- gminy Janów Podlaski, Kodeń, Tucznia, Leśna Podlaska, Rossosz, Łomazy, Konstantynów, Piszczac, Rokitno, Biała Podlaska, Zalesie, Terespol z miastem Terespol, Drelów, Międzyrzec Podlaski z miastem Międzyrzec Podlaski w powiecie białskim,
- powiat miejski Biała Podlaska,
- gmina Łęczna i część gminy Spiczyn położona na zachód od linii wyznaczonej przez drogę nr 829 w powiecie łęczyńskim,

- część gminy Siemień położona na zachód od linii wyznaczonej przez drogę nr 815 i część gminy Milanów położona na zachód od drogi nr 813 w powiecie parczewskim,
 - gminy Niedźwiada, Ostrówek, Abramów, Firlej, Kamionka, Michów i Lubartów z miastem Lubartów, w powiecie lubartowskim,
 - gminy Niemce i Garbów w powiecie lubelskim,
 - część gminy Piaski położona na północ od linii wyznaczonej przez drogę nr 17 biegnącą od wschodniej granicy gminy Piaski do skrzyżowania z drogą nr S12 i na wschód od linii wyznaczonej przez drogę biegnącą od skrzyżowania dróg nr 17 i nr S12 przez miejscowość Majdan Brzezicki do północnej granicy gminy w powiecie świdnickim;
 - gmina Fajslawice, Izbica, Kraśniczyn, część gminy Krasnystaw położona na zachód od linii wyznaczonej przez drogę nr 17 biegnącą od północno – wschodniej granicy gminy do granicy miasta Krasnystaw, miasto Krasnystaw i część gminy Łopiennik Górny położona na zachód od linii wyznaczonej przez drogę nr 17 w powiecie krasnostawskim,
 - gminy Dołhobyczów, Mircze i część gminy wiejskiej Hrubieszów położona na południe od linii wyznaczonej przez drogę nr 844 oraz na południe od linii wyznaczonej przez drogę nr 74 i miasto Hrubieszów w powiecie hrubieszowskim,
 - gmina Telatyn w powiecie tomaszowskim,
 - część gminy Wojsławice położona na zachód od linii wyznaczonej przez drogę biegnącą od północnej granicy gminy przez miejscowość Wojsławice do południowej granicy gminy w powiecie chełmskim,
 - gmina Grabowiec i Skierbieszów w powiecie zamojskim,
 - gminy Markuszów, Nałęczów, Kazimierz Dolny, Końskowola, Kurów, Wąwolnica, Żyrzyn, Baranów, część gminy wiejskiej Puławy położona na wschód od rzeki Wisły i miasto Puławy w powiecie puławskim,
 - gminy Annapol, Dzierzkowice i Gościeradów w powiecie kraśnickim,
 - gmina Józefów nad Wisłą w powiecie opolskim,
- w województwie podkarpackim:
- gminy Radomyśl nad Sanem i Zaklików w powiecie stalowowolskim.

PART III

1. Latvia

The following areas in Latvia:

- Brocēnu novads Cieceres un Gaiķu pagasts, Remtes pagasta daļa uz rietumiem no autoceļa 1154 un P109, Brocēnu pilsēta,
- Saldus novads Saldus, Zirņu, Lutriņu un Jaunlutriņu pagasts, Saldus pilsēta.

2. Lithuania

The following areas in Lithuania:

- Akmenės rajono savivaldybė,
- Alytaus miesto savivaldybė,
- Alytaus rajono savivaldybė: Alytaus, Punios seniūnijos,
- Birštono savivaldybė,
- Jurbarko rajono savivaldybė: Girdžių, Juodaičių, Raudonės, Seredžiaus, Skirsnemunės, Šimkaičių ir Veliunos seniūnijos,
- Joniškio rajono savivaldybė,
- Lazdijų rajono savivaldybė: Lazdijų miesto, Lazdijų, Seirijų, Šeštokų, Šventėžio, Teizių ir Veisiejų seniūnijos,
- Marijampolės savivaldybė: Degutių, Mokolų, Narto, Marijampolės seniūnijos,
- Mažeikių rajono savivaldybės: Laižuvos, Mažeikių apylinkės, Mažeikių, Reivyčių, Tirkšlių ir Viekšnių seniūnijos,
- Molėtų rajono savivaldybė: Dubingių, Giedraičių seniūnijos,
- Prienų rajono savivaldybė: Jiezno ir Stakliškių seniūnijos,
- Radviškio rajono savivaldybė: Baisogalos seniūnijos dalis į rytus nuo kelio Nr. 144, Grinkiškio ir Šaukoto seniūnijos,

- Raseinių rajono savivaldybė: Kalnų seniūnijos ir Girkalnio seniūnijos dalis į pietus nuo kelio Nr. A1,
- Šiaulių miesto savivaldybė,
- Šiaulių rajono savivaldybė,
- Širvintų rajono savivaldybė: Alionių seniūnija,
- Telšių rajono savivaldybė: Tryškių seniūnija,
- Vilniaus rajono savivaldybė: Paberžės sen.

3. Poland

The following areas in Poland:

w województwie warmińsko-mazurskim:

- gmina Sępólno i część gminy wiejskiej Bartoszyce położona na wschód od linii wyznaczonej przez drogę nr 51 biegnącą od północnej granicy gminy do skrzyżowania z drogą nr 57 i na wschód od linii wyznaczonej przez drogę nr 57 biegnącą od skrzyżowania z drogą nr 51 do południowej granicy gminy w powiecie bartoszyckim,
- gminy Srokowo, Barciany i część gminy Korsze położona na północ od linii wyznaczonej przez drogę biegnącą od wschodniej granicy łączącą miejscowości Kreliekijmy i Sątoczno i na zachód od linii wyznaczonej przez drogę łączącą miejscowości Sątoczno, Sajna Wielka biegnącą do skrzyżowania z drogą nr 590 w miejscowości Glitajny, a następnie na zachód od drogi nr 590 do skrzyżowania z drogą nr 592 i na północ od linii wyznaczonej przez drogę nr 592 biegnącą od zachodniej granicy gminy do skrzyżowania z drogą nr 590 w powiecie kętrzyńskim,
- gmina Budry i część gminy Węgorzewo położona na wschód od linii wyznaczonej przez drogę nr 63 biegnącą od południowo-wschodniej granicy gminy do skrzyżowania z drogą nr 650, a następnie na północ od linii wyznaczonej przez drogę nr 650 biegnącą od skrzyżowania z drogą nr 63 do skrzyżowania z drogą biegnącą do miejscowości Przysań i na zachód od linii wyznaczonej przez drogę łączącą miejscowości Przysań, Pniewo, Kamionek Wielki, Radziejewo, Dłużec w powiecie węgorzewskim,
- część gminy Banie Mazurskie położona na północ od linii wyznaczonej przez drogę nr 650 w powiecie gołdapskim,

w województwie mazowieckim:

- gminy Domanice, Korczew, Paprotnia i Wiśniew w powiecie siedleckim,

w województwie lubelskim:

- gminy Białopole, Dubienka, Chełm, Leśniowice, Wierzbica, Sawin, Ruda Huta, Dorohusk, Kamień, Rejowiec, Rejowiec Fabryczny z miastem Rejowiec Fabryczny, Siedliszcze, Żmudź i część gminy Wojsławice położona na wschód od linii wyznaczonej przez drogę biegnącą od północnej granicy gminy do miejscowości Wojsławice do południowej granicy gminy w powiecie chełmskim,
- powiat miejski Chełm,
- gmina Siennica Różana część gminy Łopiennik Górny położona na wschód od linii wyznaczonej przez drogę nr 17 i część gminy Krasnystaw położona na wschód od linii wyznaczonej przez drogę nr 17 biegnącą od północno – wschodniej granicy gminy do granicy miasta Krasnystaw w powiecie krasnostawskim,
- gminy Hanna, Hańsk, Wola Uhruska, Urszulín, Stary Brus, Wiryki i gmina wiejska Włodawa w powiecie włodawskim,
- gminy Cyców, Ludwin, Puchaczów, Milejów i część gminy Spiczyn położona na wschód od linii wyznaczonej przez drogę nr 829 w powiecie łęczyńskim,
- gmina Trawniki w powiecie świdnickim,
- gminy Jabłoń, Podedwórze, Dębowa Kłoda, Parczew, Sosnowica, część gminy Siemień położona na wschód od linii wyznaczonej przez drogę nr 815 i część gminy Milanów położona na wschód od drogi nr 813 w powiecie parczewskim,
- gminy Sławatycze, Sosnówka, i Wisznice w powiecie białskim,
- gmina Ulan Majorat w powiecie radzyńskim,
- gminy Ostrów Lubelski, Serniki i Uścimów w powiecie lubartowskim,
- gmina Wojcieszków, część gminy wiejskiej Łuków położona na zachód od linii wyznaczonej przez drogę biegnącą od północnej granicy gminy przez miejscowość Wólka Świątkowa do północnej granicy miasta Łuków, a następnie na północ, zachód, południe i wschód od linii stanowiącej północną, zachodnią, południową i wschodnią granicę miasta Łuków do jej przecięcia się z drogą nr 806 i na południe od linii wyznaczonej przez drogę nr 806 biegnącą od wschodniej granicy miasta Łuków do wschodniej granicy gminy wiejskiej Łuków i część gminy Stanin położona na wschód od linii wyznaczonej przez drogę nr 807 w powiecie łukowskim;

- gminy Horodło, Uchanie i część gminy wiejskiej Hrubieszów położona na północ od linii wyznaczonej przez drogę nr 844 biegnącą od zachodniej granicy gminy wiejskiej Hrubieszów do granicy miasta Hrubieszów oraz na północ od linii wyznaczonej przez drogę nr 74 biegnącą od wschodniej granicy miasta Hrubieszów do wschodniej granicy gminy wiejskiej Hrubieszów w powiecie hrubieszowskim,

w województwie podkarpackim:

- gminy Cieszanów, Lubaczów z miastem Lubaczów i część gminy Oleszyce położona na północ od linii wyznaczonej przez drogę biegnącą od wschodniej granicy gminy przez miejscowość Borchów do skrzyżowania z drogą nr 865 w miejscowości Oleszyce, a następnie na wschód od linii wyznaczonej przez drogę nr 865 biegnącą w kierunku północno-wschodnim do skrzyżowania z drogą biegnącą w kierunku północno-zachodnim przez miejscowość Lubomierz - na północ od linii wyznaczonej przez tę drogę do skrzyżowania z drogą łączącą miejscowości Uszkowce i Nowy Dzików – na wschód od tej drogi w powiecie lubaczowskim.

4. Romania

The following areas in Romania:

- Zona oraşului Bucureşti,
- Judeţul Constanţa,
- Judeţul Satu Mare,
- Judeţul Tulcea,
- Judeţul Bacău,
- Judeţul Bihor,
- Judeţul Brăila,
- Judeţul Buzău,
- Judeţul Călăraşi,
- Judeţul Dâmboviţa,
- Judeţul Galaţi,
- Judeţul Giurgiu,
- Judeţul Ialomiţa,
- Judeţul Ilfov,
- Judeţul Prahova,
- Judeţul Sălaj,
- Judeţul Vaslui,
- Judeţul Vrancea,
- Judeţul Teleorman,
- Partea din judeţul Maramureş cu următoarele delimitări:
 - Comuna Petrova,
 - Comuna Bistra,
 - Comuna Repedea,
 - Comuna Poienile de sub Munte,
 - Comuna Vişeu e Jos,
 - Comuna Ruscova,
 - Comuna Leordina,
 - Comuna Rozavlea,
 - Comuna Strâmtura,
 - Comuna Bârsana,
 - Comuna Rona de Sus,
 - Comuna Rona de Jos,
 - Comuna Bocoiu Mare,
 - Comuna Sighetu Marmăţiei,

- Comuna Sarasau,
- Comuna Câmpulung la Tisa,
- Comuna Săpânța,
- Comuna Remeti,
- Comuna Giulești,
- Comuna Ocna Șugatag,
- Comuna Desești,
- Comuna Budești,
- Comuna Băiuț,
- Comuna Căvnic,
- Comuna Lăpuș,
- Comuna Dragomirești,
- Comuna Ieud,
- Comuna Saliștea de Sus,
- Comuna Săcel,
- Comuna Călinești,
- Comuna Vadu Izei,
- Comuna Botiza,
- Comuna Bogdan Vodă,
- Localitatea Groșii Țibileșului, comuna Suciu de Sus,
- Localitatea Vișeu de Mijloc, comuna Vișeu de Sus,
- Localitatea Vișeu de Sus, comuna Vișeu de Sus.
- Partea din județul Mehedinți cu următoarele comune:
 - Comuna Strehaia,
 - Comuna Greci,
 - Comuna Brejnita Motru,
 - Comuna Butoiești,
 - Comuna Stângăceaua,
 - Comuna Grozești,
 - Comuna Dumbrava de Jos,
 - Comuna Băcles,
 - Comuna Bălăcița,
- Partea din județul Arges cu următoarele comune:
 - Comuna Bârla,
 - Comuna Miroși,
 - Comuna Popești,
 - Comuna Ștefan cel Mare,
 - Comuna Slobozia,
 - Comuna Mozăceni,
 - Comuna Negrași,
 - Comuna Izvoru,
 - Comuna Recea,
 - Comuna Căldăraru,
 - Comuna Ungheni,
 - Comuna Hârsești,

- Comuna Stolnici,
- Comuna Vulpești,
- Comuna Rociu,
- Comuna Lunca Corbului,
- Comuna Costești,
- Comuna Măreșești,
- Comuna Poiana Lacului,
- Comuna Vedea,
- Comuna Uda,
- Comuna Cuca,
- Comuna Morărești,
- Comuna Cotmeanaâ,
- Comuna Răchițele de Jos,
- Comuna Drăganu-Olteni,
- Comuna Băbana,
- Comuna Bascov,
- Comuna Moșoaia,
- Municipiul Pitești,
- Comuna Albota,
- Comuna Oarja,
- Comuna Bradu,
- Comuna Suseni,
- Comuna Căteasca,
- Comuna Rătești,
- Comuna Teiu,
- Județul Olt,
- Județul Dolj.

PART IV

Italy

The following areas in Italy:

- tutto il territorio della Sardegna.’
-

ACTS ADOPTED BY BODIES CREATED BY INTERNATIONAL AGREEMENTS

Only the original UN/ECE texts have legal effect under international public law. The status and date of entry into force of this Regulation should be checked in the latest version of the UN/ECE status document TRANS/WP.29/343, available at:

<http://www.unece.org/trans/main/wp29/wp29wgs/wp29gen/wp29docstts.html>

Regulation No 39 of the Economic Commission for Europe of the United Nations (UN/ECE) — Uniform provisions concerning the approval of vehicles with regard to the speedometer and odometer equipment including its installation [2018/1857]

Incorporating all valid text up to:

Supplement 1 to the 01 series of amendments – Date of entry into force: 10 October 2017

CONTENTS

REGULATION

1. Scope
2. Definitions
3. Application for approval
4. Approval
5. Specifications
6. Modifications of the vehicle type
7. Conformity of production
8. Penalties for non-conformity of production
9. Names and addresses of Technical Services responsible for conducting approval tests and of Type Approval Authorities
10. Transitional provisions

ANNEXES

1. Communication
2. Arrangements of approval marks
3. Test of speedometer accuracy for conformity of production

1. SCOPE

This Regulation applies to the approval of vehicles of categories L, M and N. ⁽¹⁾

2. DEFINITIONS

For the purposes of this Regulation:

- 2.1. 'Approval of a vehicle' means the approval of a vehicle type with regard to the speedometer and odometer equipment including its installation.
- 2.2. 'Type of vehicle in respect of its speedometer and odometer' means vehicles which do not among themselves display any essential differences, where those differences can apply, in particular, to the following:
 - 2.2.1. The size designation of the tyres chosen from the range of tyres normally fitted;

⁽¹⁾ As defined in the Consolidated Resolution on the Construction of Vehicles (R.E.3.), document ECE/TRANS/WP.29/78/Rev.6, para. 2. - www.unece.org/trans/main/wp29/wp29wgs/wp29gen/wp29resolutions.html

- 2.2.2. The overall transmission ratio, including any reduction drives, to the speedometer;
- 2.2.3. The type of speedometer as characterised by:
 - 2.2.3.1. The tolerances of the speedometer's measuring mechanism;
 - 2.2.3.2. The technical constant of the speedometer;
 - 2.2.3.3. The range of speeds displayed.
- 2.2.4. The type of odometer as characterised by:
 - 2.2.4.1. The technical constant of odometer;
 - 2.2.4.2. The number of numerals.
- 2.3. 'Tyres normally fitted' means the type or types of tyre provided by the manufacturer on the vehicle type in question; snow tyres shall not be regarded as tyres normally fitted;
- 2.4. 'Normal running pressure' means the cold inflation pressure specified by the vehicle manufacturer increased by 0,2 bar;
- 2.5. 'Speedometer' means that part of the speedometer equipment which indicates to the driver the speed of his vehicle at any given moment; ⁽¹⁾
- 2.5.1. 'Tolerances of the speedometer's measuring mechanism' shall mean the accuracy of the speedometer instrument itself, expressed as the upper and the lower speed indication limits for a range of speed inputs;
- 2.5.2. 'Technical constant of the speedometer' shall mean the relationship between the input revolutions or pulses per minute and a specified displayed speed;
- 2.6. 'Odometer' means that part of the odometer equipment which indicates to the driver the total distance recorded by the vehicle since its entry into service.
- 2.6.1. 'Technical constant of the odometer' means the relationship between the input revolutions or pulses and the distance travelled by the vehicle.
- 2.7. 'Unladen vehicle' means the vehicle in running order, complete with fuel, coolant, lubricant, tools and a spare wheel (if provided as standard equipment by the vehicle manufacturer), carrying a driver weighing 75 kg, but no driver's mate, optional accessories or load.
- 3. APPLICATION FOR APPROVAL
 - 3.1. The application for approval of a vehicle type with regard to the speedometer and odometer equipment including its installation shall be submitted by the vehicle manufacturer or by his duly accredited representative.
 - 3.2. It shall be accompanied by the following documents in triplicate and by the following particulars:
 - 3.2.1. A description of the vehicle type with regard to the items mentioned in paragraphs 2.2, 2.3, 2.4, 2.5 and 2.6 above; the vehicle type shall be specified.
 - 3.3. An unladen vehicle representative of the vehicle type to be approved shall be submitted to the technical service conducting approval tests.
 - 3.4. The Type Approval Authority shall verify the existence of satisfactory arrangements for ensuring effective control of the conformity of production before type approval is granted.
- 4. APPROVAL
 - 4.1. If the vehicle type submitted for approval pursuant to this Regulation meets the requirements of the Regulation in respect of the speedometer and odometer equipment including its installation, approval of that vehicle type shall be granted.
 - 4.2. An approval number shall be assigned to each type approved. The first two digits shall be the highest number of the series of amendments incorporated in the Regulation at the time of issue of the approval. The same Contracting Party may not assign the same number to another vehicle type subject to the provisions of paragraph 6 of this Regulation.

⁽¹⁾ This does not include the speed-indicating part of a tachograph if this complies with type approval specifications which do not permit an absolute difference between true and indicated speed which is higher than the values resulting from the requirements in paragraph 5.4 below.

- 4.3. Notice of approval or of refusal of approval of a vehicle type pursuant to this Regulation shall be communicated to the Parties to the Agreement which apply this Regulation by means of a form conforming to the model in Annex 1 to this Regulation and of diagrams, supplied by the applicant for approval, of the installation in a format not larger than A4 (210 × 297 mm) or folded to that format, and on an appropriate scale.
- 4.4. To every vehicle conforming to a vehicle type approved under this Regulation there shall be affixed in a conspicuous and easily accessible position, specified on the approval form, an international approval mark consisting of:
- 4.4.1. A circle surrounding the letter 'E' followed by the distinguishing number of the country which has granted approval ⁽¹⁾;
- 4.4.2. The number of this Regulation, followed by the letter 'R', a dash and the approval number to the right of the circle described in paragraph 4.4.1.
- 4.5. If the vehicle conforms to a vehicle type approved under one or more other Regulations annexed to the Agreement in the country which has granted approval under this Regulation, the symbol prescribed in paragraph 4.4.1 need not be repeated; in such a case the additional numbers and symbols of all the Regulations under which approval has been granted in the country which has granted approval under this Regulation shall be placed in vertical columns to the right of the symbol prescribed in paragraph 4.4.1.
- 4.6. The approval mark shall be clearly legible and shall be indelible.
- 4.7. The approval mark shall be placed close to or on the vehicle data plate affixed by the manufacturer.
- 4.8. Annex 2 to this Regulation gives examples of arrangements of approval marks.
5. SPECIFICATIONS
- 5.1. An onboard speedometer and odometer complying with the requirements of this Regulation shall be fitted to the vehicle to be approved.
- 5.2. The display of the speedometer shall be located within the direct field of view of the driver and shall be clearly legible both day and night. The range of speeds displayed shall be sufficiently wide to include the maximum speed of this type of vehicle as stated by the manufacturer.
- 5.2.1. In the case of speedometers intended for vehicles of categories M, N, and L₃, L₄, L₅, and L₇, the graduation shall be 1, 2, 5 or 10 km/h. The numerical values of the speed shall be indicated on the display as follows: when the highest value on the display does not exceed 200 km/h, speed values shall be indicated at intervals not exceeding 20 km/h. When the maximum value on the display exceeds 200 km/h, then the speed values shall be indicated at intervals not exceeding 30 km/h. The indicated numerical speed value intervals need not be uniform.
- If a setting makes it possible for the driver to choose between the speed in km/h and mph (miles per hour), then the speed may be displayed only in either km/h or mph at any one time. The corresponding unit shall permanently be displayed.
- 5.2.2. In the case of vehicles of categories M, N, and L₃, L₄, L₅, and L₇ manufactured for sale in any country where imperial units are used, the speedometer shall also be marked in miles per hour (mph); the graduations shall be of 1, 2, 5 or 10 mph.
- The speed may be displayed either in km/h or mph at any one time provided that a setting makes it possible for the driver to choose between the speed in km/h and mph, in that case the corresponding unit shall permanently be displayed.
- The numerical values of the speed shall be indicated on the display at intervals not exceeding 20 mph and commencing at 10 or 20 mph. The indicated numerical speed value intervals need not be uniform.
- 5.2.3. In the case of speedometers intended for vehicles of categories L₁ (mopeds), L₂, and L₆, the display readings shall not exceed 80 km/h. The graduation shall be 1, 2, 5 or 10 km/h and the marked numerical values of the speed indicated shall not exceed 10 km/h. The indicated numerical speed value intervals need not be uniform.

⁽¹⁾ The distinguishing numbers of the Contracting Parties to the 1958 Agreement are reproduced in Annex 3 to the Consolidated Resolution on the Construction of Vehicles (R.E.3), document ECE/TRANS/WP.29/78/Rev. 6, Annex 3 - www.unece.org/trans/main/wp29/wgs/wp29gen/wp29resolutions.html

- 5.2.4. In the case of vehicles of categories L₁, L₂ and L₆ manufactured for sale in any country where imperial units are used, the speedometer shall also be marked in mph; the graduation shall be of 1, 2, 5 or 10 mph. The numerical values of the speed shall be indicated on the display at intervals not exceeding 10 mph and starting at 10 or 20 mph. The indicated numerical speed value intervals need not be uniform. If a setting makes it possible for the driver to choose between the speed in km/h and mph, then the speed may be displayed only in km/h or mph at one time at any one time. The corresponding unit shall permanently be displayed.
- 5.3. The accuracy of the speedometer equipment shall be tested in accordance with the following procedure:
- 5.3.1. The tyres shall be one of the types normally fitted to the vehicle as defined in paragraph 2.3 of this Regulation. A test shall be carried out for each type of speedometer intended to be fitted by the manufacturer.
- 5.3.2. The test shall be carried out with the vehicle at its unladen weight. An additional weight can be carried for purposes of measurement. The weight of the vehicle and its distribution between the axles shall be indicated in the approval communication (see Annex 1, item 7);
- 5.3.3. The reference temperature at the speedometer shall be 23 ± 5 °C;
- 5.3.4. During each test the pressure of the tyres shall be the normal running pressure as defined in paragraph 2.4;
- 5.3.5. The vehicle is tested at the following speeds:

Maximum design speed (V_{\max}) of the vehicle specified by the vehicle manufacturer (km/h)	Test speed (V_1) (km/h)
$V_{\max} \leq 45$	80 % of V_{\max}
$45 < V_{\max} \leq 100$	40 km/h and 80 % V_{\max} (if the resulting speed is ≥ 55 km/h)
$100 < V_{\max} \leq 150$	40 km/h, 80 km/h and 80 % V_{\max} (if the resulting speed is ≥ 100 km/h)
$150 < V_{\max}$	40 km/h, 80 km/h and 120 km/h

- 5.3.6. The test instrumentation used for measuring the true vehicle speed shall be accurate to $\pm 0,5$ per cent;
- 5.3.6.1. The surface of a test track when used shall be flat and dry, and provide sufficient adhesion;
- 5.3.6.2. If a roller dynamometer is used for the test, the diameter of the roller should be at least 0,4 m;
- 5.4. The speed indicated shall not be less than the true speed of the vehicle. At the test speeds specified in paragraph 5.3.5 above, there shall be the following relationship between the speed displayed (V_1) and the true speed (V_2).

$$0 \leq (V_1 - V_2) \leq 0,1 V_2 + 4 \text{ km/h}$$

- 5.5. The display of the odometer shall be visible or accessible to the driver. The odometer shall display at least an integer number composed of a minimum of 6 numerals for the vehicles of categories M and N, and at least an integer number composed of a minimum of 5 numerals for the vehicles of category L. Nevertheless, the Type Approval Authorities may also accept an integer number composed of at least 5 numerals for the vehicles of categories M and N if the intended use of the vehicle justifies it.
- 5.5.1. In the case of vehicles manufactured for sale in any country where imperial units are used, the odometer shall be marked in miles.
6. MODIFICATIONS OF THE VEHICLE TYPE
- 6.1. Every modification of the vehicle type shall be communicated to the Type Approval Authority which approved the vehicle type. The Authority may then either:
- 6.1.1. Consider that the modifications made are unlikely to have an appreciable adverse effect and that in any case the vehicle still meets the requirements; or
- 6.1.2. Require a further test report from the Technical Service responsible for conducting the tests.

- 6.2. Notice of confirmation or refusal of approval, accompanied by particulars of the modifications, shall be communicated by the procedure specified in paragraph 4.3 above to the Parties to the Agreement applying this Regulation.

7. CONFORMITY OF PRODUCTION

- 7.1. The conformity of production procedures shall comply with those set out in the Agreement, Schedule 1 (E/ECE/TRANS/505/Rev.3), with the following requirements:
- 7.2. Every vehicle approved under this Regulation shall be so manufactured as to conform to the type approved by meeting the requirements of the relevant part(s) of this Regulation.
- 7.3. For each type of vehicle sufficient checks are carried out regarding the speedometer equipment and its installation; in particular, for each type of vehicle at least the test prescribed in Annex 3 to this Regulation shall be carried out.
- 7.4. The Authority, which has granted type approval, may at any time verify the conformity control methods applied in each production facility. The normal frequency of these verifications shall be once every two years.
- 7.5. Where unsatisfactory results are found during verifications and checks pursuant to paragraph 7.4 above, the competent authority shall ensure that all necessary steps are taken to restore conformity of production as rapidly as possible.

8. PENALTIES FOR NON-CONFORMITY OF PRODUCTION

- 8.1. The approval granted for a vehicle type pursuant to this Regulation may be withdrawn if the requirement laid down in paragraph 7.1 above is not met or if the vehicles have failed to pass the checks prescribed in paragraph 7 above.
- 8.2. If a Party to the Agreement which applies this Regulation withdraws an approval it has previously granted, it shall forthwith so notify the other Contracting Parties applying this Regulation, by means of a communication form conforming to the model in Annex 1 to this Regulation.

9. NAMES AND ADDRESSES OF TECHNICAL SERVICES RESPONSIBLE FOR CONDUCTING APPROVAL TESTS AND OF TYPE APPROVAL AUTHORITIES

The Contracting Parties to the Agreement applying this Regulation shall communicate to the secretariat of the United Nations the names and addresses of the Technical Services responsible for conducting approval tests and of the Type Approval Authorities which grant approval and to which forms certifying approval or extension or refusal or withdrawal of approval, issued in other countries, are to be sent.

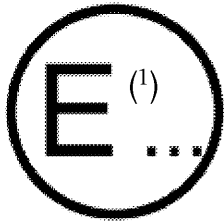
10. TRANSITIONAL PROVISIONS

- 10.1. As from the official date of entry into force of the 01 series of amendments, no Contracting Party applying this Regulation shall refuse to grant or refuse to accept type approvals under this Regulation as amended by the 01 series of amendments.
- 10.2. As from 1 September 2017, Contracting Parties applying this Regulation shall grant new type approvals only if the vehicle type to be approved meets the requirements of this Regulation as amended by the 01 series of amendments.
- 10.3. Contracting Parties applying this Regulation shall not refuse to grant extensions of type approvals for existing types which have been granted according to the preceding series of amendments to this Regulation.
- 10.4. After the date of entry into force of the 01 series of amendments to this Regulation, Contracting Parties applying this Regulation shall continue to accept type approvals granted according to the preceding series of amendments to the Regulation.
-

ANNEX 1

COMMUNICATION

(Maximum format: A4 (210 × 297 mm))



issued by: Name of administration

.....

.....

.....

Concerning ⁽²⁾: Approval granted

Approval extended

Approval refused

Approval withdrawn

Production definitively discontinued

of a vehicle type with regard to the speedometer and odometer equipment including its installation pursuant to Regulation No 39.

Approval No Extension No

1. Trade name or mark of the vehicle:
2. Vehicle type:
3. Manufacturer's name and address:
4. If applicable, name and address of the manufacturer's representative:
5. Description of the speedometer equipment:
- 5.1. Details of tyres normally fitted:
- 5.2. Details of tyres fitted during the test:
- 5.3. Ratio of speedometer equipment:
6. Description of the odometer equipment:
7. Mass of vehicle as tested and its distribution between the axles:
8. Variants:
9. Vehicle submitted for approval on:
10. Technical Service responsible for conducting approval tests:
11. Date of report issued by that Service:
12. Number of report issued by that Service:
13. Approval granted/refused/extended/withdrawn ⁽²⁾
14. Position of approval mark on the vehicle:
15. Place:
16. Date:
17. Signature:

⁽¹⁾ Distinguishing number of the country which has granted, extended, refused or withdrawn approval (see approval provisions in the Regulation).

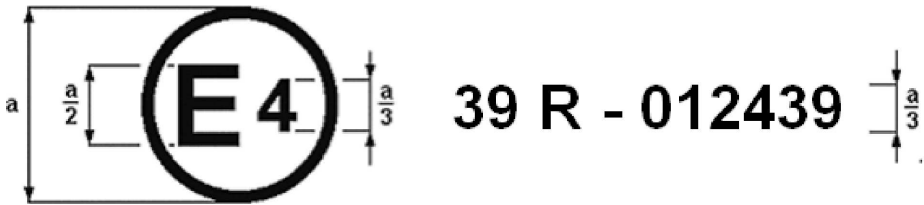
⁽²⁾ Strike out what does not apply.

ANNEX 2

ARRANGEMENTS OF APPROVAL MARKS

MODEL A

(see paragraph 4.4 of this Regulation)

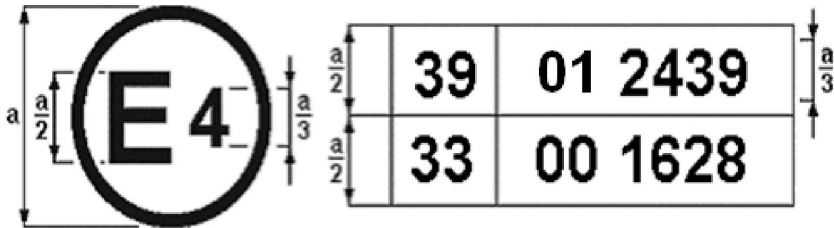


a = 8 mm min.

The above approval mark affixed to a vehicle shows that the vehicle type concerned has been approved in the Netherlands (E 4), pursuant to Regulation No 39. The approval number indicates that the approval was granted in accordance with the requirements of UN Regulation No 39 incorporating the 01 series of amendments.

MODEL B

(see paragraph 4.5 of this Regulation)



a = 8 mm min.

The above approval mark affixed to a vehicle shows that the vehicle type concerned has been approved in the Netherlands (E 4) pursuant to Regulations Nos 39 and 33 ⁽¹⁾ The approval numbers indicate that, at the dates when the respective approvals were granted, UN Regulation No 39 incorporated the 01 series of amendments and Regulation No 33 was still in its original form.

⁽¹⁾ The second number is given merely as an example.

ANNEX 3

TEST OF SPEEDOMETER ACCURACY FOR CONFORMITY OF PRODUCTION**1. TEST CONDITIONS**

The test conditions shall be as set out in paragraphs 5.3.1 to 5.3.6 of this Regulation.

2. REQUIREMENTS

The production shall be deemed to conform to this Regulation if the following relationship between the speed indicated on the display of the speedometer (V_1) and the actual speed (V_2) is observed:

In the case of vehicles of categories M and N:

$$0 \leq (V_1 - V_2) \leq 0,1 V_2 + 6 \text{ km/h};$$

In the case of vehicles of categories L₃, L₄ and L₅:

$$0 \leq (V_1 - V_2) \leq 0,1 V_2 + 8 \text{ km/h};$$

In the case of vehicles of categories L₁ and L₂:

$$0 \leq (V_1 - V_2) \leq 0,1 V_2 + 4 \text{ km/h}.$$

Only the original UN/ECE texts have legal effect under international public law. The status and date of entry into force of this Regulation should be checked in the latest version of the UN/ECE status document TRANS/WP.29/343, available at:

<http://www.unece.org/trans/main/wp29/wp29wgs/wp29gen/wp29fdocstts.html>

Amendments to Regulation No 100 of the Economic Commission for Europe of the United Nations (UN/ECE) — Uniform provisions concerning the approval of vehicles with regard to specific requirements for the electric power train [2018/1858]

Amendments to Regulation No 100 published in OJ L 87 of 31 March 2015

Incorporating:

Supplement 2 to the 02 series of amendments — Date of entry into force: 29 January 2016

Supplement 3 to the 2 series of amendments — Date of entry into force: 18 June 2016

Through all the text of the Regulation (including all annexes), Rechargeable Energy Storage System (REESS), amend to read: Rechargeable Electrical Energy Storage System (REESS).

Paragraphs 5.1 to 5.1.1.3, amend to read:

‘5.1. Protection against electrical shock

These electrical safety requirements apply to high voltage buses under conditions where they are not connected to external high voltage power supplies.

5.1.1. Protection against direct contact

Protection against direct contact with live parts is also required for vehicles equipped with any REESS type approved under Part II of this Regulation.

Live parts shall be protected against direct contact and shall comply with paragraphs 5.1.1.1 and 5.1.1.2. Barriers, enclosures, solid insulators and connectors shall not be able to be opened, separated, disassembled or removed without the use of tools.

However, connectors (including the vehicle inlet) are allowed to be separated without the use of tools, if they meet one or more of the following requirements:

- (a) They comply with paragraphs 5.1.1.1 and 5.1.1.2 when separated; or
- (b) They are located underneath the floor and are provided with a locking mechanism; or
- (c) They are provided with a locking mechanism. Other components, not being part of the connector, shall be removable only with the use of tools in order to be able to separate the connector; or
- (d) The voltage of the live parts becomes equal or below 60 V DC or equal or below 30 V AC (rms) within 1 s after the connector is separated.

5.1.1.1. For protection of live parts inside the passenger compartment or luggage compartment, the protection degree IPXXD shall be provided.

5.1.1.2. For protection of live parts in areas other than the passenger compartment or luggage compartment, the protection degree IPXXB shall be satisfied.’

Paragraphs 5.1.1.4 to 5.1.1.5.3 (former), renumber as paragraphs 5.1.1.3 to 5.1.1.4.3.

CORRIGENDA**Corrigendum to Commission Decision (EU) 2018/860 of 7 February 2018 on the Aid Scheme SA.45852 — 2017/C (ex 2017/N) which Germany is planning to implement for Capacity Reserve**

(Official Journal of the European Union L 153 of 15 June 2018)

On page 156, footnote 2:

- for:* 'The European Commission points to the fact that a proposal for a new Regulation on the internal market on electricity (COM(2016)861 final of 30 November 2016) is currently being negotiated; however, the present measure remains uninfluenced by the future rules on the design of the electricity market.'
- read:* 'The Commission underlines that the present decision needs and will need to be interpreted in the light of relevant secondary legislation, including legislation that has not been adopted yet at the time of this decision. In this regard, the Commission would like to point to the proposal for a Regulation on the internal market for electricity (recast), COM (2016) 861, and in particular to the principles (such as the requirements regarding CO₂ emission limits) which capacity mechanisms need to incorporate and apply, even if they are already in force and have been deemed as compliant with Union state aid rules, in line with the final text of the Regulation when it becomes effective.'
-

