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Contents

II *Non-legislative acts*

INTERNATIONAL AGREEMENTS

- ★ **Council Decision (EU) 2023/750 of 28 March 2023 on the conclusion, on behalf of the European Union and its Member States, of the Protocol to the Cooperation Agreement on a Civil Global Navigation Satellite System (GNSS) between the European Community and its Member States, of the one part, and the Republic of Korea, of the other part, to take account of the accession of the Republic of Bulgaria, the Republic of Croatia and Romania to the European Union** 1
- ★ **Protocol to the Cooperation Agreement on a civil Global Navigation Satellite System (GNSS) between the European Community and its Member States, of the one part, and the Republic of Korea, of the other part, to take account of the accession of the Republic of Bulgaria, the Republic of Croatia and Romania to the European Union** 3

REGULATIONS

- ★ **Commission Delegated Regulation (EU) 2023/751 of 30 January 2023 amending Delegated Regulation (EU) 2020/687 supplementing Regulation (EU) 2016/429 of the European Parliament and the Council as regards rules for the prevention and control of certain listed diseases ⁽¹⁾** 7
- ★ **Commission Implementing Regulation (EU) 2023/752 of 12 April 2023 imposing a definitive anti-dumping duty on imports of sodium gluconate originating in the People's Republic of China following an expiry review pursuant to Article 11(2) of Regulation (EU) 2016/1036 of the European Parliament and of the Council** 16
- ★ **Commission Implementing Regulation (EU) 2023/753 of 12 April 2023 granting a Union authorisation for the biocidal product family “C(M)IT/MIT formulations” ⁽¹⁾** 48
- ★ **Commission Implementing Regulation (EU) 2023/754 of 12 April 2023 granting a Union authorisation for the single biocidal product ‘Arche Chlorine’ in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council ⁽¹⁾** 83

⁽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.

Corrigenda

- ★ Corrigendum to Council Decision (CFSP) 2023/432 of 25 February 2023 amending Decision 2014/145/CFSP concerning restrictive measures in respect of actions undermining or threatening the territorial integrity, sovereignty and independence of Ukraine (OJ L 59 I, 25.2.2023)..... 98
- ★ Corrigendum to Council Implementing Regulation (EU) 2023/429 of 25 February 2023 implementing Regulation (EU) No 269/2014 concerning restrictive measures in respect of actions undermining or threatening the territorial integrity, sovereignty and independence of Ukraine (OJ L 59 I, 25.2.2023) 99
- ★ Corrigendum to Commission Implementing Regulation (EU) 2023/453 of 2 March 2023 extending the definitive anti-dumping duty imposed by Implementing Regulation (EU) 2017/141 on imports of certain stainless steel tube and pipe butt welding fittings, whether or not finished, originating in the People's Republic of China to imports of certain stainless steel tube and pipe butt-welding fittings, whether or not finished, consigned from Malaysia, whether declared as originating in Malaysia or not (OJ L 67, 3.3.2023) 100
- ★ Corrigendum to Commission Implementing Regulation (EU) 2023/254 of 6 February 2023 amending Implementing Regulation (EU) 2020/761 as regards certain technical rules on the management of tariff rate quotas (OJ L 35, 7.2.2023) 101

II

(Non-legislative acts)

INTERNATIONAL AGREEMENTS

COUNCIL DECISION (EU) 2023/750

of 28 March 2023

on the conclusion, on behalf of the European Union and its Member States, of the Protocol to the Cooperation Agreement on a Civil Global Navigation Satellite System (GNSS) between the European Community and its Member States, of the one part, and the Republic of Korea, of the other part, to take account of the accession of the Republic of Bulgaria, the Republic of Croatia and Romania to the European Union

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 172, in conjunction with point (a)(v) of the second subparagraph of Article 218(6) thereof,

Having regard to the Acts of Accession of the Republic of Bulgaria and Romania ⁽¹⁾ and of the Republic of Croatia ⁽²⁾, and in particular Article 6(2) thereof,

Having regard to the proposal from the European Commission,

Having regard to the consent of the European Parliament ⁽³⁾,

Whereas:

- (1) The Cooperation Agreement on a Civil Global Navigation Satellite System (GNSS) between the European Community and its Member States, of the one part, and the Republic of Korea, of the other part ⁽⁴⁾ (the 'Agreement') was signed on 9 September 2006 ⁽⁵⁾ and entered into force on 1 July 2016 ⁽⁶⁾.
- (2) Bulgaria and Romania became Member States of the Union on 1 January 2007 and Croatia on 1 July 2013.
- (3) In accordance with Article 6(2) of the Acts of Accession of Bulgaria and Romania and of Croatia, accession to the Agreement is to be agreed by means of a protocol to that Agreement (the 'Protocol'). In accordance with Article 6(2) of those Acts of Accession, a simplified procedure is to apply to such accession, whereby a protocol is to be concluded by the Council, acting unanimously on behalf of the Member States, and by the third country concerned.

⁽¹⁾ Act concerning the conditions of accession of the Republic of Bulgaria and Romania and the adjustments to the Treaties on which the European Union is founded (OJ L 157, 21.6.2005, p. 203).

⁽²⁾ Act concerning the conditions of accession of the Republic of Croatia and the adjustments to the Treaty on European Union, the Treaty on the Functioning of the European Union and the Treaty establishing the European Atomic Energy Community (OJ L 112, 24.4.2012, p. 21).

⁽³⁾ Consent of 15 February 2023 (not yet published in the Official Journal).

⁽⁴⁾ OJ L 288, 19.10.2006, p. 31.

⁽⁵⁾ Council Decision 2006/700/EC of 1 September 2006 on the signing, on behalf of the Community, of the Cooperation Agreement on a Civil Global Navigation Satellite System (GNSS) between the European Community and its Member States, of the one part, and the Republic of Korea, of the other part (OJ L 288, 19.10.2006, p. 30).

⁽⁶⁾ Council Decision (EU) 2016/944 of 6 June 2016 on the conclusion of the Cooperation Agreement on a Civil Global Navigation Satellite System (GNSS) between the European Community and its Member States of the one part, and the Republic of Korea, of the other part (OJ L 157, 15.6.2016, p. 19).

- (4) On 23 October 2006 and on 14 September 2012 the Council authorised the Commission to open negotiations with the third country concerned in order to conclude protocols to international agreements concluded by the Union and its Member States.
- (5) The negotiations with the Republic of Korea were successfully concluded by exchange of *notes verbales*.
- (6) In accordance with Council Decision (EU) 2019/1934 ⁽⁷⁾, the Protocol was signed on 26 September 2022, subject to its conclusion at a later date.
- (7) The Secretary-General of the Council of the European Union is the depositary of this Protocol.
- (8) The Protocol should be approved,

HAS ADOPTED THIS DECISION:

Article 1

The Protocol to the Cooperation Agreement on a Civil Global Navigation Satellite System (GNSS) between the European Community and its Member States, of the one part, and the Republic of Korea, of the other part, to take account of the accession of the Republic of Bulgaria, the Republic of Croatia and Romania to the European Union is hereby approved on behalf of the Union and its Member States.

The text of the Protocol is attached to this Decision.

Article 2

The President of the Council shall, on behalf of the Union and its Member States, give the notification provided for in Article 4 of the Protocol.

Article 3

This Decision shall enter into force on the day of its adoption.

Done at Brussels, 28 March 2023.

For the Council
The President
E. BUSCH

⁽⁷⁾ Council Decision (EU) 2019/1934 of 18 March 2019 on the signing, on behalf of the European Union and its Member States, of the Protocol to the Cooperation Agreement on a Civil Global Navigation Satellite System (GNSS) between the European Community and its Member States, of the one part, and the Republic of Korea, of the other part, to take account of the accession of the Republic of Bulgaria, the Republic of Croatia and Romania to the European Union (OJ L 301, 22.11.2019, p. 1).

PROTOCOL

to the Cooperation Agreement on a civil Global Navigation Satellite System (GNSS) between the European Community and its Member States, of the one part, and the Republic of Korea, of the other part, to take account of the accession of the Republic of Bulgaria, the Republic of Croatia and Romania to the European Union

THE EUROPEAN UNION,

and

THE KINGDOM OF BELGIUM,

THE REPUBLIC OF BULGARIA,

THE CZECH REPUBLIC,

THE KINGDOM OF DENMARK,

THE FEDERAL REPUBLIC OF GERMANY,

THE REPUBLIC OF ESTONIA,

IRELAND,

THE HELLENIC REPUBLIC,

THE KINGDOM OF SPAIN,

THE FRENCH REPUBLIC,

THE REPUBLIC OF CROATIA,

THE ITALIAN REPUBLIC,

THE REPUBLIC OF CYPRUS,

THE REPUBLIC OF LATVIA,

THE REPUBLIC OF LITHUANIA,

THE GRAND DUCHY OF LUXEMBOURG,

HUNGARY,

THE REPUBLIC OF MALTA,

THE KINGDOM OF THE NETHERLANDS,

THE REPUBLIC OF AUSTRIA,

THE REPUBLIC OF POLAND,

THE PORTUGUESE REPUBLIC,

ROMANIA,

THE REPUBLIC OF SLOVENIA,

THE SLOVAK REPUBLIC,

THE REPUBLIC OF FINLAND,

THE KINGDOM OF SWEDEN,

THE UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND,

hereinafter referred to as the "Member States",

of the one part, and

THE REPUBLIC OF KOREA,

of the other part,

RECALLING the Cooperation Agreement on a Civil Global Navigation Satellite System (GNSS) between the European Community and its Member States, of the one part, and the Republic of Korea, of the other part (hereinafter referred to as the "Agreement"), signed on 9 September 2006, which entered into force on 1 July 2016, and, in particular, Article 18(3) thereof;

HAVING REGARD TO the accession of the Republic of Bulgaria and Romania to the European Union on 1 January 2007 and the accession of the Republic of Croatia to the European Union on 1 July 2013;

DESIRING that the Republic of Bulgaria, the Republic of Croatia and Romania accede to the Agreement;

CONSIDERING Article 6(2) of the Act concerning the conditions of accession of the Republic of Bulgaria and Romania, Article 6(2) of the Act concerning the conditions of accession of the Republic of Croatia, and the adjustments to the Treaties on which the European Union is founded, the accession of these States to the Agreement is to be agreed by the conclusion of a protocol to the Agreement,

HAVE AGREED AS FOLLOWS:

Article 1

The Republic of Bulgaria, the Republic of Croatia and Romania shall be Parties to the Cooperation Agreement on a Civil Global Navigation Satellite System (GNSS) between the European Community and its Member States, of the one part, and the Republic of Korea, of the other part, and shall respectively adopt and take note, in the same manner as the other Member States, of the text of the Agreement.

Article 2

This Protocol shall form an integral part of the Agreement.

Article 3

The texts of the Agreement drawn up in the Bulgarian, Croatian and Romanian languages are attached to this Protocol ⁽¹⁾.

Article 4

This Protocol shall enter into force on the first day of the month following the date on which the Parties have notified the Depository of the Agreement through diplomatic notes of the completion of their respective internal legal procedures for the entry into force of this Protocol.

IN WITNESS WHEREOF, the undersigned, being duly authorised thereto by their respective Governments, have signed this Protocol.

Done in duplicate in the Bulgarian, Croatian, Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Hungarian, Italian, Latvian, Lithuanian, Maltese, Polish, Portuguese, Romanian, Slovak, Slovenian, Spanish, Swedish and Korean languages, each text being equally authentic.

⁽¹⁾ OJ L 288, 19.10.2006, p. 31.

Съставено в Брюксел на двадесет и шести септември две хиляди двадесет и втора година.

Hecho en Bruselas, el veintiseis de septiembre de dos mil veintidós.

V Bruselu dne dvacátého šestého září dva tisíce dvacet dva.

Udfærdiget i Bruxelles den seksogtyvende september to tusind og toogtyve.

Geschehen zu Brüssel am sechszwanzigsten September zweitausendzweiundzwanzig.

Kahe tuhande kahekümne teise aasta septembrikuu kahekümne kuuendal päeval Brüsselis.

Έγινε στις Βρυξέλλες, στις είκοσι έξι Σεπτεμβρίου δύο χιλιάδες είκοσι δύο.

Done at Brussels on the twenty-sixth day of September in the year two thousand and twenty two.

Fait à Bruxelles, le vingt-six septembre deux mille vingt-deux.

Sastavljeno u Bruxellesu dvadeset šestog rujna godine dvije tisuće dvadeset druge.

Fatto a Bruxelles, addì ventisei settembre duemilaventidue.

Briselē, divi tūkstoši divdesmit otrā gada divdesmit sestajā septembrī.

Priimta du tūkstančiai dvidešimt antrą metų rugsėjo dvidešimt šeštą dieną Briuselyje.

Kelt Brüsszelben, a kétezer-huszonkettedik év szeptember havának huszonhatodik napján.

Magħmul fi Brussell, fis-sitta u ghoxrin jum ta' Settembru fis-sena elfejn u tnejn u ghoxrin.

Gedaan te Brussel, zesentwintig september tweeduizend tweeëntwintig.

Sporządzono w Brukseli dnia dwudziestego szóstego września roku dwa tysiące dwudziestego drugiego.

Feito em Bruxelas, em vinte e seis de setembro de dois mil e vinte e dois.

Întocmit la Bruxelles la douăzeci și șase septembrie două mii douăzeci și doi.

V Bruseli dvadsiateho šiesteho septembra dvetisícdvadsaťdva.

V Bruslju, šestindvajsetega septembra dva tisoč dvaindvajset.

Tehty Brysselissä kahdentenakymmenentenäkuudentena päivänä syyskuuta vuonna kaksituhattakaksikymmentäkaksi.

Som skedde i Bryssel den tjugosjätte september år tjugohundratjugotvå.

2022 년 9 월 26 일 브뤼셀에서 작성하였다.

За държавите-членки
 Por los Estados miembros
 Za členské státy
 For medlemsstaterne
 Für die Mitgliedstaaten
 Liikmesriikide nimel
 Για τα κράτη μέλη
 For the Member States
 Pour les États membres
 Za države članice
 Per gli Stati membri
 Dalībvalstu vārdā –
 Valstybių narių vardu
 A tagállamok részéről
 Għall-Istati Membri
 Voor de lidstaten
 W imieniu Państw Członkowskich
 Pelos Estados-Membros
 Pentru statele membre
 Za členské štáty
 Za države članice
 Jäsenvaltioiden puolesta
 För medlemsstaterna
 회원국을 대표하여

За Европейския съюз
 Por la Unión Europea
 Za Evropskou unii
 For Den Europæiske Union
 Für die Europäische Union
 Euroopa Liidu nimel
 Για την Ευρωπαϊκή Ένωση
 For the European Union
 Pour l'Union européenne
 Za Europsku uniju
 Per l'Unione europea
 Eiropas Savienības vārdā –
 Europos Sąjungos vardu
 Az Európai Unió részéről
 Għall-Unjoni Ewropea
 Voor de Europese Unie
 W imieniu Unii Europejskiej
 Pela União Europeia
 Pentru Uniunea Europeană
 Za Európsku úniu
 Za Evropsko unijo
 Euroopan unionin puolesta
 För Europeiska unionen
 유럽연합을 대표하여




За Република Корея
 Por la República de Corea
 Za Korejskou republiku
 For Republikken Korea
 Für die Republik Korea
 Korea Vabariigi nimel
 Για τη Δημοκρατία της Κορέας
 For the Republic of Korea
 Pour la République de Corée
 Za Republiku Koreju
 Per la Repubblica di Corea
 Korejas Republikas vārdā
 Korėjos Respublikos vardu,
 A Koreai Köztársaság részéről
 Għar-Repubblika tal-Korea
 Voor de Republiek Korea
 W imieniu Republiki Korei
 Pela República da Coreia
 Pentru Republica Coreea
 Za Kórejскую republiku
 Za Republiko Korejo
 Korean tasavallan puolesta
 På Republiken Koreas vägnar
 대한민국을 대표하여



REGULATIONS

COMMISSION DELEGATED REGULATION (EU) 2023/751

of 30 January 2023

amending Delegated Regulation (EU) 2020/687 supplementing Regulation (EU) 2016/429 of the European Parliament and the Council as regards rules for the prevention and control of certain listed diseases

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') ⁽¹⁾, and in particular Article 67 thereof,

Whereas:

- (1) Regulation (EU) 2016/429 lays down rules for the prevention and control of animal diseases which are transmissible to animals or to humans, including rules on disease awareness, preparedness and control. In particular, Regulation (EU) 2016/429 lays down disease-specific rules for the prevention and control of diseases listed in its Article 5.
- (2) Commission Delegated Regulation (EU) 2020/687 ⁽²⁾ lays down rules supplementing Regulation (EU) 2016/429 as regards the prevention and control of certain listed diseases, notably category A, B and C diseases in accordance with Commission Implementing Regulation (EU) 2018/1882 ⁽³⁾. More particularly, Delegated Regulation (EU) 2020/687 provides for the establishment of a restricted zone in the event of an outbreak of a category A disease and for restrictions and conditions for movements of animals and products thereof within and from restricted zones, as part of the measures to control the spread of category A diseases.
- (3) Delegated Regulation (EU) 2020/687 and Commission Delegated Regulation (EU) 2020/692 ⁽⁴⁾ provide different definitions for 'casings', the correct definition being the one laid down in Delegated Regulation (EU) 2020/692. To ensure coherence among the provisions of the delegated acts supplementing the animal health requirements laid down in Regulation (EU) 2016/429, the definition for 'casings' laid down in Delegated Regulation (EU) 2020/687 should therefore be corrected and aligned with the one in Delegated Regulation (EU) 2020/692.

⁽¹⁾ OJ L 84, 31.3.2016, p. 1.

⁽²⁾ Commission Delegated Regulation (EU) 2020/687 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and the Council, as regards rules for the prevention and control of certain listed diseases (OJ L 174, 3.6.2020, p. 64).

⁽³⁾ Commission Implementing Regulation (EU) 2018/1882 of 3 December 2018 on the application of certain disease prevention and control rules to categories of listed diseases and establishing a list of species and groups of species posing a considerable risk for the spread of those listed diseases (OJ L 308, 4.12.2018, p. 21).

⁽⁴⁾ Commission Delegated Regulation (EU) 2020/692 of 30 January 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for entry into the Union, and the movement and handling after entry of consignments of certain animals, germinal products and products of animal origin (OJ L 174, 3.6.2020, p. 379).

- (4) Article 23, point (c), of Delegated Regulation (EU) 2020/687 provides for the possibility for the competent authority to grant derogations from the measures to be applied in the restricted zone in case an outbreak of a category A disease occurs in an establishment keeping up to 50 captive birds, but not from the obligation to establish a restricted zone, which derives from the provisions laid down in Article 21 of that Delegated Regulation. This obligation may create unnecessary trade constraints and impose an unjustified burden on operators and competent authorities.
- (5) The disease control measures provided for in Delegated Regulation (EU) 2020/687 should be proportionate to the risks involved. In certain circumstances, if an establishment where up to 50 captive birds are kept has no direct or indirect contact with other establishments where poultry or captive birds are kept, the risk of such outbreak to contribute to the spread of the disease may be insignificant. For that reason, the competent authorities should be allowed to derogate from the establishment of a restricted zone when an outbreak of a category A disease occurs in an establishment keeping up to 50 captive birds, if a risk assessment carried out by the competent authority provides that the establishment does not have direct or indirect contact with poultry or other establishments keeping captive birds.
- (6) Therefore, Article 21(3) of Delegated Regulation (EU) 2020/687 should be amended to include establishments keeping up to 50 captive birds among the locations where, if an outbreak of a category A disease occurs, the competent authority may decide in certain circumstances whether or not to establish a restricted zone.
- (7) Articles 28 and 43 of Delegated Regulation (EU) 2020/687 lay down the general conditions to grant derogations from the prohibitions of movements of animals and products in the protection and surveillance zones, respectively. These general conditions specify the measures to be applied by the competent authority to ensure that the risk of spreading a category A disease with such movements is negligible. These measures include certain strict supplementary biosecurity measures during all transport operations from the establishment of origin until the unloading in the establishment of destination, which is, in accordance with Articles 28 and 43 of Delegated Regulation (EU) 2020/687, designated by the competent authority of the establishment of origin. When the competent authority of the establishment of origin is different from the competent authority of the establishment of destination, the competent authority of origin may not be able to ensure the implementation of all these measures, in particular to know the location of the establishments with animals of listed species, to select a route avoiding those locations, or to ensure that supplementary biosecurity measures are implemented at the unloading in the designated establishment of destination.
- (8) Moreover, if the competent authority of the establishment of origin is different from the competent authority of the designated establishment of destination, the competent authority of the establishment of origin should inform the competent authority of the establishment of destination about such designation. However, to ensure the correct implementation of all the measures laid down by Articles 28 and 43 of Delegated Regulation (EU) 2020/687, the designation of the establishment of destination should be done in cooperation between the competent authority of the establishment of origin and that of the establishment of destination. Therefore, Articles 28(3) and 43(3) of Delegated Regulation (EU) 2020/687 should be amended accordingly.
- (9) Articles 30(2) and 46(2) of Delegated Regulation (EU) 2020/687 provide for the specific conditions for authorising movements of ready-to-lay poultry from establishments located in the protection and surveillance zones established in response to an outbreak of a category A disease, respectively. In accordance with these Articles, the competent authority may authorise such movements only if there is no other kept animal of listed species in the establishment of destination. In practice, in some cases, the establishments of laying hens where the ready-to-lay poultry are moved to may consist of several epidemiological units, as defined in Article 4, point (39), of Regulation (EU) 2016/429, which have to be populated at different times to be able to ensure a steady production of eggs over the year. Therefore, Articles 30(2) and 46(2) of Delegated Regulation (EU) 2020/687 should be amended, to offer the possibility that ready-to-lay poultry from protection or surveillance zone may be moved as well in an empty epidemiological unit within an establishment where animals of listed species are kept in other epidemiological units.

- (10) Articles 39 and 55 of Delegated Regulation (EU) 2020/687 lay down the conditions for lifting the control measures applied in the protection and surveillance zones, respectively. Preliminary cleaning and disinfection are essential measures that must be performed effectively to avoid spreading the category A disease from the affected establishment. The procedures for cleaning and disinfection are set out in points A and B of Annex IV to that Delegated Regulation. According with these procedures, the preliminary cleaning and disinfection is completed if the disinfectant has remained on the treated surface for at least 24 hours. As a well-known principle for the control and eradication of category A diseases, the minimum period of duration of the measures to be implemented in the restricted zones is counted only after completion of the preliminary cleaning and disinfection.
- (11) The current text of Articles 39 and 55 of Delegated Regulation (EU) 2020/687 is not clear about the starting point for the minimum period of duration of the measures to be implemented in the protection and surveillance zones and it may lead to different implementation of that requirement by the Member States. Therefore, Articles 39 and 55 of Delegated Regulation (EU) 2020/687 should be amended to clearly specify the starting point for the counting of the minimum period of duration of the measures in the protection and surveillance zones.
- (12) Article 31(1), point (a), of Delegated Regulation (EU) 2020/687 allows the competent authority to authorise the movement of hatching eggs from an establishment located in the protection zone to a hatchery located in the same Member State, which includes the movement of hatching eggs from an establishment located in the protection zone to a hatchery located in the surveillance zone. However, in accordance with the provisions laid down in Article 46(1), point (a), of that Delegated Regulation, movements of day-old chicks originating in the surveillance zone to establishments in the same Member State may be authorised only if they were hatched from eggs originating in establishments within the surveillance zone. Therefore, under Article 46(1), point (a), of Delegated Regulation (EU) 2020/687, the competent authority is not allowed to authorise movements from the surveillance zone of day-old chicks hatched from eggs originating in establishments within the protection zone.
- (13) Article 30(1), point (a), of Delegated Regulation (EU) 2020/687 allows the movement of day-old chicks from an establishment located in the protection zone, if they hatched from eggs originating in the restricted zone. Consequently, according with Article 30(1), point (a) of Delegated Regulation (EU) 2020/687, movement from the restriction zone of day-old chicks hatched from eggs originating from establishments within the protection zone may be authorised by the competent authority, if certain conditions are fulfilled. The competent authority should also be able to authorise, if similar conditions are fulfilled, movement from the surveillance zone of day-old chicks hatched from eggs originating in establishments within the protection zone. Therefore, article 46(1), point (a), should be amended accordingly.
- (14) Article 52 of Delegated Regulation (EU) 2020/687 provides for the specific conditions to be fulfilled when the competent authority authorises movements of feed materials of plant origin and straw produced in the surveillance zone. With the current wording of Article 52 of Delegated Regulation (EU) 2020/687 it can be understood that all conditions listed in points (a) to (d) of that Article have to be fulfilled. However, Article 52, point (d) of Delegated Regulation (EU) 2020/687 refers to the case where the feed materials of plant origin and straw have undergone at least one of the risk-mitigation treatments set out in Annex VIII to that Delegated Regulation. Consequent to the application of the risk-mitigation treatment, the feed materials of plant origin and straw become safe commodities and therefore may be moved outside the surveillance zone. In addition, Article 36 of Delegated Regulation (EU) 2020/687 provides for the specific conditions for authorising the movement of feed materials of plant origin and straw from the protection zone. In accordance with Article 36 of Delegated Regulation (EU) 2020/687, movements of feed materials of plant origin and straw from the protection zone may be authorised if they have undergone at least one of the risk-mitigating treatments in accordance with Annex VIII to Delegated Regulation (EU) 2020/687. Moreover, the conditions set out in Article 52, points (a) to (d) of Delegated Regulation (EU) 2020/687 are similar to the ones laid down in Article 36 of that Delegated Regulation. Therefore, the movement of feed materials of plant origin and straw produced in the surveillance zone should not be subject to stricter conditions than those applicable to the movement of feed material of plant origin and straw produced in the protection zone. Article 52 of Delegated Regulation (EU) 2020/687 should therefore be corrected to ensure similar restrictions in the surveillance zone as in the protection zone when similar conditions are fulfilled.

- (15) Article 59(2) of Delegated Regulation (EU) 2020/687 lays down the requirements for kept animals of listed species intended for repopulation of establishments affected by an outbreak of a category A disease. Those animals must originate from an establishment that is not located in a restricted zone and subject to disease control measures for category A diseases of kept terrestrial animals, as laid down in Part II, Chapter II, of Delegated Regulation (EU) 2020/687. However, Article 59(2), point (a) of Delegated Regulation (EU) 2020/687 erroneously refers to restrictions provided for in Chapter III of that Delegated Regulation. Therefore, the text in Article 59(2), point (a), of Delegated Regulation (EU) 2020/687 should be corrected to refer to the restrictions provided in Chapter II of that Delegated Regulation.
- (16) Articles 27 and 42 of Delegated Regulation (EU) 2020/687 lay down prohibitions in relation to activities, including movements, concerning animals, products and other materials within, from or to the protection and surveillance zones. The prohibitions are listed in the table set out in Annex VI to that Delegated Regulation. Movements of kept animals of listed species to establishments in the restricted zone are prohibited in accordance with that table, in order to prevent the increase in the population of the kept animals which are susceptible to the category A disease confirmed in that zone. Hatching eggs, if moved to a hatchery located in a restricted zone may lead to production of day-old chicks, which will increase the population of kept animals of listed species in the restricted zone. Therefore, such a movement would be in contradiction with the purpose of the prohibition of moving kept animals of listed species to establishments in the restricted zone. Consequently, as a general rule, such movement is considered prohibited. However, the table set out in Annex VI to Delegated Regulation (EU) 2020/687 wrongly lists only the prohibition of movement of hatching eggs from establishments in the restricted zone. Therefore, the text in the table set out in Annex VI to Delegated Regulation (EU) 2020/687 should be corrected, to refer also to the prohibition of movements of hatching eggs to establishments in the restricted zone.
- (17) In addition, the prohibition listed in Annex VI to Delegated Regulation (EU) 2020/687 for movements of feed material of plant origin and straw is wrongly limited to the ones obtained in the protection zone, allowing the movements of feed material of plant origin and straw obtained in the surveillance zone, which may pose a risk of spreading the disease. Annex VI to Delegated Regulation (EU) 2020/687 should therefore be corrected to prohibit the movements of feed materials of plant origin and straw obtained in the restricted zone.
- (18) Annex VII to Delegated Regulation (EU) 2020/687 provides for risk-mitigating treatments for products of animal origin, in particular meat, casings and milk, from the restricted zone. Those treatments, which inactivate the disease agents, should be in line with existing Union legislation, international standards and new scientific evidence. The entry in that Annex for sheep pox and goat pox virus for those commodities is currently empty, due to the lack of scientific data or studies concerning treatments obtained so far. Given the recent occurrence in the Union of outbreaks of sheep pox and goat pox, the treatment of meat and milk from caprine and ovine animals originating from the protection and surveillance zones should be made possible for Member States managing such outbreaks. No such treatments were provided for in Annex VII to Delegated Regulation (EU) 2020/687, as the Commission is awaiting the results of a study commissioned to the EU Reference Laboratory for *Capripox* viruses, or more scientific advice provided by the European Food Safety Authority ('the Authority'). However, taking into account the similarity between sheep pox and goat pox virus and lumpy skin disease virus, both belonging to the family *Poxviridae* and genus *Capripoxvirus*, it is appropriate to allow the application of risk-mitigating treatments in the relevant table of Annex VII to Delegated Regulation (EU) 2020/687. The application of the risk-mitigating treatments for sheep pox and goat pox is to be reviewed once further scientific evidence is available.
- (19) In a recent scientific opinion ⁽⁵⁾, the Authority has assessed the effectiveness of certain risk-mitigation treatments for products of animal origin and other materials with respect to category A diseases. Among other treatments, the Authority considered that meat heat treatment to achieve a core temperature of 70 °C for at least 30 minutes was an effective treatment to inactivate the African swine fever virus. Therefore, based on the new scientific evidence, and in line with the World Organisation for Animal Health (WOAH) international standard ⁽⁶⁾ related to African swine fever, Annex VII to Delegated Regulation (EU) 2020/687 should be amended accordingly to include an additional risk-mitigating treatment for African swine fever.

⁽⁵⁾ EFSA Journal 2022;20(8):7443.

⁽⁶⁾ WOAH Terrestrial Animal Health Code, 30th Edition, 2022. Volumes I and II, ISBN 978-92-95121-28-7; <https://www.woah.org/en/what-we-do/standards/codes-and-manuals/terrestrial-code-online-access/>

- (20) Annex VIII to Delegated Regulation (EU) 2020/687 lays down the 'risk-mitigation treatments for products not of animal origin from the protection zone', although references to those treatments are made also in Article 52 of that Delegated Regulation, which relates to specific conditions for authorising the movement of feed materials of plant origin and straw from the surveillance zone. Therefore, the title of Annex VIII to Delegated Regulation (EU) 2020/687 should be corrected to refer to the 'risk-mitigation treatments for products not of animal origin from the restricted zone'.
- (21) Delegated Regulation (EU) 2020/687 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Delegated Regulation (EU) 2020/687 is amended as follows:

- (1) in Article 21(3), the following point (g) is added:

'(g) establishments keeping up to 50 captive birds, provided that they have no direct or indirect contact with poultry or other establishments keeping captive birds.');

- (2) Article 28(3) is replaced by the following:

'3. The competent authority of the establishment of origin shall designate the establishment of destination for movements from or to the protection zone. If the competent authority of the establishment of origin is different from the competent authority of the establishment of destination, it shall make that designation in cooperation with the competent authority of the establishment of destination.');

- (3) in Article 30(2), point (a) is replaced by the following:

'(a) there is no other kept animal of listed species in the establishment or epidemiological unit of destination.');

- (4) Article 39(1) is replaced by the following:

'1. The competent authority may lift the measures provided for in Sections 1 and 2 of this Chapter only if:

- (a) the minimum period set out in Annex X has elapsed following the date of completion of preliminary cleaning and disinfection and, where relevant, control of insects and rodents, performed in accordance with Article 15 in the affected establishment; and
- (b) in all establishments keeping animals of listed species in the protection zone, animals of listed species have undergone, with favourable results, clinical and, when necessary, laboratory examinations in accordance with Article 26.;

- (5) Article 43(3) is replaced by the following:

'3. The competent authority of the establishment of origin shall designate the establishment of destination for movements from or to the surveillance zone. If the competent authority of the establishment of origin is different from the competent authority of the establishment of destination, it shall make that designation in cooperation with the competent authority of the establishment of destination.');

- (6) Article 46(1), point (a), is amended as follows:

- (a) the introductory sentence is replaced by the following:

'to establishments in the same Member State where they were hatched from eggs originating from establishments within the restricted zone, if:'

- (b) the following point (iii) is added:

'(iii) the means of transport is sealed at the moment of loading by the competent authority or under its supervision.');

- (7) in Article 46(2), point (a) is replaced by the following:

'(a) there is no other kept animal of listed species in the establishment or epidemiological unit of destination.');

(8) Article 55(1) is replaced by the following:

‘1. The competent authority may lift the disease control measures applied in the surveillance zone pursuant to Sections 1 and 3 only if:

- (a) the minimum period set out in Annex XI has elapsed after the date of completion of preliminary cleaning and disinfection and, where relevant, control of insects and rodents, performed in accordance with Article 15 in the affected establishment,
- (b) the requirements provided for in Article 39(1), point (b), have been met in the protection zone, and
- (c) a representative number of establishments keeping animals of listed species have undergone, with favourable results, visits carried out by official veterinarians, in accordance with Article 41.’;

(9) in Annex VII, the first table, related to meat, casings and milk, is replaced by the table set out in the Annex to this Regulation.

Article 2

Delegated Regulation (EU) 2020/687 is corrected as follows:

(1) in Article 2, point (10), the definition for ‘casings’ is replaced by the following:

‘(10) “casings” means the bladders and intestines that after cleaning have been processed by tissue scraping, defatting and washing and have been treated with salt or dried;’;

(2) in Article 52, point (c) is replaced by the following:

‘(c) are intended for use within the surveillance zone; or’;

(3) in Article 59(2), point (a) is replaced by the following:

‘(a) not originate from an establishment subject to the restrictions provided for in Chapter II; and’;

(4) in Annex VI, the table is corrected as follows:

(a) the text in the first column of the tenth row of the table is replaced by the following:

‘Movements of hatching eggs to and from establishments in the restricted zone’;

(b) the text in the first column of the last row of the table is replaced by the following:

‘Movements of feed materials of plant origin and straw obtained in the restricted zone’;

(5) in Annex VIII, the title is replaced by the following:

‘RISK-MITIGATING TREATMENTS FOR PRODUCTS NOT OF ANIMAL ORIGIN FROM THE RESTRICTED ZONE’.

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, 30 January 2023.

For the Commission
The President
Ursula VON DER LEYEN

In Annex VII to Delegated Regulation (EU) 2020/687, the first table, related to meat, casings and milk, is replaced by the following:

Treatment	FMD ⁽¹⁾	RP	RVFV	LSD	CBPP	SPCP	PPR	CCPP	CSF	ASF	AHS	HPAI	NCD
MEAT													
Heat treatment in an hermetically sealed container, to achieve a minimum F ₀ ⁽²⁾ value of 3	x						X		X	X		X	X
Heat treatment to achieve a core temperature of 80 °C	X						X		X	X		X	X
Heat treatment to achieve a core temperature of 70 °C	X						X		X			X	X
Heat treatment (to meat previously de-boned and defatted) to achieve a core temperature of 70 °C for a minimum of 30 minutes	X						X		X	X			
In an hermetically sealed container, applying 60 °C for a minimum of 4 hours	X						X		X	X			
Core temperature of 73,9 °C for a minimum of 0,51 seconds ⁽³⁾	X											X	X
Core temperature of 70,0 °C for a minimum of 3,5 seconds ⁽³⁾												X	X
Core temperature of 65,0 °C for a minimum of 42 seconds ⁽³⁾												X	X
Core temperature of 60 °C for a minimum of 507 seconds ⁽³⁾												X	X
Heat treatment to achieve desiccation to maximum values of Aw of 0,93 and pH of 6													
Heat treatment to achieve a core temperature of 65 °C for a period of time to achieve a minimum pasteurisation value of 40							X						
Natural fermentation and maturation for bone-in meat: minimum 9 months, to achieve maximum values of Aw of 0,93 and pH of 6	X								X				
Natural fermentation and maturation for de-boned meat: minimum 9 months, to achieve maximum values of Aw of 0,93 and pH of 6	X								X	X			
Natural fermentation for loins: minimum 140 days to achieve maximum values of Aw of 0,93 and pH of 6 ⁽⁴⁾									X	X			
Natural fermentation for hams: minimum 190 days to achieve maximum values of Aw of 0,93 and pH of 6 ⁽⁴⁾									X	X			
Drying after salting Italian style bone-in hams: minimum 313 days ⁽⁴⁾									X				

Treatment	FMD ⁽¹⁾	RP	RVFV	LSD	CBPP	SPCP	PPR	CCPP	CSF	ASF	AHS	HPAI	NCD
Drying after salting Spanish style bone-in hams and loins ⁽⁴⁾ : — Iberian hams: minimum 252 days — Iberian shoulders: minimum 140 days — Iberian loins: minimum 126 days — Serrano hams: minimum 140 days	X								X	X			
Maturation of carcasses at a minimum temperature of 2 °C for a minimum of 24 hours following slaughter			X										
Removal of offal				X	X	X		X					
CASINGS													
Salting with sodium chloride (NaCl) either dry or as saturated brine ($A_w < 0,80$), for a continuous period of 30 days or longer at an ambient temperature of 20 °C or above	X			SC ⁽⁵⁾			X		X	X			
Salting with phosphate supplemented salt 86,5 % NaCl, 10,7 % Na ₂ HPO ₄ and 2,8 % Na ₃ PO ₄ either dry or as saturated brine ($A_w < 0,80$) for a continuous period of 30 days or longer at an ambient temperature of 20 °C or above	X						X		X	X			
Salting with sodium chloride (NaCl) minimum 30 days ⁽⁶⁾													
Bleaching ⁽⁶⁾													
Drying ⁽⁶⁾													
MILK													
Heat treatment (sterilization process) to achieve a minimum F_0 value of 3	X				SC ⁽⁵⁾			SC ⁽⁵⁾					
Heat treatment UHT (Ultra high temperature): Minimum 132 °C for a minimum of 1 second	X						X						
Heat treatment UHT (Ultra high temperature): Minimum 135 °C for a suitable holding time	X												
Heat treatment HTST (High temperature short time pasteurisation) if milk pH is lower than 7, minimum 72 °C for a minimum of 15 seconds	X						X						
Heat treatment HTST (High temperature short time pasteurisation) if milk pH is 7 or higher, minimum 72 °C for a minimum of 15 seconds, applied twice	X						X						

'Treatment	FMD ⁽¹⁾	RP	RVFV	LSD	CBPP	SPCP	PPR	CCPP	CSF	ASF	AHS	HPAI	NCD
Heat treatment HTST (High temperature short time pasteurisation) combined with a physical treatment to achieve pH value below 6 for a minimum of 1 hour or to achieve a minimum of 72 °C, combined with desiccation	X												
Pasteurisation consisting in a single heat treatment with an effect at least equivalent to that achieved by applying 72 °C for 15 seconds	X		X	X		X							

⁽¹⁾ Disease abbreviations in accordance with Annex II.

⁽²⁾ F₀ is the calculated killing effect on bacterial spores. An F₀ value of 3 means that the coldest point in the product has been heated sufficiently to achieve the same killing effect as 121 °C (250°F) in three minutes with instantaneous heating and chilling.

⁽³⁾ Only for poultry meat.

⁽⁴⁾ Only for porcine animals.

⁽⁵⁾ Safe commodity.

⁽⁶⁾ Not for bovine, ovine, caprine and porcine casings.'

COMMISSION IMPLEMENTING REGULATION (EU) 2023/752**of 12 April 2023****imposing a definitive anti-dumping duty on imports of sodium gluconate originating in the People's Republic of China following an expiry review pursuant to Article 11(2) of Regulation (EU) 2016/1036 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 Regulation (EU) 2016/1036 of the European Parliament and of the Council of 8 June 2016 on protection against dumped imports from countries not members of the European Union ⁽¹⁾, and in particular Article 11(2) thereof,

Whereas:

1. PROCEDURE**1.1. Previous investigations and measures in force**

- (1) By Council Implementing Regulation (EU) No 965/2010 ⁽²⁾, the Council imposed definitive anti-dumping duties on imports of sodium gluconate originating in the People's Republic of China ('the PRC', 'China' or 'the country concerned') ('the original measures'). The investigation that led to the imposition of the original measures will hereinafter be referred to as 'the original investigation'.
- (2) By Commission Implementing Decision (EU) 2016/2229 ⁽³⁾, the Commission terminated the partial interim review, pursuant to Article 11(3) of Regulation (EU) 2016/1036 ('the basic Regulation') of the anti-dumping measures applicable to imports of sodium gluconate originating in the PRC, limited to one Chinese exporting producer Shandong Kaisen Biochemical Co., Ltd ('Shandong Kaisen') without amending the level of the anti-dumping measures in force.
- (3) Following an expiry review investigation pursuant to Article 11(2) of the basic Regulation, the European Commission ('the Commission') prolonged the original measures for another five years by Commission Implementing Regulation (EU) 2017/94 ⁽⁴⁾ ('the previous expiry review').
- (4) The anti-dumping duties currently in force are *ad valorem* duties established at 53,2 % with the exception of Shandong Kaisen Biochemical Co., Ltd (5,6 %) and Qingdao Kehai Biochemistry Co., Ltd (27,1 %).

1.2. Request for an expiry review

- (5) Following the publication of a notice of impending expiry ⁽⁵⁾ the Commission received a request for a review pursuant to Article 11(2) of the basic Regulation.

⁽¹⁾ OJ L 176, 30.6.2016, p. 21.

⁽²⁾ Council Implementing Regulation (EU) No 965/2010 of 25 October 2010 imposing a definitive anti-dumping duty and collecting definitively the provisional duty imposed on imports of sodium gluconate originating in the People's Republic of China (OJ L 282, 28.10.2010, p. 24).

⁽³⁾ Commission implementing Decision (EU) 2016/2229 of 9 December 2016 terminating the partial interim review pursuant to Article 11(3) of Regulation (EU) 2016/1036 of the European Parliament and of the Council of the anti-dumping measures applicable to imports of sodium gluconate originating in the People's Republic of China, limited to one Chinese exporting producer, Shandong Kaisen (OJ L 336, 10.12.2016, p. 40).

⁽⁴⁾ Commission Implementing Regulation (EU) 2017/94 of 19 January 2017 imposing a definitive anti-dumping duty on imports of sodium gluconate originating in the People's Republic of China following an expiry review pursuant to Article 11(2) of Regulation (EU) 2016/1036 of the European Parliament and of the Council (OJ L 16, 20.1.2017, p. 3).

⁽⁵⁾ OJ C 25, 18.1.2022, p. 8.

- (6) The request for review was submitted on 19 October 2021 by Jungbunzlauer S.A. (France) ('the applicant') on behalf of the European industry manufacturing sodium gluconate in the sense of Article 5(4) of the basic Regulation. The request for review was based on the grounds that the expiry of the measures would be likely to result in continuation and/or recurrence of dumping and recurrence of injury to the Union industry.

1.3. Initiation of an expiry review

- (7) Having determined, after consulting the Committee established by Article 15(1) of the basic Regulation, that sufficient evidence existed for the initiation of an expiry review, on 18 January 2022 the Commission initiated an expiry review with regard to imports into the Union of sodium gluconate originating in the PRC on the basis of Article 11(2) of the basic Regulation. It published a Notice of Initiation in the *Official Journal of the European Union* ⁽⁶⁾ ('the Notice of Initiation').

1.4. Review investigation period and period considered

- (8) The investigation of continuation or recurrence of dumping covered the period from 1 January 2021 to 31 December 2021 ('review investigation period'). The examination of trends relevant for the assessment of the likelihood of a continuation or recurrence of injury covered the period from 1 January 2018 to the end of the review investigation period ('the period considered').

1.5. Interested parties

- (9) In the Notice of Initiation, interested parties were invited to contact the Commission in order to participate in the investigation. In addition, the Commission specifically informed the applicant, the other known Union producer, the known producers in the PRC and the authorities of the PRC, known importers, users, traders, as well as associations known to be concerned about the initiation of the expiry review investigation and invited them to participate.
- (10) Interested parties had an opportunity to comment on the initiation of the expiry review and to request a hearing with the Commission and/or the Hearing Officer in trade proceedings.

1.6. Sampling

- (11) In view of the apparent large number of producers in the country concerned and unrelated importers in the Union, the Commission stated in the Notice of initiation that it might sample the exporting producers and unrelated importers in accordance with Article 17 of the basic Regulation.

Sampling of importers

- (12) To decide whether sampling was necessary and, if so, to select a sample, the Commission asked unrelated importers to provide the information specified in the Notice of Initiation.
- (13) No unrelated importer provided the requested information. In view of the absence of replies, the Commission decided that sampling was not necessary.

Sampling of exporting producers in the PRC

- (14) To decide whether sampling was necessary and, if so, to select a sample, the Commission asked all exporting producers in the PRC to provide the information specified in the Notice of Initiation. In addition, the Commission asked the Mission of the People's Republic of China to identify and/or contact other producers, if any, that could be interested in participating in the investigation.
- (15) None of the exporting producers in the country concerned provided the requested information and agreed to be included in the sample.

⁽⁶⁾ Notice of initiation of an expiry review of the anti-dumping measures applicable to imports of Sodium gluconate originating in the People's Republic of China (OJ C 25, 18.1.2022, p. 8).

1.7. Replies to the questionnaire

- (16) The Commission sent a questionnaire concerning the existence of significant distortions in the PRC within the meaning of Article 2(6a)(b) of the basic Regulation to the Government of the People's Republic of China ('GOC').
- (17) The Commission sent letters with links to questionnaires to the two known Union producers and to known unrelated importers and users. The same questionnaires were also made available in the file for inspection by interested parties and on DG Trade's website online ⁽⁷⁾ on the day of initiation.
- (18) Questionnaire replies were received from the Union producer, Jungbunzlauer S.A. No unrelated importer and no user submitted a questionnaire reply.

1.8. Verification visits

- (19) The Commission sought and verified all the information deemed necessary for the determination of likelihood of continuation or recurrence of dumping and injury and of the Union interest. Verification visits pursuant to Article 16 of the basic Regulation were carried out at the premises of the applicant in France.

2. PRODUCT UNDER REVIEW, PRODUCT CONCERNED AND LIKE PRODUCT

2.1. Product under review

- (20) The product under review is the same as in the original investigation and previous expiry review, namely dry sodium gluconate, with a Customs Union and Statistics (CUS) number 0023277-9 and a Chemical Abstracts Service (CAS) registry number 527-07-1 ('the product under review' or 'sodium gluconate'), currently falling under CN code ex 2918 16 00 (TARIC code 2918 16 00 10).
- (21) Sodium gluconate is used mainly in the construction industry as a set retarder and concrete plasticiser and in other industries as surface treatment for metals (removal of rust, oxides and fat) and for the cleaning of bottles and industrial equipment. The product can also be used in the food and pharmaceutical industries.

2.2. Product concerned

- (22) The product concerned by this investigation is the product under review originating in the PRC.

2.3. Like product

- (23) Similarly to what was established in the original investigation as well as in the previous expiry review, this expiry review investigation confirmed that the following products have the same basic physical, chemical and technical characteristics as well as the same basic uses:
 - the product concerned when exported to the Union;
 - the product under review produced and sold on the domestic market of the PRC; and
 - the product under review produced and sold in the Union by the Union industry.
- (24) These products are therefore considered to be like products within the meaning of Article 1(4) of the basic Regulation.

⁽⁷⁾ <https://tron.trade.ec.europa.eu/investigations/case-view?caseId=2570>

3. DUMPING

3.1. Preliminary remarks

- (25) As mentioned in recital (15), none of the exporters/producers from the PRC cooperated in the investigation. Therefore, on 11 July 2022, the Commission informed the authorities of the PRC that due to the absence of cooperation, the Commission might apply Article 18 of the basic Regulation concerning the findings with regard to the PRC. The Commission did not receive any comments or requests for an intervention of the Hearing Officer in this regard.
- (26) Consequently, in accordance with Article 18 of the basic Regulation, the findings in relation to the likelihood of continuation of dumping were based on facts available, in particular information in the request for review, and information obtained from cooperating parties in the course of the review investigation (namely, the applicant) and information from other publicly available sources, in particular the Global Trade Atlas ('GTA') ⁽⁸⁾.
- (27) During the review investigation period, imports of sodium gluconate from the PRC continued albeit at lower levels than in the investigation period of the original investigation but slightly higher than in the review investigation period of the previous expiry review investigation. According to Eurostat import of sodium gluconate from the PRC accounted for [6 %-10 %] of the Union market in the review investigation period compared to 24,8 % market share in the original investigation and [3 %-15 %] during the previous expiry review.

3.2. Procedure for the determination of the normal value under Article 2(6a) of the basic Regulation for the imports of product under review originating in the PRC

- (28) Given that sufficient evidence had been available at the initiation of the investigation tending to show, with regard to the PRC, the existence of significant distortions within the meaning of point (b) of Article 2(6a) of the basic Regulation, the Commission initiated the investigation on the basis of Article 2(6a) of the basic Regulation.
- (29) In order to obtain information it deemed necessary for its investigation with regard to the alleged significant distortions, the Commission sent a questionnaire to the GOC. In addition, in point 5.3.2 of the Notice of Initiation, the Commission invited all interested parties to make their views known, submit information and provide supporting evidence regarding the application of Article 2(6a) of the basic Regulation within 37 days of the date of publication of the Notice of Initiation in the *Official Journal of the European Union*. No questionnaire reply was received from the GOC and no submission on the application of Article 2(6a) of the basic Regulation was received within the deadline. Subsequently, on 11 July the Commission informed the GOC that it would use facts available within the meaning of Article 18 of the basic Regulation for the determination of the existence of the significant distortions in the PRC.
- (30) In point 5.3.2. of the Notice of Initiation, the Commission also specified that, in view of the evidence available, it may need to select an appropriate representative country pursuant to Article 2(6a)(a) of the basic Regulation for the purpose of determining the normal value based on undistorted prices or benchmarks and suggested Colombia in this regard. The Commission further stated that it would examine other possibly appropriate countries in accordance with the criteria set out in first indent of Article 2(6a) of the Basic regulation.
- (31) On 22 September 2022, the Commission informed interested parties by a Note about the relevant sources it intended to use for the determination of the normal value ('the Note'), with Colombia as a representative country. It also informed interested parties that it would establish selling, general and administrative costs ('SG&A') and profits based on available information for the company Sucroal S.A. ('Sucroal SA'), a producer of products in the same category and/or sector of the product under review, as sodium gluconate was only produced in the European Union, the PRC, and the United States of America ('United States').

⁽⁸⁾ <https://www.gtis.com/gta/>

- (32) In their comments to the Note the applicant claimed that the Commission should take into account also other factors of productions used in the manufacturing of sodium gluconate such as filter aid, other auxiliary chemicals, steam, utilities, maintenance and consumables.
- (33) In the Note the Commission presented the main factors of production. In addition to those factors of production the Commission also added overheads as explained in recital (84). Furthermore, considering that the current investigation is an expiry review pursuant to Article 11(2) on the basic Regulation, which does not require a precise dumping margin calculation, but rather to establish the likelihood of continuation or recurrence of dumping, the Commission considered that in this case it could exceptionally focus on the main factors of production for the calculation of the normal value and therefore the dumping margin. As stated in recital (92), calculating the normal value by using only the main factors of production showed significant dumping. Including additional factors of productions for the calculation of the normal value would increase the dumping margin even more.

3.3. Normal value

- (34) According to Article 2(1) of the basic Regulation, 'the normal value shall normally be based on the prices paid or payable, in the ordinary course of trade, by independent customers in the exporting country'.
- (35) However, according to Article 2(6a)(a) of the basic Regulation, 'in case it is determined [...] that it is not appropriate to use domestic prices and costs in the exporting country due to the existence in that country of significant distortions within the meaning of point (b), the normal value shall be constructed exclusively on the basis of costs of production and sale reflecting undistorted prices or benchmarks', and 'shall include an undistorted and reasonable amount of administrative, selling and general costs and for profits' ('administrative, selling and general costs' is referred hereinafter as 'SG&A').
- (36) As further explained below, the Commission concluded in the present investigation that, based on the evidence available, and in view of the lack of cooperation of the GOC and the producers, the application of Article 2(6a) of the basic Regulation was appropriate.

3.3.1. Existence of significant distortions

- (37) Even though the Commission did not specifically investigate exports of sodium gluconate in the context of Article 2(6a) in the past, in the recent investigations into other chemical compounds, notably the food additives acesulfame potassium⁽⁹⁾, sodium cyclamate⁽¹⁰⁾ and aspartame⁽¹¹⁾, the Commission found that significant distortions in the sense of Article 2(6a)(b) of the basic Regulation were present in the chemical and petrochemical sectors in the PRC. The Commission concluded in these investigations that, based on the evidence available, the application of Article 2(6a) of the basic Regulation was also appropriate.
- (38) In these investigations, the Commission found that there is substantial government intervention in the PRC resulting in a distortion of the effective allocation of resources in line with market principles⁽¹²⁾.

⁽⁹⁾ Commission Implementing Regulation (EU) 2022/116 of 27 January 2022 imposing a definitive anti-dumping duty on imports of acesulfame potassium originating in the People's Republic of China, following an expiry review pursuant to Article 11(2) of Regulation (EU) 2016/1036 of the European Parliament and of the Council (OJ L 19, 28.1.2022, p. 22).

⁽¹⁰⁾ Commission Implementing Regulation (EU) 2022/1924 of 10 October 2022 imposing a definitive anti-dumping duty on imports of sodium cyclamate originating in the People's Republic of China and Indonesia following an expiry review pursuant to Article 11(2) of Regulation (EU) 2016/1036 of the European Parliament and of the Council (OJ L 264, 11.10.2022, p. 12).

⁽¹¹⁾ Commission Implementing Regulation (EU) 2022/2001 of 21 October 2022 imposing a definitive anti-dumping duty on imports of aspartame originating in the People's Republic of China, following an expiry review pursuant to Article 11(2) of Regulation (EU) 2016/1036 of the European Parliament and of the Council (OJ L 274, 24.10.2022, p. 24).

⁽¹²⁾ Regulation (EU) 2022/116, recitals 82-88 and 121-122, Regulation (EU) 2022/1924, recitals 71-77 and Regulation (EU) 2022/2001, recitals 105-108.

- (39) In particular, the Commission concluded that in the sectors of acesulfame potassium, sodium cyclamate and aspartame, not only does a substantial degree of ownership by the GOC persist in the sense of Article 2(6a)(b), first indent of the basic Regulation ⁽¹³⁾, but the GOC is also in a position to interfere with prices and costs through State presence in firms in the sense of Article 2(6a)(b), second indent of the basic Regulation ⁽¹⁴⁾.
- (40) The Commission further found that the State's presence and intervention in the financial markets, as well as in the provision of raw materials and inputs, have an additional distorting effect on the market. Indeed, overall, the system of planning in the PRC results in resources being concentrated in sectors designated as strategic or otherwise politically important by the GOC, rather than being allocated in line with market forces ⁽¹⁵⁾. Moreover, the Commission concluded that the Chinese bankruptcy and property laws do not work properly in the sense of Article 2(6a)(b), fourth indent of the basic Regulation, thus generating distortions in particular when maintaining insolvent firms afloat and when allocating land use rights in the PRC ⁽¹⁶⁾.
- (41) In the same vein, the Commission found distortions of wage costs in the acesulfame potassium, sodium cyclamate and aspartame sectors in the sense of Article 2(6a)(b), fifth indent of the basic Regulation ⁽¹⁷⁾, as well as distortions in the financial markets in the sense of Article 2(6a)(b), sixth indent of the basic Regulation, in particular concerning access to capital for corporate actors in the PRC ⁽¹⁸⁾.
- (42) Like in the previous investigations concerning acesulfame potassium, sodium cyclamate and aspartame, the Commission examined in the present investigation whether it was appropriate or not to use domestic prices and costs in the PRC, due to the existence of significant distortions within the meaning of point (b) of Article 2(6a) of the basic Regulation. The Commission did so on the basis of the evidence available on the file, including the evidence contained in the review request, as well as in the Report ⁽¹⁹⁾, which relies on publicly available sources. That analysis covered the examination of the substantial government interventions in the PRC's economy in general, but also the specific market situation in the relevant sector including the product under review. The Commission further supplemented these evidentiary elements with its own research on the various criteria relevant to confirm the existence of significant distortions in the PRC as also found by its previous investigations in this respect.
- (43) The review request in this case referred to the Report, mentioning distortions regarding the key factors of production, such as land, energy, capital, raw materials and labour. Moreover, with regard to the sodium gluconate sector in particular, the request underlined that the producers in China are closely interconnected with the Chinese State, listing Xiwang Sugar, the third largest sodium gluconate producer as an example. The request provided instances of the close relations of the Xiwang Sugar with the State, mentioning various titles awarded to the company, as listed on company's website: 'national key leading enterprise in agricultural industrialization', 'national

⁽¹³⁾ Regulation (EU) 2022/116, recitals 91-92, Regulation (EU) 2022/1924, recitals 55-56 and Regulation (EU) 2022/2001, recital 94.

⁽¹⁴⁾ Regulation (EU) 2022/116, recitals 93-94, 96, Regulation (EU) 2022/1924, recital 57-61 and Regulation (EU) 2022/2001, recitals 95-96: While the right to appoint and to remove key management personnel in SOEs by the relevant State authorities, as provided for in the Chinese legislation, can be considered to reflect the corresponding ownership rights, CCP cells in enterprises, state owned and private alike, represent another important channel through which the State can interfere with business decisions. According to the PRC's company law, a CCP organisation is to be established in every company (with at least three CCP members as specified in the CCP Constitution) and the company shall provide the necessary conditions for the activities of the party organisation. In the past, this requirement appears not to have always been followed or strictly enforced. However, since at least 2016 the CCP has reinforced its claims to control business decisions in SOEs as a matter of political principle. The CCP is also reported to exercise pressure on private companies to put 'patriotism' first and to follow party discipline. In 2017, it was reported that party cells existed in 70 % of some 1,86 million privately owned companies, with growing pressure for the CCP organisations to have a final say over the business decisions within their respective companies. These rules are of general application throughout the Chinese economy, across all sectors, including to the producers of acesulfame potassium and the suppliers of their inputs.

⁽¹⁵⁾ Regulation (EU) 2022/116, recitals 97-100, Regulation (EU) 2022/1924, recitals 62-67 and Regulation (EU) 2022/2001, recitals 97-101.

⁽¹⁶⁾ Regulation (EU) 2022/116, recitals 101-104, Regulation (EU) 2022/1924, recital 68 and Regulation (EU) 2022/2001, recital 102.

⁽¹⁷⁾ Regulation (EU) 2022/116, recitals 105-106, Regulation (EU) 2022/1924, recital 69 and Regulation (EU) 2022/2001, recital 103.

⁽¹⁸⁾ Regulation (EU) 2022/116, recitals 107-117, Regulation (EU) 2022/1924, recital 70 and Regulation (EU) 2022/2001, recital 104.

⁽¹⁹⁾ Commission staff working document SWD(2017) 483 final/2, 20. 12. 2017, available at: [https://ec.europa.eu/transparency/documents-register/detail?ref=SWD\(2017\)483&lang=en](https://ec.europa.eu/transparency/documents-register/detail?ref=SWD(2017)483&lang=en)

environment-friendly enterprise' and 'key high-tech enterprise in the national Torch Plan'. It has won the titles of 'national advanced grass-roots party organization', 'first place in the national starch sugar industry', 'top 10 enterprises in China's light industry fermentation industry', 'top 100 enterprises in China's food industry.' In addition, the request lists a number of Chinese Communist Party ('CCP') members present among the management of the company ⁽²⁰⁾.

- (44) Furthermore, the request stated that Zhucheng City is a major shareholder in the holding company of Xingmao Corn Developing, the second largest Chinese sodium gluconate producer. This enterprise was also granted various awards and it participated to a number of national projects, including: 'national high-tech enterprises and China Patent Shandong star enterprise, the company has finished more than 10 projects, such as a national "fifteen", "eleven five", "863", the state transformation, the State Torch Program, Spark Program, the national scientific research plan of Shandong Province ⁽²¹⁾.'
- (45) Furthermore, the request explained that several companies are so-called high-tech enterprises with the corresponding privileges, such as the largest sodium gluconate producer, Shandong Fuyang Biotechnology, the second largest producer Zhucheng Xingmao Corn Developing Co., Ltd, and the third largest producer Shandong Xiwang Sugar.
- (46) The request underlined that there are also new entrants to the sodium gluconate market which are State owned enterprises ('SOEs'), for example the newcomer Heilongjiang Zhonglang Biotech Co., Ltd. has as majority shareholder the Qitaihe City Construction Investment Development Co., Ltd., a company held by local authorities. Also, Qingdao Kehai Biochemical Co., Ltd. has certain government background ⁽²²⁾. Moreover, the request explained that there are also SOEs supplying the main materials required to produce sodium gluconate, such as corn starch, caustic soda or energy. One such example is COFCO Biotech, an SOE and a major corn starch producer. Zhucheng Xingmao Corn Developing (see recital (45)) is another leading corn starch producer.
- (47) With regard to the policy documents in place, the request mentioned that according to the 14th Five Year Plan, the state is determined to keep the tight supervision on the chemical industry.
- (48) The request pointed out that distortions were already found in the past in the chemical sector by the Commission in a number of investigations ⁽²³⁾. In addition, a Countervailing Duty Investigation conducted by the U.S. Department of Commerce revealed existence of a number of distortions in the sector ⁽²⁴⁾.

⁽²⁰⁾ See the request, pages 19-20.

⁽²¹⁾ See the request, page 20.

⁽²²⁾ See the request, page 20.

⁽²³⁾ Commission Implementing Regulation (EU) 2021/633 of 14 April 2021 imposing a definitive anti-dumping duty on imports of monosodium glutamate originating in the People's Republic of China and in Indonesia following an expiry review pursuant to Article 11(2) of Regulation (EU) 2016/1036 of the European Parliament and of the Council (OJ L 132, 19.4.2021, p. 63); Commission Implementing Regulation (EU) 2021/607 of 14 April 2021 imposing a definitive anti-dumping duty on imports of citric acid originating in the People's Republic of China as extended to imports of citric acid consigned from Malaysia, whether declared as originating in Malaysia or not, following an expiry review pursuant to Article 11(2) of Regulation (EU) 2016/1036 of the European Parliament and of the Council (OJ L 129, 15.4.2021, p. 73); Commission Implementing Regulation (EU) 2021/441 of 11 March 2021 imposing a definitive anti-dumping duty on imports of sulphanilic acid originating in the People's Republic of China following an expiry review pursuant to Article 11(2) of Regulation (EU) 2016/1036 of the European Parliament and of the Council (OJ L 85, 12.3.2021, p. 154); Commission Implementing Regulation (EU) 2020/1336 of 25 September 2020 imposing definitive anti-dumping duties on imports of certain polyvinyl alcohols originating in the People's Republic of China (OJ L 315, 29.9.2020, p. 1); Commission Implementing Regulation (EU) 2020/39 of 16 January 2020 imposing a definitive anti-dumping duty on imports of peroxosulphates (persulphates) originating in the People's Republic of China following an expiry review pursuant to Article 11(2) of Regulation (EU) 2016/1036 of the European Parliament and of the Council (OJ L 13, 17.1.2020, p. 18).

⁽²⁴⁾ See US DOC, ITA, Decision Memorandum for the Preliminary Affirmative Determination: Countervailing Duty Investigation of Sodium Gluconate, gluconic acid and derivative products (GNA) from the People's Republic of China, 2 May 2018; Issues and Decision Memorandum for the Final Affirmative Determination in Countervailing Duty Investigation of Sodium Gluconate, gluconic acid and derivative products from the People's Republic of China, 17 September 2018.

- (49) The investigation revealed that in the sodium gluconate sector, a certain degree of ownership and control by the GOC persists in the sense of Article 2(6a)(b), first indent of the basic Regulation, including in the following enterprises producing sodium gluconate which, while they are not full SOEs, but have an important proportion of direct and indirect state shareholding: Xingmao Corn Developing and Heilongjiang Zhonglang Biotech.
- (50) As to the GOC being in a position to interfere with prices and costs through State presence in firms in the sense of Article 2(6a)(b), second indent of the basic Regulation, during the investigation the Commission established the existence of personal connections between producers of the product under review and the CCP both among the industry associations representing sodium gluconate and corn starch producers as well as among the manufacturing enterprises.
- (51) It was established that some sodium gluconate producers are active members of the China Food Additive and Ingredients Association ('CFAA'), which stipulates the following in its Articles of Association: 'Article 3: The Association adheres to the overall leadership of the Communist Party of China, and, in accordance with the provisions of the Constitution of the Communist Party of China, establishes an organization of the Communist Party of China, develops Party activities, and provides necessary conditions for the activities of the Party organization. The registration and management authority of the Association is the Ministry of Civil Affairs of the People's Republic of China, and the leading authority for Party building is the Party Committee of the State-owned Assets Supervision and Administration Commission of the State Council. The Association accepts the business guidance, supervision and management of the registration and management authority, the party building leading authority, and of the relevant industry management departments. [...] Article 22: The election and removal of directors: (1) The first directors shall be jointly nominated by the association members upon establishment and shall be elected by the members' representative assembly after being approved by the Party building leadership.'
- (52) The industry association representing the producers of corn starch, which is the main raw material to produce sodium gluconate, is the China Starch Industry Association ('CSIA'). It lists in its Articles of Association the following principles in Article 3: 'This entity adheres to the overall leadership of the Communist Party of China, establishes an organization of the Communist Party of China, and, in accordance with the provisions of the Communist Party of China, develops party activities and provides necessary conditions for the activities of the party organization. The registration authority of this entity is the Ministry of Civil Affairs, and the leading authority for party building is the Party Committee of the State-owned Assets Supervision and Administration Commission of the State Council. The entity accepts the business guidance and supervision and management of registration management agencies, party building leading agencies and relevant industry management departments ⁽²⁵⁾.'
- (53) Both public and privately owned enterprises in the sodium gluconate sector are subject to policy supervision and guidance. Producers of the product under review explicitly emphasise Party building activities on their websites, have Party members in the company management and underline their affiliation to the CCP. The investigation revealed Party building activities in Shandong Fuyang Biotechnology. The company participated to Party building activities organised in August 2022 by CSIA for its member enterprises. The activities were carried out with the following goals: 'In order to promote the integrated development of party building in the industry together with enterprise business work, [we shall] adhere to the leadership of party building, practice the general requirements of "turning to the grassroots level, attending party classes, practicing original aspirations, conducting research and solving problems, and fully foster a new phase in the high-quality development of the starch industry ⁽²⁶⁾". Furthermore, the Chairman of Shandong Fuyang Biotechnology underlines the links of his company with the State and the CCP in the following way: "In recent years, under the strong leadership of the city and county party committees and governments, Fuyang Biotech has maintained a steady development momentum through refined management and innovative breakthroughs. [...] without the strong support of the local party committee and government, the enterprise would not be where it is today. Especially since last year, when the city issued many policies and measures benefitting to enterprises, such as the "Three-Year Action Plan", "20 Opinions for a New Industrialized City" and "Support policy for the Top 50 taxpaying and Top 50 socially contributing Enterprises". (...) It has also strengthened our confidence and determination to expand and to accelerate our development ⁽²⁷⁾.'

⁽²⁵⁾ CSIA Articles of Association available at: <http://www.siacn.org/>

⁽²⁶⁾ See the article on CSIA's website: <https://www.siacn.org.cn/ds/2209ce7a3f.html>

⁽²⁷⁾ China Industrial Economic Information Network, 'Private Entrepreneur Speech | Zhang Dada, Chairman of Shandong Fuyang Biotechnology Co., Ltd.: Promote the construction of high-tech projects and build the world's top biological product manufacturing base' published on 16 August 2021 (original text in Chinese), available at: <http://www.cinic.org.cn/xy/dezhou/cjgc/1139848.html>

- (54) Another sodium gluconate producer, Shandong Xiwang Sugar, describes the role of Party building activities in the following way: 'It is reported that Xiwang Sugar has always regarded party building work as an important task. In addition to doing regular party building activities, it has also actively mobilized party members to go deep into the production line and solve arising problems, to fully involve the party organization as a fighting fortress and has also embarked on a specific development path ensuring the coordination of party building and production as well as their mutual reinforcement'.
- (55) Furthermore, policies discriminating in favour of domestic producers or otherwise influencing the market in the sense of Article 2(6a)(b), third indent of the basic Regulation are in place in the sodium gluconate sector. The sodium gluconate industry is covered by a number of plans, directives and other documents focused on chemicals, including food additives, which are issued at national, regional and municipal level. For example, the 14th Five Year Plan ('FYP') on Economic and Social Development, the general, overarching FYP setting out the goals for the five years covered by it, gives an important role to the chemical industry: 'Section VIII-3: Accelerate the transformation and upgrading of enterprises in key industries such as the chemical industry ⁽²⁸⁾'.
- (56) The 14th FYP on Developing the Raw Materials Industry lists the reiterates the technological ambitions set out in the 14th FYP on Economic and Social Development in the following way: 'Table 1 Key Guidelines as to Technological Innovation Petrochemical and Chemical Sectors. [...] foster the preparation of comprehensive industry chains of bio-based materials ⁽²⁹⁾'.
- (57) Furthermore, the State involvement into developing the chemical industry is also included in the Guiding Opinions to Promote the High-Quality Development of the Petrochemical and Chemical Industries during the 14th FYP: 'Section III.5 (5) Speed up the transformation and upgrading of the industry and improve its competitiveness. Dynamically update the catalogue of technologies and products that the petrochemical and chemical industry is encouraged to promote and apply ⁽³⁰⁾'.
- (58) In addition, the 2018 'MOA + 15 administrations' Notice of Several Policy Measures to Support the High-Quality Development of Agricultural Products' Deep Processing sets out the following: '1. Optimize the industry structure. Organise and promote the coordinated development of the intensive processing of agricultural products with their primary processing and comprehensive use and ensure connexion with upstream and downstream industries such as the production of specific raw materials, Regularly monitor and analyse the production capacity layout of intensive processing and comprehensive use of bulk agricultural products, guide the transformation of excess production capacity and accelerate the construction of lacking production capacity, as well as optimize the layout of the industry chain. Increase the added value of corn processing, especially in Northeast China ⁽³¹⁾'.
- (59) Also, at the regional level, there are instruments setting out the State intervention into the sodium gluconate industry. For example, the Shandong province published a Notice of a Plan Fostering the Building of a Strong Agricultural Province (2021-2025) which includes the following provisions regulating the agricultural sector, which is also relevant for the sodium gluconate producers as well as the producers of the main raw material, which is glucose syrup: '(1) Guiding ideology. Guided by Xi Jinping Thought on Socialism with Chinese Characteristics for a New Era, thoroughly implement the spirit of the 19th National Congress of the Communist Party of China and the Second, Third, Fourth, and Fifth Plenary Sessions of the 19th Central Committee, and earnestly implement General Secretary Xi Jinping's important interventions on the work of "agriculture, rural areas and farmers [...] Construction goals. By 2025, a major breakthrough shall be achieved in the construction of Shandong as a modern agricultural province. The total output value of the province's agriculture, forestry, animal husbandry and fishery will reach over RMB 1,3 trillion, the added value will exceed RMB 690 billion (...) a strong province in agricultural product processing shall be built, with an annual operating income exceeding RMB 3,3 trillion and the ratio of the

⁽²⁸⁾ Full text of the 14th Five Year Plan ('FYP') on Economic and Social Development available at: https://www.ndrc.gov.cn/xxgk/zcfb/ghwb/202103/t20210323_1270124.html?code=&state=123

⁽²⁹⁾ Full text of the 14th FYP on Developing the Raw Materials Industry available at: https://www.miit.gov.cn/zwgk/zcwj/wjfb/tz/art/2021/art_2960538d19e34c66a5eb8d01b74cbb20.html

⁽³⁰⁾ Full text of the Guiding Opinions to Promote the High-Quality Development of the Petrochemical and Chemical Industries during 14FYP available at: http://www.gov.cn/zhengce/zhengceku/2022-04/08/content_5683972.htm#msdyntrid=WRmyf07ph0z74SHmXoOLKjRWl09BdZ4lGdYp9fi9xU

⁽³¹⁾ Full text of the 'MOA + 15 administrations' Notice of Several Policy Measures to Support the High Quality Development of Agricultural Products' Deep Processing available at: http://www.xccys.moa.gov.cn/gzdt/201901/t20190102_6314547.htm

output value of the agricultural product processing industry to the total agricultural output value shall exceed 3:1; build a province with strong agricultural development, whose export volume of agricultural products continues to grow steadily and which is the leading province of the country, and also build a number of strong counties and cities that are oriented towards agricultural exports”⁽³²⁾. The plan furthermore indicates specific goals as to the future development and location of enterprises: ‘promote the integration of agricultural product processing into the production area and ensure it is concentrated in the parks; guide processing enterprises to gather in central towns and specialized villages, build more than 100 national and provincial modern agricultural industrial parks and 1 000 strong agricultural districts’.

- (60) In addition, sodium gluconate is explicitly listed in the development goals of the Heilongjiang province’s 14thFYP on Developing Corn Processing Industry. More specifically, the plan entails creation of industrial clusters in the province’s corn processing areas, including the producers of sodium gluconate⁽³³⁾. Heilongjiang further describes its goal of development of the corn processing industry in the following way: ‘Improving the industrial chain is becoming an important way for Heilongjiang Province to promote the development of the agricultural industry. According to the staff of the Department of Agriculture and Rural Affairs of Heilongjiang Province, Heilongjiang Province is currently implementing the “industry concept” based on the appointment of a “head of an industry chain” where for example the “head of the corn industry chain” is responsible for the organisation of surveys and research, for devising industry development plans, for ensuring coordination and solving problems, carry out targeted investment promotion, and fostering the corn industry to become bigger and stronger⁽³⁴⁾.’ The output planned for 2021 included 3,4 million tons of corn processing capacity, with 1,8 million tons of processed corn starch. The target for output value in 2021 was set at RMB 10 billion⁽³⁵⁾. The development of the state supported sodium gluconate industrial project in Heilongjiang is ongoing and successful, according to a report on the Ministry of Agriculture website: ‘Until now, the corn processing industry of Qinggang County has cumulated an investment exceeding RMB 6 billion in total, and has successively started construction of starch, [...], liquid glucose, sodium gluconate, ... and other series of 29 industrial projects⁽³⁶⁾’.
- (61) The Jilin province also includes sodium gluconate among its supported industries. Jilin Province’s 14thFYP on Strategic and Emerging Industries confirms the priority given to bio-industry: ‘Improve the level of biochemical industrialization. Improve corn transformation capacity, actively develop deep processing and raw material substitution⁽³⁷⁾.’ The Jilin province launched a major development project for sodium gluconate. As announced on the Jilin province’s internet website: ‘A project of 100 000 tonnes/year of sodium gluconate is announced. As a new industry, the sodium gluconate industry is developing rapidly. In the past 10 years, the output of the domestic sodium gluconate industry has maintained an aggregate growth rate of nearly 33 %. China has become an important producer and exporter in the world, with a total annual production capacity of more than 600 000 tonnes. The overall plan for the development of strategic emerging industries of the country was released, and the biological industry was listed among them. The development and application of new processes, new technologies and new equipment opened up new space for the development of the sodium gluconate industry. [...] Jilin Province, Lishu Economic Development Zone, benefits from the new round of national measures to stimulate domestic demand in a timely manner and relies on the advantages of the existing chemical industry park in the development zone and proposes an annual output of 100 thousand tons of sodium gluconate. The project will [...], further optimize the industrial structure of the economic development zone, [...], and expand the total economic volume, which has a vast, deep, practical and historical significance for accelerating the industrialization process of Lishu County. Therefore, the market prospects for this project are optimistic⁽³⁸⁾’.

⁽³²⁾ Article 1 of Shandong province’s Notice of a Plan fostering the building of a strong agricultural province (2021—2025). Full text of the document available at: http://www.shandong.gov.cn/art/2021/10/28/art_107851_114919.html

⁽³³⁾ Heilongjiang province’s 14FYP on Developing Corn Processing Industry, box 3.3. Full text available at: <https://zwgk.hl.j.gov.cn/zwgk/publicInfo/detail?Id=450171>

⁽³⁴⁾ See Ministry of Agriculture website: http://www.moa.gov.cn/xw/qg/202012/t20201207_6357665.htm

⁽³⁵⁾ See Ministry of Agriculture website: http://www.moa.gov.cn/xw/qg/202206/t20220614_6402372.htm

⁽³⁶⁾ http://www.moa.gov.cn/xw/qg/202206/t20220614_6402372.htm

⁽³⁷⁾ Article 3.4. Full text of the document published on Jilin government’s website: http://xxgk.jl.gov.cn/szf/gkml/202112/t20211227_8357122.html

⁽³⁸⁾ See Jilin province’s website: http://www.jl.gov.cn/szfzt/tzci/zdxm/ncpjg/201902/t20190215_5605767.html

- (62) As can be seen from the above examples, the GOC guides the development of the sodium gluconate sector in accordance with a broad range of policy tools and directives and controls virtually every aspect in the development and functioning of the sector. Thus, the sodium gluconate industry benefits from governmental guidance and intervention concerning the main raw material, namely corn starch.
- (63) In sum, the GOC has measures in place to induce operators to comply with the public policy objectives of supporting encouraged industries, including the production of corn starch as the main raw material used in the manufacturing of the product under review. Such measures impede market forces from operating freely.
- (64) The present investigation has not revealed any evidence that the discriminatory application or inadequate enforcement of bankruptcy and property laws according to Article 2(6a)(b), fourth indent of the basic Regulation in the sodium gluconate sector referred to above in recital (40) would not affect the manufacturers of the product under review.
- (65) The sodium gluconate sector is also affected by the distortions of wage costs in the sense of Article 2(6a)(b), fifth indent of the basic Regulation, as also referred to above in recital (41). Those distortions affect the sector both directly (when producing the product under review or the main inputs), as well as indirectly (when having access to capital or inputs from companies subject to the same labour system in the PRC).
- (66) Moreover, no evidence was submitted in the present investigation demonstrating that the sodium gluconate sector is not affected by the government intervention in the financial system in the sense of Article 2(6a)(b), sixth indent of the basic Regulation, as also referred to above in recital (41). Therefore, the substantial government intervention in the financial system leads to the market conditions being severely affected at all levels.
- (67) Finally, the Commission recalls that, in order to produce the product under review, a number of inputs is needed. When the producers of the product under review purchase or contract for these inputs, the prices paid (and which are recorded as their costs) are exposed to the same systemic distortions mentioned before. For instance, suppliers of inputs employ labour that is subject to the distortions; they may borrow money that is subject to the distortions on the financial sector/capital allocation; and they are subject to the planning system that applies across all levels of government and sectors.
- (68) As a consequence, not only the domestic sales prices of the product under review are not appropriate for use within the meaning of Article 2(6a)(a) of the basic Regulation, but all the input costs (including raw materials, energy, land, financing, labour, etc.) are also affected because their price formation is affected by substantial government intervention, as described in Parts A and B of the Report. Indeed, the government interventions described in relation to the allocation of capital, land, labour, energy and raw materials are present throughout the PRC. This means, for instance, that an input that in itself was produced in the PRC by combining a range of factors of production is exposed to significant distortions. The same applies for the input to the input and so forth.
- (69) No evidence or argument to the contrary has been adduced by the GOC or the exporting producers in the present investigation.
- (70) In sum, the evidence available showed that prices or costs of the product under review, including the costs of raw materials, energy and labour, are not the result of free market forces because they are affected by substantial government intervention within the meaning of Article 2(6a)(b) of the basic Regulation as shown by the actual or potential impact of one or more of the relevant elements listed therein. On that basis, and in the absence of any cooperation from the GOC, the Commission concluded that it is not appropriate to use domestic prices and costs to establish normal value in this case. Consequently, the Commission proceeded to construct the normal value exclusively on the basis of costs of production and sale reflecting undistorted prices or benchmarks, that is, in this case, on the basis of corresponding costs of production and sale in an appropriate representative country, in accordance with Article 2(6a)(a) of the basic Regulation, as discussed in the following section.

3.3.2. *Representative country*

3.3.2.1. *General remarks*

- (71) The choice of the representative country was based on the following criteria pursuant to Article 2(6a) of the basic Regulation:
- A level of economic development similar to the PRC. For this purpose, the Commission used countries with a gross national income per capita similar to the PRC on the basis of the database of the World Bank ⁽³⁹⁾;
 - Production of the product under review in that country ⁽⁴⁰⁾;
 - Availability of relevant public data in the representative country;
 - Where there is more than one possible representative country, preference should be given, where appropriate, to the country with an adequate level of social and environmental protection.
- (72) As explained in recital (31), the Commission issued a Note on relevant sources to use for the determination of the normal value. This Note described the facts and evidence underlying the relevant criteria. The Note informed interested parties of the Commission's intention to consider Colombia as an appropriate representative country in the present case if the existence of significant distortions pursuant to Article 2(6a) of the basic Regulation were confirmed.
- (73) In line with the criteria listed under Article 2(6a) of the basic Regulation, the Commission identified Colombia as a country with a similar level of economic development as the PRC as it was suggested by the applicant in the request for review. Colombia is classified by the World Bank as 'upper-middle income' country on a gross national income basis. Given that neither the United States nor the EU have a similar level of development as the PRC, the Commission focused on a product in the same category and/or sector of the product under review and established that there was production of naturally occurring fruit acids belonging to the same general category as the product under review in Colombia and relevant data was readily available.
- (74) Finally, given the absence of cooperation and having established that Colombia was an appropriate representative country, based on all of the above elements, there was no need to carry out an assessment of the level of social and environmental protection in accordance with the last sentence of Article 2(6a)(a) first indent of the basic Regulation.

3.3.2.2. *Conclusion*

- (75) In the absence of cooperation, as proposed in the expiry review request and given that Colombia met the criteria laid down in Article 2(6a)(a), first indent of the basic Regulation, the Commission selected Colombia as the appropriate representative country.

3.3.3. *Sources used to establish undistorted costs*

- (76) In the Note the Commission listed the factors of production such as materials, energy and labour used in the production of the product under review by the exporting producers. The Commission also stated that, in order to construct the normal value in accordance with Article 2(6a)(a) of the basic Regulation, it would use Global Trade Atlas ('GTA') to establish the undistorted cost of most of the factors of production, notably the raw materials. In addition, the Commission stated that it would use information from: the International Labour Organization ('ILO') for establishing undistorted costs of labour and public tariffs from electricity suppliers in Colombia.
- (77) Finally, the Commission stated that to establish SG&A costs and profit, it would use the financial data from one Colombian producer of products from the same general category as the product under review as set out in recital (31).

⁽³⁹⁾ World Bank Open Data – Upper Middle Income, <https://data.worldbank.org/income-level/upper-middle-income>.

⁽⁴⁰⁾ If there is no production of the product under review in any country with a similar level of development, production of a product in the same general category and/or sector of the product under review may be considered.

3.3.3.1. Undistorted costs and benchmarks

3.3.3.1.1. Factors of production

- (78) Considering all the information based on the request and subsequent information collected during the proceeding, the following factors of production and their sources have been identified in order to determine the normal value in accordance with Article 2(6a)(a) of the basic Regulation:

Table 1

Factors of production of sodium gluconate

Factor of Production	Commodity Code in Colombia	Undistorted value (RMB)	Unit of measurement
<i>Raw materials</i>			
Glucose syrup	17023010 17023020 17023090	5,72	kg
Caustic soda	28151200	1,46	kg
<i>Labour</i>			
Labour cost per man-hour	NA	13,41	hour
<i>Energy</i>			
Electricity	NA	0,77	Kwh

Raw materials

- (79) In order to establish the undistorted price of raw materials as delivered at the gate of a representative country producer, the Commission used as a basis the weighted average import price to the representative country as reported in the GTA to which import duties were added. An import price in the representative country was determined as a weighted average of unit prices of imports from all third countries excluding the PRC and countries which are not members of the WTO, listed in Annex I of Regulation (EU) 2015/755 of the European Parliament and the Council ⁽⁴¹⁾. The Commission decided to exclude imports from the PRC into the representative country as it concluded in section 3.3.1 that it is not appropriate to use domestic prices and costs in the PRC due to the existence of significant distortions in accordance with Article 2(6a)(b) of the basic Regulation. Given that there is no evidence showing that the same distortions do not equally affect products intended for export, the Commission considered that the same distortions affected export prices. After excluding imports from the PRC into the representative country, the volume of imports from other third countries remained representative.
- (80) Normally, domestic transport prices should also be added to these import prices. However, considering the nature of this expiry review investigation, which is focused on finding whether dumping continued during the review investigation period or could reoccur, rather than finding its exact magnitude, the Commission decided that adjustments for domestic transport were unnecessary. Such adjustments would only result in increasing the normal value and hence the dumping margin.

⁽⁴¹⁾ Regulation (EU) 2015/755 of the European Parliament and of the Council of 29 April 2015 on common rules for imports from certain third countries (OJ L 123, 19.5.2015, p. 33). Article 2(7) of the basic Regulation considers that domestic prices in those countries cannot be used for the purpose of determining normal value and, in any event, such import data was negligible.

Labour

- (81) The Commission used ILO statistics to determine the wages in Colombia ⁽⁴²⁾. These provide information on monthly wages of employees in the manufacturing sector and average weekly hours worked in Colombia for the investigation period (year 2021).

Electricity

- (82) For electricity, the Commission used the readily available price from Enel ⁽⁴³⁾, the major electricity supplier in Colombia. This source provides a single average price of electricity per month.

3.3.3.1.2. Manufacturing overhead costs, SG&A, profits and depreciation

- (83) According to Article 2(6a)(a) of the basic Regulation, 'the constructed normal value shall include an undistorted and reasonable amount for administrative, selling and general costs and for profits'. In addition, a value for manufacturing overhead costs needs to be established to cover costs not included in the factors of production referred to above.
- (84) In order to establish an undistorted value of the manufacturing overheads and given the absence of cooperation from the Chinese producers, the Commission used facts available in accordance with Article 18 of the basic Regulation. Therefore, based on the data provided by the applicant the Commission established the ratio of manufacturing overheads to the total manufacturing and labour costs. This percentage was then applied to the undistorted value of the cost of manufacturing to obtain the undistorted value of manufacturing overheads.
- (85) For establishing an undistorted and reasonable amount for SG&A and profit, the Commission relied on the most recent available financial data the company in Colombia that had been identified in the Note as active and profitable producer of products in the similar category as sodium gluconate as well as the additional four Colombian producers of products in the similar category as sodium gluconate suggested by the applicant in its comments to the Note. Financial data for the following companies as extracted from Orbis Bureau van Dijk was used for the financial year 2021: Sucroal SA, DSM Nutritional Products Colombia SA, Fonandes SAS, Nutresol SAS and Quimica International Quintal SA.

3.3.3.2. Calculation of the normal value

- (86) On the basis of the above, the Commission constructed the normal value on an ex-works basis in accordance with Article 2(6a)(a) of the basic Regulation.
- (87) First, the Commission established the undistorted manufacturing costs. In the absence of cooperation by the exporting producers, the Commission relied on the information provided by the applicant in the review request on the usage of each factor (materials and labour) for the production of product under review.
- (88) Once the undistorted manufacturing cost established, the Commission added the manufacturing overheads, SG&A and profit as noted in recitals (84) and (85). Manufacturing overheads were determined based on data provided by the applicant. SG&A and profit were determined based on the average financial data of five representative Colombian producers of products in the similar category as sodium gluconate for the year 2021 as reported in the company's financial statements. The Commission added the following items to the undistorted costs of manufacturing:
- Manufacturing overheads, which accounted in total for 13 % of the direct costs of manufacturing,
 - SG&A and other costs, which accounted for 19,44 % of the Costs of Goods Sold ('COGS') of five Colombian producers of products in the similar category as sodium gluconate, and

⁽⁴²⁾ <https://www.ilo.org/ilostat>

⁽⁴³⁾ www.enel.com.co

— Profits, which amounted to 8,68 % of the COGS as achieved by five Colombian producers of products in the similar category as sodium gluconate, were applied to the total undistorted costs of manufacturing.

- (89) On that basis, the Commission constructed an average normal value per unit on an ex-works basis in accordance with Article 2(6a)(a) of the basic Regulation.

3.4. Export price

- (90) In the absence of cooperation by exporting producers from the PRC, the export price was determined based on CIF extracted from Eurostat data corrected to *ex-works* level. Thus, the CIF price was reduced by the sea freight, insurance cost and domestic transport cost. Domestic Chinese and international transport costs were based on information provided by the applicant in the request for review.

3.5. Comparison

- (91) The Commission compared, the normal value established in accordance with Article 2(6a)(a) of the basic Regulation and the export price on an ex-works basis as established above.

3.6. Dumping margin

- (92) On this basis, the dumping margin was found to be significant (over 100 %). It was therefore concluded that dumping continued during the review investigation period.

4. LIKELIHOOD OF CONTINUATION OF DUMPING

- (93) Further to the finding of the existence of dumping during the review investigation period, the Commission investigated, in accordance with Article 11(2) of the basic Regulation, the likelihood of continuation of dumping, should the measures be allowed to lapse. The following additional elements were analysed: the production capacity and spare capacity in the PRC, the attractiveness of the Union market and export prices to third countries as well as trade defence measures in other export markets.
- (94) As a consequence of the non-cooperation of Chinese exporting producers and of the GOC, the Commission based its assessment on the facts available in accordance with Article 18 of the basic Regulation, namely on information provided in the request for review, readily available information, and information from the GTA database.

4.1. Production capacity and spare capacity in the PRC

- (95) The applicant provided estimates of sodium gluconate production capacity and output in the PRC. These estimates were based on a report ⁽⁴⁴⁾ and two newsletters ⁽⁴⁵⁾ by KComber/CCM, a Chinese market intelligence provider across the industries of agriculture, chemical and life sciences.
- (96) For the review investigation period, the report estimated the total production capacity in the PRC at 1 306 800 tonnes. For the same year, the report estimated the total output in the PRC at 701 400 tonnes. These estimates imply a capacity utilisation rate of 54 %, and a spare capacity of 605 400 tonnes in that year, which amounts to more than 25 times the Union consumption in the free market. Furthermore, the newsletters provided evidence of plans by three sodium gluconate producers for further capacity expansions of a total of 290 000 tonnes/year, from 2022 onwards ⁽⁴⁶⁾.

⁽⁴⁴⁾ Sodium Gluconate and Glucono Delta-Lactone's Major Producers Capacity and Output in China in 2021, published April 2022.

⁽⁴⁵⁾ Corn Products China News July 2022; Corn Products China News September 2022.

⁽⁴⁶⁾ BBKA Biochemical: 60 000 tonnes, Shandong Fuyang Biotechnology (through Dezhou Heyang Biotechnology): 200 000 tonnes, and Tongliao Zhongyuan Biological Development: 30 000 tonnes.

- (97) The Commission noted that, in view of the main applications of sodium gluconate, the evolution of its consumption is closely associated with the growth of the construction industry. According to the development plan of the Chinese government for the construction industry over the 14th FYP period (2021-2025) ⁽⁴⁷⁾, that industry will maintain a constant share (6 %) of the country's GDP into 2025. Moreover, based on data on production and exports from 2013 to 2021 ⁽⁴⁸⁾, the Commission has calculated the domestic consumption of sodium gluconate in the PRC over that period and found that it increased from 527 000 to 701 400 tonnes, representing an annual growth rate of less than 3 %. It follows that, even under highly optimistic scenarios of economic development, the domestic consumption of sodium gluconate will be unable to absorb a large part of the spare capacity which has been built in the country, and which is likely to increase further. Therefore, Chinese producers of sodium gluconate will have strong incentives to use this spare capacity for exports, including notably to the Union market.
- (98) Based on the above, the Commission concluded that the Chinese exporting producers have significant spare capacities, which could be used for exports to the Union if the measures were allowed to lapse.

4.2. Attractiveness of the Union market and export prices to third countries

- (99) In view of the size of its construction industry, as well as of other industries that make use of sodium gluconate, the Union market for sodium gluconate is of global importance. In that respect, it is noteworthy that, even with the measures in place, Chinese exports to the Union not only continued, but also increased significantly during the period considered (see table 3), showing that the Union market remains attractive to Chinese exporting producers.
- (100) Moreover, the Commission examined whether it is likely that Chinese exporting producers would increase even more their export sales to the Union at dumped prices should measures be allowed to lapse. Therefore, the Commission examined the price level of Chinese exports to third country markets and compared them to the price level of Chinese exports to the Union.
- (101) As a starting point, the Commission used data from the GTA database, a market-leading dataset on global trade flows at the level of harmonized system code (HS code). According to GTA, during the review investigation period (2021), as well as during the part of 2022 for which data were available, the average price of Chinese exports to the Union of products falling under HS Code 291816 was significantly higher than the average price of exports to third countries. However, due to the fact that this HS Code includes also products other than sodium gluconate, the Commission complemented its analysis based on other sources.
- (102) In particular, the applicant provided detailed data sourced from ThinkReal, a specialised market research company, on exports of sodium gluconate from China ⁽⁴⁹⁾. According to this data, the average price (in FOB terms) of exports of sodium gluconate from China to the Union was between 1 % and 5 % higher compared to the average price of exports to third countries, both during the review investigation period (2021), as well as during the part of 2022 for which data were available. In the absence of measures, Chinese producers would be able to export to the Union at prices that are even higher (in FOB terms) compared to the prices to third countries which, however, would still be dumped given the magnitude of the dumping margins found during this review, while increasing their market share in the Union.
- (103) It follows that the Union market is attractive for the Chinese exporting producers, which would have an economic incentive to shift exports from third countries to the more lucrative Union market at dumped prices, should the measures be allowed to lapse.

⁽⁴⁷⁾ See: http://english.scio.gov.cn/pressroom/2022-01/26/content_78011624.htm

⁽⁴⁸⁾ KComber/CCM and ThinkReal.

⁽⁴⁹⁾ Exhibit 23 of the verification report: Chinese export statistics (all destinations)/Chinese export statistics (EU 27 destinations).

4.3. Trade defence measures in other export markets

- (104) The Commission noted that in 2018 the United States also imposed trade defence measures, including anti-dumping duties and countervailing duties, against imports of sodium gluconate from the PRC ⁽⁵⁰⁾.
- (105) Given the high level of these measures, it has been difficult for sodium gluconate from the PRC to enter the United States in meaningful quantities. Consequently, a substantial part of the available spare capacity could not be absorbed by the US market. Moreover, there is no information available to the Commission, suggesting that these measures would be repealed in the foreseeable future.
- (106) As a result of the trade defence measures in the United States, Chinese producers of sodium gluconate face reduced possibilities for exports. The Union market is therefore of high relative importance, and would attract a significant part of Chinese sodium gluconate production should the Union measures be allowed to lapse.

4.4. Conclusion

- (107) Considering the significant spare capacity in the PRC and taking into account the trade defence measures imposed by the United States, as well as the evidence on the attractiveness of the Union market, the Commission concluded that should the measures lapse, it is likely that the Chinese exporting producers will activate the spare capacity and even redirect exports from third countries towards the Union market at dumped prices and in significant volumes.
- (108) In view of its findings on the continuation of dumping during the review investigation period and on the likely development of exports should the measures lapse, the Commission concluded that there is a strong likelihood that the expiry of the anti-dumping measures on imports from the PRC would result in the continuation of dumping.

5. INJURY

5.1. Definition of the Union industry and Union production

- (109) The like product was manufactured by two producers in the Union during the period considered: Jungbunzlauer S.A. and Roquette Italia S.p.A. These two companies account for 100 % of the Union production and therefore constitute the 'Union industry' within the meaning of Article 4(1) of the basic Regulation.
- (110) As the data relating to the injury assessment was derived from only two Union producers, the figures for the injury analysis are given in ranges for reasons of confidentiality. However, the indexes are based on actual data and not on the ranges.
- (111) The total Union production during the review investigation period was established in the range of [50 000 to 61 000] tonnes. The Commission established the figure on the basis of all the available information concerning the Union industry, such as the request for the expiry review and the questionnaire reply of the Union industry.
- (112) A verification visit was carried out at the premises of the cooperating producer of the product under review, Jungbunzlauer SA.

5.2. Union consumption

- (113) The Commission established the Union consumption on the basis of the total sales volume of the Union industry on the Union market obtained from the reply to the questionnaire for Union producers and on the basis of the total import volume as available in Eurostat.

⁽⁵⁰⁾ <https://www.federalregister.gov/documents/2018/11/13/2018-24705/sodium-gluconate-gluconic-acid-and-derivative-products-from-the-peoples-republic-of-china>

(114) The Union consumption developed as follows:

Table 2

Union consumption

	2018	2019	2020	Review investigation period (2021)
Total Union consumption (tonnes)	[36 991-44 778]	[36 113-43 716]	[38 126-46 153]	[40 222-48 690]
<i>Index</i>	100	98	103	109
Captive market	[18 294-22 145]	[17 792-21 538]	[20 758-25 128]	[20 822-25 206]
<i>Index</i>	100	97	113	114
Free market	[18 696-22 633]	[18 321-22 178]	[17 368-21 025]	[19 400-23 484]
<i>Index</i>	100	98	93	104

Source: Data from the Union industry and Eurostat.

- (115) The investigation showed that total consumption of sodium gluconate includes a large share of captive use by the Union industry, namely the quantities used for further processing by the Union industry. This means that the product under review is also important for the downstream products of the Union Industry.
- (116) The Union consumption on the free market increased by 4 % during the period considered. However, it decreased by 7 % between 2018 and 2020, of which 2 percentage points decrease in 2019 and a further 5 percentage points decrease in 2020, the year of the pandemic. It rebounded from 2020 to the review investigation period by 11 percentage points, as user industries started recovering from the economic downturn caused by the pandemic.

5.3. Imports from the country concerned

5.3.1. Volume and market share of the imports from the country concerned

- (117) In the absence of cooperation from Chinese exporting producers, the Commission established the volume of imports on the basis of Eurostat import statistics.
- (118) Imports into the Union from China developed as follows:

Table 3

Import volume and market share

	2018	2019	2020	Review investigation period (2021)
Volume of imports from China (tonnes)	[873-1 057]	[1 296-1 569]	[1 526-1 847]	[1 516-1 835]
<i>Index</i>	100	149	175	174
Market share (%)	[3-7]	[5-9]	[7-12]	[6-10]
<i>Index</i>	100	152	188	167

Source: Eurostat.

- (119) Over the period considered, the Chinese import volume increased overall by 74 %. It increased first by 75 % between 2018 and 2020 and then slightly decreased by 1 % in the review investigation period. This development shows that the Chinese imports followed the opposite trend of Union consumption. The Chinese market share grew by 88 % from 2018 to 2020 and showed a decline of 11 % from 2020 to the review investigation period. Chinese exporters managed to increase their market share considerably from 2018 to 2020 in a shrinking market, but did not increase market share in the review investigation period when Union consumption rebounded. Overall, the share of the market held by Chinese exporters sharply increased over the period considered to the detriment of the Union industry.

5.4. Prices of the imports from the country concerned and price undercutting

- (120) The Commission established the trend of the prices of Chinese imports on the basis of Eurostat import statistics.
- (121) The average price of imports into the Union from China developed as follows:

Table 4

Import Price (EUR/tonne)

	2018	2019	2020	Review investigation period (2021)
Average import price from China	[578-700]	[590-714]	[580-702]	[817-990]
Index	100	102	100	141

Source: Eurostat.

- (122) Chinese average import prices were rather stable until 2020 and then significantly increased by 41 % during the review investigation period, above the Union industry average price level, as reflected in Table 9 below.
- (123) In the absence of cooperation from Chinese exporting producers, the Commission relied on information available to it that could explain this development. It is recalled, that the year 2020, the third year of the period considered in the current investigation, coincided with the start of the Covid-19 sanitary crisis, which caused worldwide disruption in the purchase and supply chains. Based on submissions by the Union industry and on publicly available information, the severe sanitary restrictions in place since 2020 led to higher costs in China, in particular for raw materials, energy and transport in 2021. The price of corn in China increased by 50 to 70 % between 2018 and 2021 ⁽⁵¹⁾, and the hike in transport costs can explain the increase of the sodium gluconate export price between 2020 and 2021 ⁽⁵²⁾.
- (124) Given the absence of cooperation, the Commission did not have information concerning the product mix exported from China to the Union, or concerning the type of customers that imported the product concerned. This is of particular importance because the investigation showed that significant price differences exist amongst product types, depending on the application. The available verified data showed that prices of sodium gluconate intended for the food and pharmaceutical sectors could be up to 37 % higher than types destined for other applications, such as construction.
- (125) The information collected during the investigation also revealed that whilst the Chinese exporters were selling on spot basis, the Union industry was mainly selling sodium gluconate based on yearly contracts. This means that most sales were made at fixed prices that could not be increased. According to the Union industry, sales agreements with Chinese exporters are often made on spot or short term basis. Their prices are thus reflecting immediately unexpected market circumstances, such as increases in raw material and transport costs.

⁽⁵¹⁾ See submission of Jungbunzlauer 'Exhibit 23'.

⁽⁵²⁾ See submission of Jungbunzlauer 'Exhibit 23'.

- (126) Based on the limited and unverified information available concerning Chinese imports, the Commission examined the possible price undercutting during the review investigation period by comparing:
- (a) the weighted average sales price of the verified Union producer charged to unrelated customers on the Union market, adjusted to an ex-works level; and
 - (b) the weighted average price of imports from China at cost, insurance, freight (CIF) level as per Eurostat import statistics, with appropriate adjustments for anti-dumping and customs duties.
- (127) This comparison showed no undercutting by Chinese imports on the Union market during the review investigation period, even when anti-dumping duties are not taken into account.
- (128) This comparison is based on an unknown product mix of Chinese products during the review investigation period, namely on price data, which details were not available and could thus not be verified.
- (129) The Commission then examined in more detail the product types produced and sold by the Union industry and found that about 30 % of its sales were made at prices between 8 to 14 % above the average Chinese price. In view of the absence of cooperation from Chinese exporters, the Commission does not have verified information concerning the product types sold by the Chinese exporters and therefore cannot conclude that the comparison made in recital (126) is meaningful.
- (130) The Union industry provided information showing that the transport cost from China to the Union has significantly increased in the review investigation period, reaching EUR 210 to EUR 250 per tonne. This temporary cost increase would be, by far, the main factor explaining the relatively high export price of Chinese sodium gluconate during the review investigation period. Taking into account the above average transport cost, the ex-works price of Chinese sodium gluconate exported to the Union would be at around EUR 600 per tonne, namely between 20 to 30 % lower than the ex-work price of the Union industry.
- (131) The Commission also collected publicly available information ⁽⁵³⁾ suggesting that the output of the main Chinese producers decreased by 5,4 %. In parallel, the price of corn starch, the main raw material used to produce sodium gluconate, was increasing in 2021. According to the same public source, the ex-work price of Chinese sodium gluconate increased in 2021 was, on average, at EUR 560/tonne. This price is between 25 to 35 % below the ex-works price of the Union Industry and confirms that the Chinese price level observed during the review investigation period is mainly due to the temporary increase in transport costs.
- (132) Based on another public source ⁽⁵⁴⁾, it was estimated that the average transport cost from China to the EU in 2021 was around EUR 130 – 170/tonne, namely 3 times the cost of 2020. Adding the average transport costs to the average ex-works price for all Chinese sodium gluconate would lead to a constructed average export price at around EUR 700/tonne. This price concerns all types of sodium gluconate produced in China.
- (133) A price comparison on that basis would lead to an average price undercutting of 9 % of Union industry turnover, when anti-dumping duties are not taken into account.

⁽⁵³⁾ Sodium Gluconate and Glucono Delta-Lactone's Major Producers Capacity and Output in China in 2021 (marketresearch.com) <https://www.marketresearch.com/CCM-International-Limited-v3539/Sodium-Gluconate-Glucono-Delta-Lactone-32039947/#:~:text=In%202017%20%E2%80%93%20the%20output%20of%20sodium%20gluconate%20in,which%20was%205,44%25%20lower%20than%20that%20of%202020.>

⁽⁵⁴⁾ China to Europe container freight rate index | Statista
Shipping costs quadruple to record highs on China-Europe 'bottleneck' | Financial Times (ft.com)

5.5. Imports from third countries other than China

- (134) As mentioned in recital (31) sodium gluconate is produced in China, in the United States and in the Union. The imports of sodium gluconate from third countries other than China were negligible (well below 1 % of Union consumption) during the review investigation period. It is therefore considered that these imports did not have any material impact on the Union market during the period considered. For this reason, the Commission did not consider these imports further in its injury analysis.

Table 5

Imports from third countries

		2018	2019	2020	Review investigation period (2021)
Rest of the world	Volume (tonnes)	[3-4]	[1-2]	[6-7]	[5-6]
	Index	100	54	186	146

Source: Eurostat.

5.6. Economic situation of the Union industry

5.6.1. General remarks

- (135) The assessment of the economic situation of the Union industry included an evaluation of all economic indicators having a bearing on the state of the Union industry during the period considered.
- (136) The Union industry is composed of two producers. The bigger producer (the applicant) fully cooperated by filling in the Union producer questionnaire and providing all data necessary for the injury analysis. Both producers provided the information, which allowed establishing the macroeconomic injury indicators. The smaller producer did not provide a response to the Union producer questionnaire.
- (137) For the injury determination, the Commission distinguished between macroeconomic and microeconomic injury indicators. The macroeconomic indicators were established on the basis of data contained in the request for review, the verified questionnaire reply of the cooperating Union producer, and data provided by the smaller Union producer. This covered the macroeconomic data relating to the two Union producers. The Commission evaluated the microeconomic indicators on the basis of data contained in the verified questionnaire reply of the cooperating Union producer. The sets of data were found to be representative of the economic situation of the Union industry.
- (138) The macroeconomic indicators are: production, production capacity, capacity utilisation, sales volume, market share, growth, employment, productivity, magnitude of the dumping margin, and recovery from past dumping.
- (139) The microeconomic indicators are: average unit prices, unit cost, labour costs, inventories, profitability, cash flow, investments, return on investments, and ability to raise capital.

5.6.2. Macroeconomic indicators

5.6.2.1. Production, production capacity and capacity utilisation

- (140) The total Union production, production capacity and capacity utilisation developed over the period considered as follows:

Table 6 A

Union production, production capacity and capacity utilisation

	2018	2019	2020	Review investigation period (2021)
Production volume (tonnes)	[47 169-57 099]	[46 207-55 935]	[47 376-57 350]	[50 049-60 586]
<i>Index</i>	100	98	100	106
Production capacity (tonnes)	[55 765-67 505]	[55 765-67 505]	[55 765-67 505]	[55 765-67 505]
<i>Index</i>	100	100	100	100
Capacity utilisation (%)	[80-97]	[79-95]	[81-98]	[85-100]
<i>Index</i>	100	98	100	106

Source: Data provided by the Union industry.

- (141) Production of sodium gluconate increased by 6 % during the period considered, in particular during the review investigation period. The investigation showed that the main reasons for this increase were the increase in export sales (+ 18 %) and a higher captive use (+ 14 %) for downstream products in that period.
- (142) This positive trend in production allowed the Union industry to make economies of scale with a higher utilisation of production capacity and to decrease certain costs, in particular during the review investigation period.
- (143) As already stated above, the table below shows that the share of production intended for captive use is important and represents around 35 to 45 % of total production. That share increased by 14 % and remained important for the Union Industry during the period considered. Both producers composing the Union industry use sodium gluconate for downstream products. This means that the production of sodium gluconate is very important for the whole activity and the survival of the Union industry in the medium and long term.
- (144) The production capacity of the Union industry remained unchanged during the entire period considered. The table below shows that the increase in capacity utilisation was mainly due to an increased demand in the export markets and by downstream activities. Sales in the Union market remained by and large stable during the period considered.

Table 6B

Union production intended for captive use

	2018	2019	2020	Review investigation period (2021)
Production volume (tonnes)	[18 294-22 145]	[17 792-21 538]	[20 758-25 128]	[20 822-25 206]
<i>Index</i>	100	97	113	114

Source: Data provided by the Union industry.

- (145) The production intended for captive use represents a large share of the Union industry production and activity. The internal demand for sodium gluconate increased in particular in 2020 and in the review investigation period. As mentioned in recital (141), it allowed the Union industry to achieve economies of scale and reduce costs.

5.6.2.2. Sales volume and market share

(146) The Union industry's sales volume and market share developed over the period considered as follows:

Table 7

Union sales volume and market share

	2018	2019	2020	Review investigation period (2021)
Sales volume on the Union market (tonnes)	[17 896-21 664]	[17 114-20 717]	[15 908-19 256]	[18 128-21 944]
<i>Index</i>	100	96	89	101
Market share (%)	[93-97]	[91-95]	[88-93]	[90-94]
<i>Index</i>	100	97	96	97

Source: Data provided by the Union industry.

- (147) The sales of sodium gluconate on the free market slightly increased by 1 % over the period considered. Sales volume decreased by 11 % up to 2020, then recovered during the review investigation period.
- (148) Although the Union market was growing, the Union industry lost 3 percentage points of market share to Chinese imports in the review investigation period. The loss of market share was particularly pronounced between 2018 and 2020 (4 percentage points) and could not be recovered in the upturn of the free market during the review investigation period. Nevertheless, the market share of the Union industry stayed well below the level at the beginning of the period considered.

5.6.2.3. Growth

- (149) The investigation showed that, on the one hand certain volume indicators such as production (+ 6 %) and in parallel, employment (+ 4 %) developed positively, in particular during the review investigation period. On the other hand, even if sales in the free market increased marginally and production capacity remained stable, the Union industry lost 3 percentage points of market share to imports from China and its investments had to be reduced by more than 50 % over the period considered.
- (150) It is recalled that production developed positively because of a higher demand in the export markets and in the downstream products of the Union industry. Despite the measures in force and an increase in the free market consumption by 4 %, the Union industry could only increase its sales on the Union market by 1 % during the period considered.

5.6.2.4. Employment and productivity

(151) Employment and productivity developed over the period considered as follows:

Table 8

Employment and productivity in the Union

	2018	2019	2020	Review investigation period (2021)
Number of employees	[48-59]	[49-60]	[50-61]	[50-61]
<i>Index</i>	100	102	104	104

Productivity (tonne/FTE)	[926-1 121]	[892-1 079]	[898-1 087]	[948-1 148]
<i>Index</i>	100	96	97	102

Source: Data provided by the Union industry.

- (152) The number of employees in the Union industry increased by 4 % up to 2020 and then stabilized in the review investigation period. As a result of the decrease in production and increased employment in 2019, productivity temporarily decreased in that year. It improved in 2020 and especially in the review investigation period, in line with an increasing production.

5.6.2.5. Magnitude of the dumping margin and recovery from past dumping

- (153) The original dumping margins ranged from 5,6 % to 79,2 %. The investigation showed that Chinese prices were very low from 2018 to 2020. They were on average 15 to 25 % lower than prices charged by the Union industry to its Union customers in the same period. This situation did not allow the Union industry to recover from past dumping. Profitability was negative or close to break-even and investments were significantly reduced. The analysis of the injury indicators shows that the Union industry was still impacted by past injurious dumping up to 2020. The measures in place only had a positive impact as from the review investigation period.

- (154) The dumping margin established during the review investigation period was significant.

5.6.3. Microeconomic indicators

5.6.3.1. Prices and factors affecting prices

- (155) The weighted average unit sales prices of the Union industry to unrelated customers in the Union developed as follows over the period considered:

Table 9

Sales prices in the Union and unit cost of production

	2018	2019	2020	Review investigation period (2021)
Average unit sales price in the Union (EUR/tonne)	[685-829]	[722-875]	[712-862]	[719-870]
<i>Index</i>	100	105	104	105
Unit cost of production (EUR/tonne)	[695-841]	[735-890]	[702-850]	[668-809]
<i>Index</i>	100	106	101	96

Source: Verified data provided by the cooperating Union producer.

- (156) The Union industry concludes yearly, in some cases two years, contracts with its customers. The investigation showed that the average sales price established on an ex-works basis increased by 5 % during the period considered. The main price increase took place in 2019 to respond to a similar increase in costs. After that, prices remained by and large stable up to the end of the review investigation period.

- (157) The unit cost of production increased by 6 % in 2019, coinciding with a decrease in production (– 2 %) and sales volume in the free market (– 4 %). Subsequently, the unit cost of production decreased by 9 % between 2019 and the review investigation period. Overall, the unit cost of production decreased by 4 % during the period considered. The decrease was due to a reduction of certain direct costs and selling, general and administrative expenses.

5.6.3.2. Labour costs

- (158) The average labour costs of the Union industry developed over the period considered as follows:

Table 10

Average labour costs per employee

	2018	2019	2020	Review investigation period (2021)
Average labour costs per employee (EUR/FTE)	[82 630-100 026]	[71 828-86 950]	[71 910-87 049]	[80 332-97 244]
Index	100	87	87	97

Source: Verified data provided by the cooperating Union producer.

- (159) Average labour costs decreased by 3 % during the period considered. In any event, as labour represents only a minor portion of the production cost, this should not be considered a meaningful indicator in the analysis of the economic situation of the Union industry.

5.6.3.3. Inventories

- (160) Stock levels of the Union industry developed over the period considered as follows:

Table 11

Inventories

	2018	2019	2020	Review investigation period (2021)
Closing stocks (tonne)	[1 784-2 160]	[2 148-2 601]	[1 959-2 371]	[1 596-1 932]
Index	100	120	110	89
Closing stocks as a percentage of production (%)	4	5	4	3
Index	100	123	109	84

Source: Verified data provided by the cooperating Union producer.

- (161) The level of inventories increased between 2018 and 2019 (+ 20 %) and then showed a decrease (– 26 %) between 2019 and the review investigation period. Overall, the level of inventories decreased by 11 % over the period considered. The investigation has shown that production of sodium gluconate is destined to both captive use by the Union industry and sales in the free market. The Union industry has shown that it could be flexible to meet its customers and internal needs and that it is mainly producing on orders for the free market. The level of stocks could thus be kept at a minimum level (3–5 % of production).

5.6.3.4. Profitability, cash flow, investments, return on investments and ability to raise capital

- (162) Profitability, cash flow, investments and return on investments of the Union Industry developed over the period considered as follows:

Table 12

Profitability, cash flow, investments and return on investments

	2018	2019	2020	Review investigation period (2021)
Profitability of sales in the Union to unrelated customers (% of sales turnover)	[– 10– 1]	[– 11– 1]	[0–+10]	[5–+20]
<i>Index</i>	– 100	– 104	34	293
Cash flow (EUR)	[– 1 001 175– 185 632]	[– 591 908 – 111 256]	[571 495– 691 810]	[1 064 837– 1 289 013]
<i>Index</i>	– 100	– 23	142	265
Investments (EUR)	[282 981– 342 556]	[140 951– 170 624]	[158 832– 192 271]	[116 361– 140 858]
<i>Index</i>	100	50	56	41
Return on investments (%)	[– 30– 37]	[– 21– 25]	[– 11– 14]	[12–16]
<i>Index</i>	– 100	– 68	– 39	42

Source: Verified data provided by the cooperating Union producer.

- (163) The Commission established the profitability of the Union industry by expressing the pre-tax net profit of the sales of the like product to unrelated customers in the Union as a percentage of the turnover of those sales.
- (164) The Union industry was loss-making during the first two years of the period considered and became slightly profitable in 2020. Profitability improved further in the review investigation period but remained still below the target profit used in the original investigation. The improvement of the profitability in 2020 and the review investigation period was mainly due to lower direct costs, the recovery in production volume and lower selling, general and administrative costs. The Union industry was able to achieve economies of scale by increasing its production and reducing costs, in particular in the review investigation period. It shows that the Union industry, which is still in a vulnerable position, is able to recover further in a market governed by effective competition conditions.
- (165) The net cash flow is the ability of the Union producers to self-finance their activities. It was established on the basis of the entire sodium gluconate sales activity of the Union industry during the period considered. It was negative in 2018 and 2019 and turned positive in 2020 and further improved during the review investigation period, in line with the recovery in profitability. Such development should be sustained in the medium term to produce lasting positive effects on the Union industry.
- (166) The return on investments is established on the basis of the profit of all sales of the product under review in percentage of the net book value of investments. As explained in recital (155), sales prices were relatively stable and in recital (163), costs could be decreased between 2020 and the review investigation period. This led to the recovery of profitability for sales made to unrelated customers in the Union market and allowed this indicator to develop positively during the period considered.

- (167) During the period considered, the Union industry's investments in its sodium gluconate activity decreased substantially by 50 to 60 %. The Union industry kept the injection of fresh capital to a minimum by lowering its level of investment to almost negligible amounts. Therefore, the ability to raise capital could not be analysed and no conclusion could be drawn. Nevertheless, it is clear that such a low level of investment could not ensure production continuity in the medium term.

5.7. Conclusion on injury

- (168) The investigation showed that the Chinese exporting producers managed to increase their import volume and market share, which significantly grew by 45 % in 2019 and a further 30 % in 2020. In that period, it was found that the Chinese average import price was between 15 to 25 % below the Union industry price. The Chinese exporting producers managed to keep this market share despite a higher average import price in the review investigation period. Given the absence of cooperation from Chinese exporters and the unavailability of relevant price data, such as the product mix to perform a meaningful price comparison, no reliable conclusion could be drawn on price undercutting.
- (169) The Union industry sales volume and market share developed negatively during the first three years of the period considered. The decline in sales volume (– 4 %) was more pronounced than the decline in consumption (– 2 %) in 2019 and sales further decreased by 7 % in 2020. Between 2018 and 2019, production remained by and large stable but inventories significantly increased (up to 20 %) due to reduced sales. Profitability was negative but eventually became slightly profitable in 2020. Between 2020 and the RIP, the Union industry managed to increase its sales volumes (+ 12 %) and market share (+ 1 %). It also managed to decrease its cost of production to further improve profitability during the RIP.
- (170) At the same time, the investigation showed that the Union industry did not fully benefit from the market growth during the period considered. Whilst consumption in the free market increased by 4 %, sales of the Union industry slightly increased by 1 % and thus lost 3 percentage points of market share.
- (171) To summarize, the investigation showed that injury indicators such as production, capacity utilisation and employment, together with financial indicators such as profitability, cash flow and return on investments, developed positively, in particular in the review investigation period. Profitability and cash flow became positive as from 2020, and the return on investments become positive in the review investigation period.
- (172) On the basis of the foregoing, the Commission concluded that the Union industry has started to recover from previous injurious dumping and did not suffer material injury within the meaning of Article 3(5) of the basic Regulation during the review investigation period. It is nevertheless considered that even if the recent developments in the economic situation of the Union industry showed signs of recovery, the industry is still in a vulnerable situation.

6. LIKELIHOOD OF RECURRENCE OF INJURY

- (173) The investigation showed that the Chinese imports entered the Union market at dumped prices during the review investigation period and that there was a likelihood of continuation of dumping should measures be allowed to lapse.
- (174) The Commission concluded in recital (172) that the Union industry did not suffer material injury during the review investigation period. Therefore, the Commission assessed, in accordance with Article 11(2) of the basic Regulation, whether there would be a likelihood of recurrence of injury caused by dumped imports from China if the measures were allowed to lapse.
- (175) The Commission examined the production capacity and spare capacity in China, the likely price levels of imports from China in the absence of anti-dumping measures and their impact on the Union industry, and the attractiveness of the Union market.

- (176) As set out in recitals (95) to (98) above, there is substantial production capacity and spare capacity in China to increase exports to the Union market rapidly in the event that the anti-dumping measures were allowed to expire. As established in recital (96), in the review investigation period, Chinese exporting producers had a capacity of around 1 300 000 tonnes, which equals more than 50 times the Union consumption on the free market. Based on data provided by the Union industry, this capacity will be increased substantially in the next years. No other party questioned this data nor provided any other elements in this respect.
- (177) Publicly available ⁽⁵⁵⁾ data confirms that the output of sodium gluconate in China increased compared to previous years of the period considered and was at 701 400 tonnes in the review investigation period. This means that the utilisation of capacity was around 54 % and the excess in capacity around 600 000 tonnes in that period. This is more than 25 times the Union consumption in the free market.
- (178) Although it is expected that consumption of sodium gluconate will increase in the next years, the low utilisation of capacity supports the Union industry's claim that Chinese capacity is far exceeding the internal needs. The spare capacity in China cannot be absorbed by the Chinese market, considering any reasonable expectation of its growth. Therefore, there are strong incentives for Chinese producers to export, in particular to the Union market, even more so if the measures are allowed to lapse.
- (179) According to the Union industry, excess in production capacities is an incentive to continue exporting at dumped prices. It is clear that Chinese exporters must exploit all existing possibilities to increase production to fully benefit from the significant investments they made in installed capacities. The most obvious way is to penetrate any open market worldwide and very likely at dumped prices as it is still the case in the current investigation. Considering the decrease in transport cost in 2022 ⁽⁵⁶⁾ and the expected price level in the Union, imports of Chinese sodium gluconate would very likely increase to large quantities at dumped prices in the Union market if the measures are allowed to lapse.
- (180) The investigation showed that the average price of Chinese sodium gluconate to the EU during the review investigation period, was higher than the average export price charged by Chinese exporters to other destinations, see recital (101). Exporting sodium gluconate to the EU if the trade defence measures are allowed to lapse, would thus make economic sense, especially given that Chinese exporting producers have large production capacity available and could easily increase their production even without diverting (less economically attractive) sales volume to the EU.
- (181) Finally, the Union industry recalled that the United States, the only country with sodium gluconate production other than China and the EU, also established that Chinese exporting producers of sodium gluconate were selling at dumped prices in their market. In parallel, these producers were also found to benefit from public subsidies encouraging exports. As explained in recital (105), the trade defence measures in place in the United States effectively limit the entry of Chinese sodium gluconate in that market.
- (182) In the rest of the world, Chinese exporting producers dominate the supply of sodium gluconate. According to data provided by the Union industry, Chinese manufacturers have a dominant market share in Africa (above 90 % in 2021), in the Middle East above (99 %) and in countries of Europe not members of the EU (almost 80 %) ⁽⁵⁷⁾.

⁽⁵⁵⁾ Sodium Gluconate and Glucono Delta-Lactone's Major Producers Capacity and Output in China in 2021 (marketresearch.com) <https://www.marketresearch.com/CCM-International-Limited-v3539/Sodium-Gluconate-Glucono-Delta-Lactone-32039947/#:~:text=In%202017%20%80%20%93%2021%20the%20output%20of%20sodium%20gluconate%20in,which%20was%205,44%25%20lower%20than%20that%20of%202020.>

⁽⁵⁶⁾ See page 4 of the open version of Jungbunzlauer's submission 'Exhibit 23' of 18 November 2022

⁽⁵⁷⁾ See pages 9-10 of the open version of Jungbunzlauer's submission 'Exhibit 23'

- (183) The applicant maintained that there was a temporary distortion in the Chinese prices in 2021 and early 2022 as the exceptionally high freight rates for container shipments from China to overseas destinations resulted in increased prices of Chinese products. This rendered the offers of the Union industry more competitive ⁽⁵⁸⁾. Therefore, the Union industry could slightly increase its sales volume and implement a higher price level. However, the applicant also claimed that the trend of increasing freight costs had recently changed and that Chinese exporting producers were selling again at lower prices which do not allow the Union industry to compete on fair terms. The decreasing freight cost in 2022 is also confirmed by the publicly available data mentioned in recital (178) above.
- (184) This claim was also supported by very low quotations offered by certain Chinese exporters to Union customers in 2022 ⁽⁵⁹⁾. As explained in recitals (96) to (98) above, the large spare production capacities in China could easily be used and a high volume of Chinese dumped imports would very likely re-enter the Union market in significant quantities. These high volumes of low-priced sodium gluconate would exert a significant price pressure on the Union industry and would most likely result in decreasing sales volume and prices. Hence, the economic situation of the Union industry is likely to deteriorate quickly jeopardizing its recent recovery and its survival in the short to medium term.
- (185) Taking into account the significant increase of the price of raw materials which has already taken place in 2022 and which is foreseen to continue in 2023 ⁽⁶⁰⁾, profitability of the Union industry is likely to be negatively affected. Even more so, if the measures were allowed to lapse which would in addition very likely lead to a surge of increased quantities of dumped imports from China, thus transforming the Union industry in a loss making industry. This situation would lead to the disappearance of the sodium gluconate production in the Union and of the downstream activities of the Union industry within a relatively short period of time. In this case, the worldwide production of sodium gluconate would be reduced to China and the United States which could impact the security of supply in the Union.
- (186) In view of the above facts and considerations, namely the large spare capacities in China, the need for Chinese exporters to increase production and find new markets, the attractiveness of the Union market and the limited access of Chinese exporters to the United States' market, the recent decrease in transport costs and the low level of prices currently offered to customers in the EU by Chinese exporters, the Commission concluded that the absence of measures would in all likelihood result in a significant increase of dumped imports from China at injurious prices and material injury would be likely to recur.

7. UNION INTEREST

- (187) In accordance with Article 21 of the basic Regulation, the Commission examined whether maintaining the existing anti-dumping measures would be against the interest of the Union as a whole. The determination of the Union interest was based on an appreciation of all the various interests involved, including those of the Union industry, importers and users.
- (188) All interested parties were given the opportunity to make their views known pursuant to Article 21(2) of the basic Regulation.
- (189) On this basis the Commission examined whether, despite the conclusions on the likelihood of continuation of dumping and recurrence of injury, compelling reasons existed, which would lead to the conclusion that it was not in the Union interest to maintain the existing measures.

⁽⁵⁸⁾ See page 7 of the open version of Jungbunzlauer's submission 'Exhibit 23'

⁽⁵⁹⁾ See pages 1-2 of the open version of Jungbunzlauer's submission of 21 November 2022

⁽⁶⁰⁾ See page 2 of the open version of Jungbunzlauer's submission of 21 November 2022

7.1. Interest of the Union industry

- (190) As stated in recital (171), the Union industry showed that it was able to recover from injurious dumping in a market governed by effective trade conditions. The share it holds on the US market further confirms that its operations are viable when not subject to unfair competition by dumped imports. Nevertheless, as explained in recital (171) above, the industry is still in a vulnerable state.
- (191) The trade defence measures currently in force in the EU and the United States aim at establishing an effective and competitive environment for all producers of sodium gluconate but also for all other operators. Data provided by the applicant show that whilst Chinese producers have less than 5 % market share in the United States' market, EU producers have around 20 % market share. This demonstrates that the Union industry is competitive and is not ready to abandon this sales segment, which is unique in the Union.
- (192) Based on the above, it was concluded that extending the measures in force against the PRC would be in the interest of the Union industry.

7.2. Interest of unrelated importers

- (193) As stated in recital (18), no unrelated importer cooperated during the investigation.
- (194) The current investigation did not reveal any significant adverse impact of the measures in force on importers.
- (195) The previous expiry review investigation concluded that importers could be negatively affected by the measures but to a very limited extent. It was found that the share of sodium gluconate represented less than 5 % of the turnover of the importers which cooperated in the previous expiry review.
- (196) Based on information available, the Commission considers that the maintenance of measures would have a very limited impact, if at all, on importers and such impact would be clearly outweighed by the benefits that the measures could bring to the Union industry.

7.3. Interest of users

- (197) None of the users of sodium gluconate cooperated in the investigation.
- (198) It was found in the previous expiry review investigation, that for the cooperating user, sodium gluconate represented less than 5 % of the cost of manufacturing of the finished products incorporating sodium gluconate. Any increase in the price of sodium gluconate should thus have a limited impact on the users' activities.
- (199) The investigation also showed that the Union industry behaved in a reasonable way in terms of price setting. In 2019, when prices of the Union industry increased on average by 5 %, it was to respond to a 6 % costs increase in that year. During the review investigation period, when Chinese prices for certain types of sodium gluconate were higher than the Union Industry, the Union industry price remained stable.
- (200) In the absence of cooperation, and as was the case in the previous investigation, the current investigation did not reveal any significant adverse impact of the measures on users.
- (201) Therefore, from the information available, the Commission concluded that the impact, if any, on users of the continuation of measures would be limited.

7.4. Conclusion on Union interest

- (202) On the basis of the above, the Commission concluded that there were no compelling reasons of the Union interest against the maintenance of the existing measures on imports of sodium gluconate originating in the PRC.

8. ANTI-DUMPING MEASURES

- (203) On the basis of the conclusions reached by the Commission on continuation of dumping, recurrence of injury and Union interest, the anti-dumping measures on sodium gluconate from the PRC should be maintained.
- (204) To minimize the risks of circumvention due to the difference in duty rates, special measures are needed to ensure the application of the individual anti-dumping duties. The companies with individual anti-dumping duties must present a valid commercial invoice to the customs authorities of the Member States. The invoice must conform to the requirements set out in Article 1(3) of this regulation. Imports not accompanied by that invoice should be subject to the anti-dumping duty applicable to 'all other companies'.
- (205) While presentation of this invoice is necessary for the customs authorities of the Member States to apply the individual rates of anti-dumping duty to imports, it is not the only element to be taken into account by the customs authorities. Indeed, even if presented with an invoice meeting all the requirements set out in Article 1(3) of this regulation, the customs authorities of Member States must carry out their usual checks and may, like in all other cases, require additional documents (shipping documents, etc.) for the purpose of verifying the accuracy of the particulars contained in the declaration and ensure that the subsequent application of the lower rate of duty is justified, in compliance with customs law.
- (206) Should the exports by one of the companies benefiting from lower individual duty rates increase significantly in volume after the imposition of the measures concerned, such an increase in volume could be considered as constituting in itself a change in the pattern of trade due to the imposition of measures within the meaning of Article 13(1) of the basic Regulation. In such circumstances and provided the conditions are met an anti-circumvention investigation may be initiated. This investigation may, inter alia, examine the need for the removal of individual duty rate(s) and the consequent imposition of a country-wide duty.
- (207) The individual company anti-dumping duty rates specified in this Regulation are exclusively applicable to imports of the product under review originating in the PRC and produced by the named legal entities. Imports of the product under review produced by any other company not specifically mentioned in the operative part of this Regulation, including entities related to those specifically mentioned, should be subject to the duty rate applicable to 'all other companies'. They should not be subject to any of the individual anti-dumping duty rates.
- (208) A company may request the application of these individual anti-dumping duty rates if it changes subsequently the name of its entity. The request must be addressed to the Commission ⁽⁶¹⁾. The request must contain all the relevant information enabling to demonstrate that the change does not affect the right of the company to benefit from the duty rate which applies to it. If the change of name of the company does not affect its right to benefit from the duty rate which applies to it, a regulation about the change of name will be published in the *Official Journal of the European Union*.
- (209) All interested parties were informed of the essential facts and considerations on the basis of which it was intended to recommend that the existing measures be maintained. They were also granted a period to make representations subsequent to this disclosure. No comments were received.
- (210) In view of Article 109 of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council ⁽⁶²⁾ when an amount is to be reimbursed following a judgment of the Court of Justice of the European Union, the interest to be paid should be the rate applied by the European Central Bank to its principal refinancing operations, as published in the C series of the *Official Journal of the European Union* on the first calendar day of each month.

⁽⁶¹⁾ European Commission, Directorate-General for Trade, Directorate G, Rue de la Loi 170, 1040 Brussels, Belgium.

⁽⁶²⁾ Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 (OJ L 193, 30.7.2018, p. 1).

(211) The measures provided for in this regulation are in accordance with the opinion of the Committee established by Article 15(1) Regulation (EU) 2016/1036,

HAS ADOPTED THIS REGULATION:

Article 1

1. A definitive anti-dumping duty is hereby imposed on imports of dry sodium gluconate, with a Customs Union and Statistics (CUS) number 0023277-9 and a Chemical Abstracts Service (CAS) registry number 527-07-1, currently falling under CN code ex 2918 16 00 (TARIC code 2918 16 00 10) and originating in the People's Republic of China.

2. The rates of the definitive anti-dumping duty applicable to the net, free-at-Union-frontier price, before duty, of the product described in paragraph 1 and produced by the companies listed below shall be as follows:

Company	Definitive anti-dumping duty (%)	TARIC additional code
Shandong Kaisen Biochemical Co., Ltd	5,6	A972
Qingdao Kehai Biochemistry Co. Ltd	27,1	A973
All other companies	53,2	A999

3. The application of the individual duty rates specified for the companies mentioned in paragraph 2 shall be conditional upon presentation to the Member States' customs authorities of a valid commercial invoice, on which shall appear a declaration dated and signed by an official of the entity issuing such invoice, identified by his/her name and function, drafted as follows: 'I, the undersigned, certify that the (volume) of (product under review) sold for export to the European Union covered by this invoice was manufactured by (company name and address) (TARIC additional code) in [country concerned]. I declare that the information provided in this invoice is complete and correct.' If no such invoice is presented, the duty applicable to all other companies shall apply.

4. Unless otherwise specified, the provisions in force concerning customs duties shall apply.

Article 2

This Regulation shall enter into force on the 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, 12 April 2023.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2023/753**of 12 April 2023****granting a Union authorisation for the biocidal product family “C(M)IT/MIT formulations”****(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 the first subparagraph of Article 44(5) thereof,

Whereas:

- (1) On 26 June 2017, ERM Regulatory Services Limited, acting on behalf of Solenis Switzerland GmbH, submitted to the European Chemicals Agency (‘the Agency’) an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 and Article 4 of Commission Implementing Regulation (EU) No 414/2013 ⁽²⁾ for authorisation of the same biocidal product family, as referred to in Article 1 of Implementing Regulation (EU) No 414/2013, named “C(M)IT/MIT formulations”, of product-types 6, 11 and 12, as described in Annex V to Regulation (EU) No 528/2012. The application was recorded under case number BC-TY032745-97 in the Register for Biocidal Products. The application also indicated the application number of the related reference product family “CMIT-MIT Aqueous 1.5-15”, recorded in that Register under case number BC-CY032700-28.
- (2) The same biocidal product family “C(M)IT/MIT formulations” contains a mixture of CMIT/MIT, 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.
- (3) On 26 January 2021, the Agency submitted to the Commission an opinion ⁽³⁾ and the draft summary of the biocidal product characteristics (‘SPC’) of “C(M)IT/MIT formulations” in accordance with Article 6(1) and (2) of Implementing Regulation (EU) No 414/2013.
- (4) The opinion concludes that “C(M)IT/MIT formulations” is a biocidal product family within the meaning of Article 3(1), point (s), of Regulation (EU) No 528/2012, that the proposed differences between the same biocidal product family and the related reference biocidal product family are limited to information which can be the subject of an administrative change in accordance with Commission Implementing Regulation (EU) No 354/2013 ⁽⁴⁾, that “C(M)IT/MIT formulations” is eligible for Union authorisation in accordance with Article 42(1) of Regulation (EU) No 528/2012, and that based on the assessment of the related reference “CMIT-MIT Aqueous 1.5-15” product family and subject to compliance with the draft SPC, the same biocidal product family meets the conditions laid down in Article 19(1) and (6) of Regulation (EU) No 528/2012.
- (5) On 30 April 2021, 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.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ Commission Implementing Regulation (EU) No 414/2013 of 6 May 2013 specifying a procedure for the authorisation of same biocidal products in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 125, 7.5.2013, p. 4).

⁽³⁾ ECHA opinion of 26 January 2021 on the Union authorisation of the same biocidal product family “C(M)IT/MIT formulations”, <https://echa.europa.eu/opinions-on-union-authorisation>

⁽⁴⁾ Commission Implementing Regulation (EU) No 354/2013 of 18 April 2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 109, 19.4.2013, p. 4).

- (6) The Commission concurs with the opinion of the Agency and considers it therefore appropriate to grant a Union authorisation for the same biocidal product family “C(M)IT/MIT formulations”.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation with authorisation number EU-0025678-0000 is granted to Solenis Switzerland GmbH for the making available on the market and use of the same biocidal product family “C(M)IT/MIT formulations” in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 3 May 2023 until 31 August 2032.

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, 12 April 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Summary of product characteristics for a biocidal product family

C(M)IT/MIT formulations

Product type 6 - Preservatives for products during storage (Preservatives)

Product type 11 - Preservatives for liquid-cooling and processing systems (Preservatives)

Product type 12 - Slimicides (Preservatives)

Authorisation number: EU-0025678-0000

R4BP asset number: EU-0025678-0000

PART I

FIRST INFORMATION LEVEL

1. ADMINISTRATIVE INFORMATION

1.1. **Family name**

Name	C(M)IT/MIT formulations
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1.2. **Product type(s)**

Product type(s)	PT06 - Preservatives for products during storage (Preservatives) PT11 - Preservatives for liquid-cooling and processing systems (Preservatives) PT12 - Slimicides (Preservatives)
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1.3. **Authorisation holder**

Name and address of the authorisation holder	Name	Solenis Switzerland GmbH
	Address	Mühlentalstrasse 38, 8200 Schaffhausen Switzerland
Authorisation number	EU-0025678-0000	
R4BP asset number	EU-0025678-0000	
Date of the authorisation	3 May 2023	
Expiry date of the authorisation	31 August 2032	

1.4. **Manufacturer(s) of the biocidal products**

Name of manufacturer	Solenis Switzerland GmbH
Address of manufacturer	Mühlentalstrasse 38, 8200 Schaffhausen Switzerland

Location of manufacturing sites	Füttingsweg 20, D-47805 Krefeld Germany Wimsey Way, Somercotes, DE55 4LR Alfreton United Kingdom Högastensgatan 18, 252 32 Helsingborg Sweden AD International B.V. Markweg Zuid 27, 4793 ZJ Fijnaart Netherlands
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1.5. Manufacturer(s) of the active substance(s)

Active substance	Mixture of 5-chloro-2-methyl-2H- isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) (Mixture of CMIT/MIT)
Name of manufacturer	Specialty Electronic Materials Switzerland GmbH
Address of manufacturer	Bachtobelstrasse 3, 8810 Horgen Switzerland
Location of manufacturing sites	Jiangsu FOPIA Chemicals Co., Ltd, Touzeng Village, 224555 Binhuai Town, Binhai County, Yancheng City, Jiangsu, China Rohm and Haas (UK) Ltd. Tyneside Works, Ellison Street,, NE32 3DJ Jarrow United Kingdom

Active substance	Mixture of 5-chloro-2-methyl-2H- isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) (Mixture of CMIT/MIT)
Name of manufacturer	Thor GmbH
Address of manufacturer	Landwehrstraße 1, 67346 Speyer Germany
Location of manufacturing sites	Landwehrstraße 1, 67346 Speyer Germany

Active substance	Mixture of 5-chloro-2-methyl-2H- isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) (Mixture of CMIT/MIT)
Name of manufacturer	Thor Quimicos de México, SA de CV
Address of manufacturer	Km 182 Autopista México – Querétaro, Pedro Escobedo, 76700 Querétaro Mexico
Location of manufacturing sites	Km 182 Autopista México – Querétaro, Pedro Escobedo, 76700 Querétaro Mexico

Active substance	Mixture of 5-chloro-2-methyl-2H- isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) (Mixture of CMIT/MIT)
Name of manufacturer	Troy Chemical Company BV
Address of manufacturer	Poortweg 4C, 2612 Delft Netherlands

Location of manufacturing sites	Weifang Heaven-sent New Materials Technology Co. Ltd, Binhai Road, Changyi Coastal Economic Development Zone, 261312 Weifang China Dalian Xingyuan Chemistry Co., Ltd, Room 1205/1206, Pearl River International Building, No.99, Xinkai Road, Xigang District, Songmudao Chemical Industry Zone, Puwan New District, 116308 Dalian China Dalian Bio-Chem Company Limited, Songmudao Plant: Songmudao Chemical Industry, Zone, Puwan New District, 116308 Dalian China
Active substance	Mixture of 5-chloro-2-methyl-2H- isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) (Mixture of CMIT/MIT)
Name of manufacturer	Jiangsu FOPIA Chemicals Co., Ltd
Address of manufacturer	Touzeng Village, Binhuai Town, Binhai County, 224555 Yancheng City China
Location of manufacturing sites	Touzeng Village, Binhuai Town, Binhai County, 224555 Yancheng City China

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
Mixture of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) (Mixture of CMIT/MIT)		Active Substance	55965-84-9		2,2	20,9

2.2. Type(s) of formulation

Formulation(s)	AL - Any other liquid
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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 3
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1.2. Suffix to the authorisation number

Number	1-1
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1.3. Product type(s)

Product type(s)	PT06 - Preservatives for products during storage (Preservatives) PT11 - Preservatives for liquid-cooling and processing systems (Preservatives) PT12 - Slimicides (Preservatives)
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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
Mixture of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) (Mixture of CMIT/MIT)		Active Substance	55965-84-9		2,2	6,5

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

Formulation(s)	AL - Any other liquid
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1

Hazard statements	Harmful if inhaled. Causes severe skin burns and eye damage. May cause an allergic skin reaction. Very toxic to aquatic life with long lasting effects. Corrosive to the respiratory tract. May be corrosive to metals. Harmful if swallowed.
Precautionary statements	Do not breathe fume. Wash skin thoroughly after handling. Do not eat, drink or smoke when using this product. Contaminated work clothing should not be allowed out of the workplace. Avoid release to the environment. Wear protective gloves/ protective clothing/ eye protection/ face protection/ hearing protection.

	Take off contaminated clothing.And wash it before reuse. If skin irritation or rash occurs:Get medical advice. IF SWALLOWED:Rinse mouth.Do NOT induce vomiting. IF ON SKIN (or hair):Take off immediately all contaminated clothing.Rinse skin with water. IF INHALED:Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER/ doctor. IF IN EYES:Rinse cautiously with water for several minutes.Remove contact lenses, if present and easy to do. Continue rinsing. Collect spillage. Store locked up. Keep only in original packaging. IF SWALLOWED:Call a POISON CENTER/ doctor if you feel unwell. Store in a corrosion-resistant container with a resistant inner liner. Absorb spillage to prevent material damage.
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4. AUTHORISED USE(S) OF THE META SPC 1

4.1. Use description

Table 1

Use # 1 – Preservation of polymer lattices

Product type	PT06 - Preservatives for products during storage (Preservatives)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Common name: Bacteria Development stage: Common name: Yeasts Development stage: Common name: Fungi Development stage:
Field(s) of use	Indoor Preservation of polymer latexes The biocidal product is recommended for the control of bacteria, yeast and fungi in the manufacture, storage, and transport of latexes, synthetic polymers including Hydrolysed Poly Acryl Amide (HPAM) and biopolymers (e.g. xanthan, dextran..) natural latexes.
Application method(s)	Method: Closed system Detailed description: Manual and automated application. The biocidal product should be dispensed to the end use fluid at a point to ensure adequate mixing using preferably automated metering pump or by manual addition.

Application rate(s) and frequency	Application Rate: Industrial uses: 1,5 - 14,5 % C(M)IT/MIT in the biocidal products; Professional uses: 14,9 - 50 mg /kg of C(M)IT/MIT (3:1) in final product. Dilution (%): - Number and timing of application: The biocidal product is added at single dose at the time of manufacture, storage or shipment. To ensure uniform distribution, slowly disperse using automated metering or manual addition, into product with agitation. Mix thoroughly until evenly dispersed throughout the product. Industrial uses: 1,5 - 14,5 % C(M)IT/MIT in the biocidal products. Professional uses 14,9 - 50 mg /kg of C(M)IT/MIT (3:1) in final product. For the biocidal product as supplied: for industrial use only.
Category(ies) of users	Industrial
Pack sizes and packaging material	For industrial and professional users: — HDPE flask: 5 l (nominal) — HDPE Pail / Jerrycan: 10 l, 20 l, 25 l, 30 l (nominal) — Box with HDPE liner: 20 l — HDPE Drum: 110 l, 120 l, 200 l, 260 l — HDPE IBC: 650 l, 800 l, 1000 l, 1250 l All products should be transport and stored in a vented room.

4.1.1. Use-specific instructions for use

- The preservative can be added at any stage of the production of the product.
- Earliest possible addition is recommended for optimal protection.
- Consult the manufacturer to determine the optimal dosage for the various products to be preserved.
- It is recommended that the optimum biocide concentration and compatibility with individual formulations is determined by means of laboratory tests.
- The duration and storage conditions of the preserved matrices may impact the efficacy of the product, microbiological tests should be conducted to determine the appropriate application rate without exceeding the maximum authorised application rate.
- The biocidal product shall be used for treatment of products (articles/mixtures) distributed only to professional users.

4.1.2. Use-specific risk mitigation measures

- During handling phases of products from Meta SPC 1, 2, 3 and 4 (mixing and loading), exposure to the product (corrosive and skin sensitizer products) has to be limited by use of PPE and application of technical and organisational RMM:
 - Minimisation of manual phases (process automation);
 - Use of a dosing device;
 - Regular cleaning of equipment and work area;
 - Avoidance of contact with contaminated tools and objects;
 - Good standard of general ventilation;
 - Training and management of staff on good practice.

- PPE is as follows:
 - protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information);
 - protective coverall (at least type 3 or 4, EN 14605) which is impermeable for the biocidal product shall be worn (coverall material to be specified by the authorisation holder within the product information);
 - Eye protection;
 - Substance/task appropriate respirator if ventilation is inadequate.
- The maximal products concentration used for the preservation of polymer lattices being above the threshold value of 15 ppm, exposure has to be limited by use of PPE, protecting skin and mucous membranes potentially exposed, and application of technical and organisational RMM:
 - Minimisation of manual phases;
 - Use of a dosing device;
 - Regular cleaning of equipment and work area;
 - Good standard of general ventilation;
 - Training and management of staff on good practice.

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 – Preservation of mineral slurries

Product type	PT06 - Preservatives for products during storage (Preservatives)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Common name: Bacteria Development stage:
Field(s) of use	Indoor Preservation of mineral slurries The biocidal product is recommended to control the growth of bacteria in aqueous-based inorganic/mineral slurries and inorganic pigments which are formulated into paints, coatings and paper.

Application method(s)	Method: Closed system Detailed description: Manual and automated application. The biocidal product should be dispensed as a tankside additive into the circulating use-dilution of the fluid, using a metering pump or by manual pouring, at a point to assure adequate mixing throughout the system.
Application rate(s) and frequency	Application Rate: Industrial uses: 1,5 - 14,5 % C(M)IT/MIT in the biocidal products; Professional uses: 10- 30 mg/kg of C(M)IT/MIT (3:1) in final product. Dilution (%): - Number and timing of application: The biocidal product is added at single dose at the time of manufacture, storage or shipment. Industrial uses: 1,5 - 14,5 % C(M)IT/MIT in the biocidal products. Professional uses: 10 - 30 mg/kg of C(M)IT/MIT (3:1) in final product. For the biocidal product as supplied: for industrial use only.
Category(ies) of users	Industrial
Pack sizes and packaging material	For industrial and professional users: — HDPE flask: 5 l (nominal) — HDPE Pail / Jerrycan: 10 l, 20 l, 25 l, 30 l (nominal) — Box with HDPE liner: 20 l — HDPE Drum: 110 l, 120 l, 200 l, 260 l — HDPE IBC: 650 l, 800 l, 1000 l, 1250 l All products should be transport and stored in a vented room.

4.2.1. Use-specific instructions for use

- The preservative can be added at any stage of the production of the product.
- Earliest possible addition is recommended for optimal protection.
- Consult the manufacturer to determine the optimal dosage for the various products to be preserved.
- It is recommended that the optimum biocide concentration and compatibility with individual formulations is determined by means of laboratory tests.
- The duration and storage conditions of the preserved matrices may impact the efficacy of the product, microbiological tests should be conducted to determine the appropriate application rate without exceeding the maximum authorised application rate.
- The biocidal product shall be used for treatment of products (articles/mixtures) distributed only to professional users.

4.2.2. Use-specific risk mitigation measures

- During handling phases of products from Meta SPC 1, 2, 3 and 4 (mixing and loading), exposure to the product (corrosive and skin sensitizer products) has to be limited by use of PPE and application of technical and organisational RMM:
 - Minimisation of manual phases (process automation);

- Use of a dosing device;
- Regular cleaning of equipment and work area;
- Avoidance of contact with contaminated tools and objects;
- Good standard of general ventilation;
- Training and management of staff on good practice.
- PPE is as follows:
 - protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information);
 - protective coverall (at least type 3 or 4, EN 14605) which is impermeable for the biocidal product shall be worn (coverall material to be specified by the authorisation holder within the product information);
 - Eye protection;
 - Substance/task appropriate respirator if ventilation is inadequate.
- The maximal products concentration used for the preservation of mineral slurries being above the threshold value of 15 ppm, exposure has to be limited by use of PPE, protecting skin and mucous membranes potentially exposed, and application of technical and organisational RMM:
 - Minimisation of manual phases;
 - Use of a dosing device;
 - Regular cleaning of equipment and work area;
 - Good standard of general ventilation;
 - Training and management of staff on good practice.

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 3

Use # 3 – Preservation of functional fluids (hydraulic fluids, antifreeze, corrosion inhibitors, etc. - excluding fuel additives)

Product type	PT06 - Preservatives for products during storage (Preservatives)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Common name: Bacteria Development stage:

Field(s) of use	Indoor Preservation of functional fluids (hydraulic fluids, antifreeze, corrosion inhibitors, etc. - excluding fuel additives) The biocidal product is recommended to control the growth of bacteria in functional fluids such as brake and hydraulic fluids, antifreeze additives, corrosion inhibitors, spinning fluids. The biocidal product inhibits the growth microorganisms, which would otherwise lead to odours formation, viscosity alteration, discolouration of product and premature product failure.
Application method(s)	Method: Closed system Detailed description: Manual and automated dosing. The biocidal product should be dispensed to the end use fluid at a point to ensure adequate mixing using preferably automated metering pump or by manual addition.
Application rate(s) and frequency	Application Rate: Industrial uses: 1,5 - 14,5 % C(M)IT/MIT in the biocidal products. Professional uses: Add at a typical use rate between 6 to 30 mg C(M)IT/MIT (3:1) per kg final product to be treated. Dilution (%): - Number and timing of application: The biocidal product is added at single dose at time of manufacturing, storage or shipment. Industrial uses: 1,5 - 14,5 % C(M)IT/MIT in the biocidal products. Professional uses: Add at a typical use rate between 6 to 30 mg C(M)IT/MIT (3:1) per kg final product to be treated For the biocidal product as supplied: for industrial use only.
Category(ies) of users	Industrial
Pack sizes and packaging material	For industrial and professional users: — HDPE flask: 5 l (nominal) — HDPE Pail / Jerrycan: 10 l, 20 l, 25 l, 30 l (nominal) — Box with HDPE liner: 20 l — HDPE Drum: 110 l, 120 l, 200 l, 260 l — HDPE IBC: 650 l, 800 l, 1000 l, 1250 l All products should be transport and stored in a vented room.

4.3.1. Use-specific instructions for use

- The preservative can be added at any stage of the production of the product.
- Earliest possible addition is recommended for optimal protection.
- Consult the manufacturer to determine the optimal dosage for the various products to be preserved.
- It is recommended that the optimum biocide concentration and compatibility with individual formulations is determined by means of laboratory tests.

- The duration and storage conditions of the preserved matrices may impact the efficacy of the product, microbiological tests should be conducted to determine the appropriate application rate without exceeding the maximum authorised application rate.
- The biocidal product shall be used for treatment of products (articles/mixtures) distributed only to professional users.

4.3.2. *Use-specific risk mitigation measures*

- During handling phases of products from Meta SPC 1, 2, 3 and 4 (mixing and loading), exposure to the product (corrosive and skin sensitizer products) has to be limited by use of PPE and application of technical and organisational RMM:
 - Minimisation of manual phases (process automation);
 - Use of a dosing device;
 - Regular cleaning of equipment and work area;
 - Avoidance of contact with contaminated tools and objects;
 - Good standard of general ventilation;
 - Training and management of staff on good practice.
- PPE is as follows:
 - protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information);
 - protective coverall (at least type 3 or 4, EN 14605) which is impermeable for the biocidal product shall be worn (coverall material to be specified by the authorisation holder within the product information);
 - Eye protection;
 - Substance/task appropriate respirator if ventilation is inadequate.
- The maximal products concentration used for the preservation of functional fluids (hydraulic fluids, antifreeze, corrosion inhibitors, etc...) being above the threshold value of 15 ppm, exposure has to be limited by use of PPE, protecting skin and mucous membranes potentially exposed, and application of technical and organisational RMM:
 - Minimisation of manual phases;
 - Use of a dosing device;
 - Regular cleaning of equipment and work area;
 - Good standard of general ventilation;
 - Training and management of staff on good practice.

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 4

Use # 4 – Preservation of liquids used in closed recirculating cooling systems

Product type	PT11 - Preservatives for liquid-cooling and processing systems (Preservatives)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Common name: Bacteria (including <i>Legionella pneumophila</i>) Development stage: Common name: Yeasts Development stage: Common name: Fungi Development stage:
Field(s) of use	Indoor Outdoor Preservation of liquids used in closed recirculating cooling systems (Closed re-circulating cooling water systems comprise compressor cooling, air conditioning chilled water, boilers, engine jacket cooling, power supply cooling, and other industrial processes). The biocidal product is used to control the growth of aerobes and anaerobes bacteria, yeast, fungi, and biofilm in the circulating water of closed systems
Application method(s)	Method: Closed system Detailed description: Manual and automated dosing.
Application rate(s) and frequency	Application Rate: Curative efficacy:- against bacteria (including <i>L. pneumophila</i>) at 5 - 14,9 g C(M)IT/MIT (3:1) / m³ of water. Contact time: 24 hours - against biofilm: 14,9 g C(M)IT/MIT (3:1) / m³ of water. Contact time: 24 hours.- against fungi and yeasts at 1 – 3 g C(M)IT/MIT (3:1) / m³ of water. Contact time: 48 hours. Preventive efficacy:- against bacteria (including <i>L. pneumophila</i>) at 3 – 14,9 g C(M)IT/MIT (3:1) / m³ of water. - against biofilm (including <i>L. pneumophila</i>): 3 g C(M)IT/MIT (3:1) / m³ of water. Dilution (%): - Number and timing of application: Curative efficacy: — against bacteria (including <i>L. pneumophila</i>) at 5 - 14,9 g C(M)IT/MIT (3:1) / m³ of water. Contact time: 24 hours — against biofilm: 14,9 g C(M)IT/MIT (3:1) / m³ of water. Contact time: 24 hours — against fungi and yeasts at 1 – 3 g C(M)IT/MIT (3:1) / m³ of water. Contact time: 48 hours Preventive efficacy: against bacteria (including <i>L. pneumophila</i>) at 3 – 14,9 g C(M)IT/MIT (3:1) / m³ of water. against biofilm (including <i>L. pneumophila</i>): 3 g C(M)IT/MIT (3:1) / m³ of water.

Category(ies) of users	Industrial
Pack sizes and packaging material	For industrial and professional users: — HDPE flask: 5 l (nominal) — HDPE Pail / Jerrycan: 10 l, 20 l, 25 l, 30 l (nominal) — Box with HDPE liner: 20 l — HDPE Drum: 110 l, 120 l, 200 l, 260 l — HDPE IBC: 650 l, 800 l, 1000 l, 1250 l All products should be transport and stored in a vented room.

4.4.1. *Use-specific instructions for use*

Microbiological tests to prove adequacy of preservation have to be undertaken by the user of C(M)IT/MIT products in order to determine the effective dose of the preservative for the specific matrix/location/system. If needed, consult the manufacturer of the preservative product.

4.4.2. *Use-specific risk mitigation measures*

- Rinse the system (especially the dispensing pumps) with water prior to perform the cleaning step.
- During handling phases (mixing and loading) and cleaning of the dispensing pumps, exposure to the product (corrosive and skin sensitizer product) has to be limited by use of PPE and application of technical and organisational RMM:
 - Minimisation of manual phases (process automation);
 - Use of a dosing device;
 - Regular cleaning of equipment and work area;
 - Avoidance of contact with contaminated tools and objects;
 - Good standard of general ventilation;
 - Training and management of staff on good practice.
- PPE is as follows:
 - protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information);
 - protective coverall (at least type 3 or 4, EN 14605) which is impermeable for the biocidal product shall be worn (coverall material to be specified by the authorisation holder within the product information);
 - Eye protection;
 - Substance/task appropriate respirator if ventilation is inadequate.

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 5

Use # 5 – Preservation of liquids used in small open recirculating cooling systems

Product type	PT11 - Preservatives for liquid-cooling and processing systems (Preservatives)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Common name: Bacteria (including <i>Legionella pneumophila</i>) Development stage: Common name: Yeasts Development stage: Common name: Fungi Development stage: Common name: Algae (green algae and cyanobacteria) Development stage:
Field(s) of use	Indoor Outdoor Preservation of liquids used in small open recirculating cooling systems (blowdown and recirculating flow rates, as well as total volume of water limited to 2 m³/h, and 100 m³/h and 300 m³ respectively) Process and cooling water: Used to control the growth of bacteria, algae, fungi and biofilm
Application method(s)	Method: Open system Detailed description: Manual and automated dosing.
Application rate(s) and frequency	Application Rate: Curative treatment Against bacteria (including <i>L. pneumophila</i>) at 5 – 14,9 g C(M)IT/MIT (3:1) / m³ of water, - against biofilm (including <i>L. pneumophila</i>) at 1,5 to 14,9 g C(M)IT/MIT (3:1) / m³ of water, - against fungi (including yeast) at 1 – 14,9 g C(M)IT/MIT (3:1) / m³ of water. Preventive treatment: - Against bacteria, green algae and cyanobacteria at 3 g C(M)IT/MIT (3:1) / m³ of water, - against biofilm (including <i>L. pneumophila</i>) at 3 g C(M)IT/MIT (3:1) / m³ of water. Dilution (%): - Number and timing of application: Curative treatment: — Against bacteria (including <i>L. pneumophila</i>) at 5 – 14,9 g C(M)IT/MIT (3:1) / m³ of water Contact time: 24 hours — against biofilm (including <i>L. pneumophila</i>) at 1,5 - 14,9 g C(M)IT/MIT (3:1) / m³ of water Contact time: 48 hours. — against fungi and yeast at 1 – 14,9 g C(M)IT/MIT (3:1) / m³ of water Contact time: 48 hours. Preventive treatment: — against bacteria, green algae and cyanobacteria at 3 g C(M)IT/MIT (3:1) / m³ of water. — against biofilm (including <i>L. pneumophila</i>) at 3 g C(M)IT/MIT (3:1) / m³ of water.

Category(ies) of users	Industrial
Pack sizes and packaging material	For industrial and professional users: — HDPE flask: 5 l (nominal) — HDPE Pail / Jerrycan: 10 l, 20 l, 25 l, 30 l (nominal) — Box with HDPE liner: 20 l — HDPE Drum: 110 l, 120 l, 200 l, 260 l — HDPE IBC: 650 l, 800 l, 1000 l, 1250 l All products should be transport and stored in a vented room.

4.5.1. *Use-specific instructions for use*

Microbiological tests to prove adequacy of preservation have to be undertaken by the user of C(M)IT/MIT products in order to determine the effective dose of the preservative for the specific matrix/location/system. If needed, consult the manufacturer of the preservative product.

4.5.2. *Use-specific risk mitigation measures*

- Rinse the system (especially the dispensing pumps) with water prior to perform the cleaning step.
- During handling phases (mixing and loading) and cleaning of the dispensing pumps, exposure to the product (corrosive and skin sensitizer product) has to be limited by use of PPE and application of technical and organisational RMM:
 - Minimisation of manual phases (process automation);
 - Use of a dosing device;
 - Regular cleaning of equipment and work area;
 - Avoidance of contact with contaminated tools and objects;
 - Good standard of general ventilation;
 - Training and management of staff on good practice.
- PPE is as follows:
 - protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information);
 - protective coverall (at least type 3 or 4, EN 14605) which is impermeable for the biocidal product shall be worn (coverall material to be specified by the authorisation holder within the product information);
 - Eye protection;
 - Substance/task appropriate respirator if ventilation is inadequate.
- Cooling fluid must not enter surface water directly. Use product only in premises that are connected to a STP.
- The product can only be used when the cooling towers are equipped with drift eliminators that reduce the drift at least by 99%.

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 6

Use # 6 – Preservation of liquids used in pasteurizers, conveyor belts and air washers

Product type	PT11 - Preservatives for liquid-cooling and processing systems (Preservatives)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Common name: Bacteria (including <i>Legionella pneumophila</i>) Development stage: Common name: Yeasts Development stage: Common name: Fungi Development stage: Common name: Algae (green algae and cyanobacteria) Development stage:
Field(s) of use	Indoor Outdoor Preservation of liquids used in non-food pasteurizers and conveyor belts, air washers.
Application method(s)	Method: - Detailed description: The biocidal product is dosed automatically in the heat transfer fluid, in a place of good mixing (e.g. collecting sump below the conveyor belt). The feeding pipe is used to dose the biocidal product below the water level in order to limit its evaporation.
Application rate(s) and frequency	Application Rate: Curative treatment: -against bacteria (including <i>L. pneumophila</i>): 5 - 14,9 g C(M)IT/MIT (3:1) / m³ of water - against biofilm (including <i>L. pneumophila</i>) at 1,5 - 14,9 g C(M)IT/MIT (3:1) / m³ of water - against fungi and yeast at 1 - 14,9 g C(M)IT/MIT (3:1) / m³ of water. Preventive treatment: Against bacteria, green algae and cyanobacteria at 3 g C(M)IT/MIT (3:1) / m³ of water, against biofilm (including <i>L. pneumophila</i>) at 3 g C(M)IT/MIT (3:1) / m³ of water. Dilution (%): - Number and timing of application: Curative treatment: — against bacteria (including <i>L. pneumophila</i>): 5 - 14,9 g C(M)IT/MIT (3:1) / m³ of water. Contact time: 24 hours — against biofilm (including <i>L. pneumophila</i>) at 1,5 - 14,9 g C(M)IT/MIT (3:1) / m³ of water Contact time: 48 hours. — against fungi and yeast at 1 - 14,9 g C(M)IT/MIT (3:1) / m³ of water Contact time: 48 hours. Preventive treatment: — Against bacteria, green algae and cyanobacteria at 3 g C(M)IT/MIT (3:1) / m³ of water. — against biofilm (including <i>L. pneumophila</i>) at 3 g C(M)IT/MIT (3:1) / m³ of water.

Category(ies) of users	Industrial
Pack sizes and packaging material	For industrial and professional users: — HDPE flask: 5 l (nominal) — HDPE Pail / Jerrycan: 10 l, 20 l, 25 l, 30 l (nominal) — Box with HDPE liner: 20 l — HDPE Drum: 110 l, 120 l, 200 l, 260 l — HDPE IBC: 650 l, 800 l, 1000 l, 1250 l All products should be transport and stored in a vented room.

4.6.1. *Use-specific instructions for use*

Microbiological tests to prove adequacy of preservation have to be undertaken by the user of C(M)IT/MIT products in order to determine the effective dose of the preservative for the specific matrix/location/system. If needed, consult the manufacturer of the preservative product.

Air washers: For use only in industrial air-washer systems that maintain effective mist eliminating components.

4.6.2. *Use-specific risk mitigation measures*

- Rinse the system (especially the dispensing pumps) with water prior to perform the cleaning step.
- During handling phases (mixing and loading) and cleaning of the dispensing pumps, exposure to the product (corrosive and skin sensitizer product) has to be limited by use of PPE and application of technical and organisational RMM:
 - Minimisation of manual phases (process automation);
 - Use of a dosing device;
 - Regular cleaning of equipment and work area;
 - Avoidance of contact with contaminated tools and objects;
 - Good standard of general ventilation;
 - Training and management of staff on good practice.
- PPE is as follows:
 - protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information);
 - protective coverall (at least type 3 or 4, EN 14605) which is impermeable for the biocidal product shall be worn (coverall material to be specified by the authorisation holder within the product information);
 - Eye protection;
 - Substance/task appropriate respirator if ventilation is inadequate.

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 7

Use # 7 – Preservation of recirculating fluids used in textile and fiber processing, leather processing, photo-processing and fountain solution systems

Product type	PT11 - Preservatives for liquid-cooling and processing systems (Preservatives)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Common name: Bacteria Development stage:
Field(s) of use	Indoor Preservation of recirculating fluids used in textile, fiber processing, leather processing, photo-processing and fountain solution systems C(M)IT/MIT (3:1) biocidal products are used for the preservation of textile and spinning fluids, photo processing solutions, leather process (e.g. washing and soaking treatment stages) and printing fountain solutions to control the integrity of recirculating fluid by reducing microbial contamination in the bulk solution.
Application method(s)	Method: - Detailed description: Manual and automated dosing. The preservation of all end-products is performed in most cases highly automated by industrial users The biocidal product is added to the central sump, basin or recirculating lines in an area with adequate mixing.
Application rate(s) and frequency	Application Rate: Curative treatment: Against bacteria at 16-30 mg C(M)IT/MIT (3:1) per l of fluid Dilution (%): - Number and timing of application: Curative treatment: Against bacteria at 16-30 mg C(M)IT/MIT (3:1) per l of fluid Contact time 5 days
Category(ies) of users	Industrial
Pack sizes and packaging material	For industrial and professional users: — HDPE flask: 5 l (nominal) — HDPE Pail / Jerrycan: 10 l, 20 l, 25 l, 30 l (nominal) — Box with HDPE liner: 20 l — HDPE Drum: 110 l, 120 l, 200 l, 260 l — HDPE IBC: 650 l, 800 l, 1000 l, 1250 l All products should be transport and stored in a vented room.

4.7.1. *Use-specific instructions for use*

Microbiological tests to prove adequacy of preservation have to be undertaken by the user of C(M)IT/MIT products in order to determine the effective dose of the preservative for the specific matrix/location/system. If needed, consult the manufacturer of the preservative product.

4.7.2. *Use-specific risk mitigation measures*

- Rinse the system (especially the dispensing pumps) with water prior to perform the cleaning step.
- During handling phases (mixing and loading) and cleaning of the dispensing pumps, exposure to the product (corrosive and skin sensitizer product) has to be limited by use of PPE and application of technical and organisational RMM:
 - Minimisation of manual phases (process automation);
 - Use of a dosing device;
 - Regular cleaning of equipment and work area;
 - Avoidance of contact with contaminated tools and objects;
 - Good standard of general ventilation;
 - Training and management of staff on good practice.
- PPE is as follows:
 - protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information);
 - protective coverall (at least type 3 or 4, EN 14605) which is impermeable for the biocidal product shall be worn (coverall material to be specified by the authorisation holder within the product information);
 - Eye protection;
 - Substance/task appropriate respirator if ventilation is inadequate.
- Liquids used in textile and fiber processing fluids must not enter surface water directly. Use product only in premises that are connected to a STP.
- Recirculating liquids in photoprocessing systems and fountain solution systems must not enter surface water directly. Use product only in premises that are connected to a STP.

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.

4.8. Use description

Table 8

Use # 8 – Preservation of re-circulating liquids used in paint spray booths and electrodeposition coating systems

Product type	PT11 - Preservatives for liquid-cooling and processing systems (Preservatives)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Common name: Bacteria Development stage: Common name: Yeasts Development stage:
Field(s) of use	Indoor Preservation of re-circulating liquids used in paint spray booths and electrodeposition coating systems. The biocidal product is used for preservation of fluids in pre- treatment processes (Cleaning treatment for grease removal and soil, degreasing Phosphating process, Rinse off tanks) paint spray booths and electrodeposition coating systems (e.g. cataphoretic baths) applied in Car Refinishing and Original equipment Car Manufacturing to control the integrity of recirculating fluid by reducing microbial contamination from bacteria and fungi in the bulk solution.
Application method(s)	Method: - Detailed description: -
Application rate(s) and frequency	Application Rate: Preventive treatment: 7,5 to 30 mg C(M)IT/MIT (3:1) per kg final product. Dilution (%): - Number and timing of application: Preventive treatment: 7,5 to 30 mg C(M)IT/MIT (3:1) per Kg final product. The biocidal product is added at the time of manufacture, storage or shipment.
Category(ies) of users	Industrial
Pack sizes and packaging material	For industrial and professional users: — HDPE flask: 5 l (nominal) — HDPE Pail / Jerrycan: 10 l, 20 l, 25 l, 30 l (nominal) — Box with HDPE liner: 20 l — HDPE Drum: 110 l, 120 l, 200 l, 260 l — HDPE IBC: 650 l, 800 l, 1000 l, 1250 l All products should be transport and stored in a vented room.

4.8.1. *Use-specific instructions for use*

Microbiological tests to prove adequacy of preservation have to be undertaken by the user of C(M)IT/MIT products in order to determine the effective dose of the preservative for the specific matrix/location/system. If needed, consult the manufacturer of the preservative product.

4.8.2. *Use-specific risk mitigation measures*

- Rinse the system (especially the dispensing pumps) with water prior to perform the cleaning step.
- During handling phases (mixing and loading) and cleaning of the dispensing pumps, exposure to the product (corrosive and skin sensitizer product) has to be limited by use of PPE and application of technical and organisational RMM:
 - Minimisation of manual phases (process automation);
 - Use of a dosing device;
 - Regular cleaning of equipment and work area;
 - Avoidance of contact with contaminated tools and objects;
 - Good standard of general ventilation;
 - Training and management of staff on good practice.
- PPE is as follows:
 - protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information);
 - protective coverall (at least type 3 or 4, EN 14605) which is impermeable for the biocidal product shall be worn (coverall material to be specified by the authorisation holder within the product information);
 - Eye protection;
 - Substance/task appropriate respirator if ventilation is inadequate.

4.8.3. *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.

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

See general directions for use.

4.8.5. *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.

4.9. **Use description**

Table 9

Use # 9 – Preservation of liquids used in closed recirculating heating systems and associated pipework

Product type	PT11 - Preservatives for liquid-cooling and processing systems (Preservatives)
Where relevant, an exact description of the authorised use	-

Target organism(s) (including development stage)	Common name: Bacteria (anaerobes and aerobes (including <i>Legionella pneumophila</i>) Development stage: Common name: Yeasts Development stage: Common name: Fungi Development stage:
Field(s) of use	Indoor Outdoor Preservation of liquids used in closed recirculating heating systems and associated pipework. Pre-commission biocide flushing of new or existing pipework systems (heating and chilling pipework) includes used or new structural pipework built on industrial building projects. Closed recirculating heating systems: pre-commission biocidal product flushing of new or existing pipework systems (heating and chilling pipework) includes used or new structural pipework built on industrial building projects. The biocidal product is used to control the growth of aerobic and anaerobic bacteria, fungi and biofilm in the circulating water of closed systems. Closed systems are less susceptible to corrosion, scaling and biological fouling than open systems. However microbial problems can occur, if the system is left filled and untreated. This is due to the presence of nitrite and glycols used as nutrients by microbes.
Application method(s)	Method: Closed system Detailed description: Manual and automated dosing. The biocidal product is dosed automatically in the heat transfer fluid, in a place of good mixing. The feeding pipe must dose the biocidal product below the water level in order to limit the evaporation of the biocidal product.
Application rate(s) and frequency	Application Rate: Curative treatment — against bacteria at 5 g C(M)IT/MIT (3:1) / m³ of water (including <i>L. pneumophila</i>) — against biofilm at 14,9 g C(M)IT/MIT (3:1) / m³ of water — against fungi and yeast at 1 g C(M)IT/MIT / m³ of water Preventive treatment — against bacteria (including <i>L. pneumophila</i>) at 3 g C(M)IT/MIT (3:1) / m³ of water — against biofilm at 3 g C(M)IT/MIT (3:1) / m³ of water. Dilution (%): - Number and timing of application: Curative treatment: — against bacteria at 5 g C(M)IT/MIT (3:1) / m³ of water (including <i>L. pneumophila</i>) Contact time: 24 hours — against biofilm at 14,9 g C(M)IT/MIT (3:1) / m³ of water Contact time: 24 hours — against fungi and yeast at 1 g C(M)IT/MIT / m³ of water Contact time: 48 hours Preventive treatment — against bacteria (including <i>L. pneumophila</i>) at 3 g C(M)IT/MIT (3:1) / m³ of water and against biofilm at 3 g C(M)IT/MIT (3:1) / m³ of water.

Category(ies) of users	Industrial
Pack sizes and packaging material	For industrial and professional users: — HDPE flask: 5 l (nominal) — HDPE Pail / Jerrycan: 10 l, 20 l, 25 l, 30 l (nominal) — Box with HDPE liner: 20 l — HDPE Drum: 110 l, 120 l, 200 l, 260 l — HDPE IBC: 650 l, 800 l, 1000 l, 1250 l All products should be transport and stored in a vented room.

4.9.1. *Use-specific instructions for use*

Microbiological tests to prove adequacy of preservation have to be undertaken by the user of C(M)IT/MIT products in order to determine the effective dose of the preservative for the specific matrix/location/system. If needed, consult the manufacturer of the preservative product.

4.9.2. *Use-specific risk mitigation measures*

- Rinse the system (especially the dispensing pumps) with water prior to perform the cleaning step.
- During handling phases (mixing and loading) and cleaning of the dispensing pumps, exposure to the product (corrosive and skin sensitizer product) has to be limited by use of PPE and application of technical and organisational RMM:
 - Minimisation of manual phases (process automation);
 - Use of a dosing device;
 - Regular cleaning of equipment and work area;
 - Avoidance of contact with contaminated tools and objects;
 - Good standard of general ventilation;
 - Training and management of staff on good practice.
- PPE is as follows:
 - protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information);
 - protective coverall (at least type 3 or 4, EN 14605) which is impermeable for the biocidal product shall be worn (coverall material to be specified by the authorisation holder within the product information);
 - Eye protection;
 - Substance/task appropriate respirator if ventilation is inadequate.

4.9.3. *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.

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

See general directions for use.

4.9.5. *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.

4.10. Use description

Table 10

Use # 10 – Preservation of polymers used in oilfield processes (e.g. enhanced oil recovery, drilling muds, etc.)

Product type	PT11 - Preservatives for liquid-cooling and processing systems (Preservatives)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Common name: Bacteria Development stage:
Field(s) of use	Outdoor Preservation of polymers used in oilfield processes (e.g. enhanced oil recovery, drilling muds, etc.)
Application method(s)	Method: - Detailed description: -
Application rate(s) and frequency	Application Rate: Preventive treatment of polymers used in the injection water: Xanthan polymer: 30 -50 g C(M)IT/MIT/m ³ solution. HPAM polymer: 30 - 50 g C(M)IT/MIT/m ³ solution. Preventive treatment of polymers used in the drilling muds: Xanthan polymer: 30 g C(M)IT/MIT/m ³ solution. HPAM polymer: 30 g C(M)IT/MIT/m ³ solution. Dilution (%): - Number and timing of application: Preventive treatment of polymers used in the injection water: Xanthan polymer: 30 -50 g C(M)IT/MIT/m ³ solution. HPAM polymer: 30 - 50 g C(M)IT/MIT/m ³ solution. Preventive treatment of polymers used in the drilling muds: Xanthan polymer: 30 g C(M)IT/MIT/m ³ solution. HPAM polymer: 30 g C(M)IT/MIT/m ³ solution.
Category(ies) of users	Industrial
Pack sizes and packaging material	For industrial and professional users: — HDPE flask: 5 l (nominal) — HDPE Pail / Jerrycan: 10 l, 20 l, 25 l, 30 l (nominal) — Box with HDPE liner: 20 l — HDPE Drum: 110 l, 120 l, 200 l, 260 l — HDPE IBC: 650 l, 800 l, 1000 l, 1250 l All products should be transport and stored in a vented room.

4.10.1. Use-specific instructions for use

Microbiological tests to prove adequacy of preservation have to be undertaken by the user of C(M)IT/MIT products in order to determine the effective dose of the preservative for the specific matrix/location/system. If needed, consult the manufacturer of the preservative product.

4.10.2. Use-specific risk mitigation measures

- Rinse the system (especially the dispensing pumps) with water prior to perform the cleaning step.

- During handling phases (mixing and loading) and cleaning of the dispensing pumps, exposure to the product (corrosive and skin sensitizer product) has to be limited by use of PPE and application of technical and organisational RMM:
 - Minimisation of manual phases (process automation);
 - Use of a dosing device;
 - Regular cleaning of equipment and work area;
 - Avoidance of contact with contaminated tools and objects;
 - Good standard of general ventilation;
 - Training and management of staff on good practice.
- PPE is as follows:
 - protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information);
 - protective coverall (at least type 3 or 4, EN 14605) which is impermeable for the biocidal product shall be worn (coverall material to be specified by the authorisation holder within the product information);
 - Eye protection;
 - Substance/task appropriate respirator if ventilation is inadequate.

4.10.3. *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.

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

See general directions for use.

4.10.5. *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.

4.11. **Use description**

Table 11

Use # 11 – Slimicide treatment in the de-inking process of the pulp and paper

Product type	PT12 - Slimicides (Preservatives)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Common name: Bacteria Development stage: Common name: Yeasts Development stage: Common name: Fungi Development stage:
Field(s) of use	Indoor Slimicide treatment in the de-inking process of the pulp and paper. Recycling paper /deinking paper mills. Deinking process is a manufacturing paper process of removing printing inks from waste paper-fibers to produce deinked pulp.

Application method(s)	Method: Closed system Detailed description: Manual and automated dosing. The biocidal product is automatically dosed by pump and fixed pipes into the circuit, usually in the pulper below the water level.
Application rate(s) and frequency	Application Rate: Curative treatment: 10 to 14,9 g C(M)IT/MIT (3:1) / m ³ of water to be treated. Preventive treatment: 5 g C(M)IT/MIT (3:1) / m ³ of water to be treated. Dilution (%): - Number and timing of application: Curative treatment: 10 to 14,9 g C(M)IT/MIT (3:1) / m ³ of water to be treated Contact time: 24 hours Preventive treatment: 5 g C(M)IT/MIT (3:1) / m ³ of water to be treated.
Category(ies) of users	Industrial
Pack sizes and packaging material	For industrial and professional users: — HDPE flask: 5 l (nominal) — HDPE Pail / Jerrycan: 10 l, 20 l, 25 l, 30 l (nominal) — Box with HDPE liner: 20 l — HDPE Drum: 110 l, 120 l, 200 l, 260 l — HDPE IBC: 650 l, 800 l, 1000 l, 1250 l All products should be transport and stored in a vented room.

4.11.1. Use-specific instructions for use

Microbiological tests to prove adequacy of preservation have to be undertaken by the user of C(M)IT/MIT products in order to determine the effective dose of the preservative for the specific matrix/location/system. If needed, consult the manufacturer of the preservative product.

4.11.2. Use-specific risk mitigation measures

- Rinse the system (especially the dispensing pumps) with water prior to perform the cleaning step.
- During handling phases (mixing and loading) and cleaning of the dispensing pumps, exposure to the product (corrosive and skin sensitizer product) has to be limited by use of PPE and application of technical and organisational RMM:
 - Minimisation of manual phases (process automation);
 - Use of a dosing device;
 - Regular cleaning of equipment and work area;
 - Avoidance of contact with contaminated tools and objects;
 - Good standard of general ventilation;
 - Training and management of staff on good practice.
- PPE is as follows:
 - protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information);
 - protective coverall (at least type 3 or 4, EN 14605) which is impermeable for the biocidal product shall be worn (coverall material to be specified by the authorisation holder within the product information);
 - Eye protection;
 - Substance/task appropriate respirator if ventilation is inadequate.

4.11.3. *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.

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

See general directions for use.

4.11.5. *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.

4.12. Use description

Table 12

Use # 12 – Slimicide treatment in the wet-end stage of paper manufacturing process

Product type	PT12 - Slimicides (Preservatives)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Common name: Bacteria Development stage: Common name: Yeasts Development stage: Common name: Fungi Development stage:
Field(s) of use	Indoor Slimicide treatment in the wet-end stage of the paper manufacturing process (paper mills, wet-end stage (water circuits), and paper mills process system).
Application method(s)	Method: Closed system Detailed description: Manual and automated dosing.
Application rate(s) and frequency	Application Rate: Curative treatment: 10 to 14,9 g C(M)IT/MIT (3:1) / m ³ of water to be treated. Preventive treatment: 5 g C(M)IT/MIT (3:1) / m ³ of water to be treated. Dilution (%): - Number and timing of application: Curative treatment: 10 to 14,9 g C(M)IT/MIT (3:1) / m ³ of water to be treated Contact time: 24 hours Preventive treatment: 5 g C(M)IT/MIT (3:1) / m ³ of water to be treated.
Category(ies) of users	Industrial
Pack sizes and packaging material	For industrial and professional users: — HDPE flask: 5 l (nominal) — HDPE Pail / Jerrycan: 10 l, 20 l, 25 l, 30 l (nominal) — Box with HDPE liner: 20 l — HDPE Drum: 110 l, 120 l, 200 l, 260 l — HDPE IBC: 650 l, 800 l, 1000 l, 1250 l All products should be transport and stored in a vented room.

4.12.1. *Use-specific instructions for use*

Microbiological tests to prove adequacy of preservation have to be undertaken by the user of C(M)IT/MIT products in order to determine the effective dose of the preservative for the specific matrix/location/system. If needed, consult the manufacturer of the preservative product.

4.12.2. *Use-specific risk mitigation measures*

- Rinse the system (especially the dispensing pumps) with water prior to perform the cleaning step.
- During handling phases (mixing and loading) and cleaning of the dispensing pumps, exposure to the product (corrosive and skin sensitizer product) has to be limited by use of PPE and application of technical and organisational RMM:
 - Minimisation of manual phases (process automation);
 - Use of a dosing device;
 - Regular cleaning of equipment and work area;
 - Avoidance of contact with contaminated tools and objects;
 - Good standard of general ventilation;
 - Training and management of staff on good practice.
- PPE is as follows:
 - protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information);
 - protective coverall (at least type 3 or 4, EN 14605) which is impermeable for the biocidal product shall be worn (coverall material to be specified by the authorisation holder within the product information);
 - Eye protection;
 - Substance/task appropriate respirator if ventilation is inadequate.
- The use of C(M)IT/MIT (3:1) containing products for the slimicide treatment in the wet-end stage of the paper manufacturing process is restricted to:
 - (a) curative treatments in plants connected to a slimicide-free water from a pulp mill and only for the treatment of the short circulation of the paper mill; and
 - (b) preventive treatments,
 - and, for both cases, only if the factory's waste water is purified in an on-site (full) industrial sewage treatment plant with a minimal capacity of 5000 m³ per day as described in the Industrial Emission Directive 2010/75/EU (Best Available Techniques for the production of pulp, paper and board) and if a dilution of at least 200 times in surface water is achieved after the industrial sewage treatment plant.

4.12.3. *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.

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

See general directions for use.

4.12.5. *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.

4.13. Use description

Table 13

Use # 13 – Preventive treatment (biofouling control) online and after cleaning in place for industrial RO/NF membranes

Product type	PT12 - Slimicides (Preservatives)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Common name: Bacteria Development stage:
Field(s) of use	Indoor Preventive treatment (biofouling control) online and after cleaning in place for industrial RO/NF membranes
Application method(s)	Method: Closed system Detailed description: Manual and automated dosing. Biocidal product application on a routine basis will prevent biofilm growth on Reverse Osmosis or Nano Filtration membrane surfaces, feed spacer, filter media and pipework. The biocidal product should be dispensed to the feed water at a point to assure adequate mixing throughout the system.
Application rate(s) and frequency	Application Rate: Preventive treatment: 5 g C(M)IT/MIT (3:1) per m ³ of fluid Dilution (%): - Number and timing of application: Preventive treatment: 5 g C(M)IT/MIT (3:1) per m ³ of fluid
Category(ies) of users	Industrial
Pack sizes and packaging material	For industrial and professional users: — HDPE flask: 5 l (nominal) — HDPE Pail / Jerrycan: 10 l, 20 l, 25 l, 30 l (nominal) — Box with HDPE liner: 20 l — HDPE Drum: 110 l, 120 l, 200 l, 260 l — HDPE IBC: 650 l, 800 l, 1000 l, 1250 l All products should be transport and stored in a vented room.

4.13.1. Use-specific instructions for use

Microbiological tests to prove adequacy of preservation have to be undertaken by the user of C(M)IT/MIT products in order to determine the effective dose of the preservative for the specific matrix/location/system. If needed, consult the manufacturer of the preservative product.

4.13.2. Use-specific risk mitigation measures

- Rinse the system (especially the dispensing pumps) with water prior to perform the cleaning step.
- During handling phases (mixing and loading) and cleaning of the dispensing pumps, exposure to the product (corrosive and skin sensitizer product) has to be limited by use of PPE and application of technical and organisational RMM:
 - Minimisation of manual phases (process automation);

- Use of a dosing device;
- Regular cleaning of equipment and work area;
- Avoidance of contact with contaminated tools and objects;
- Good standard of general ventilation;
- Training and management of staff on good practice.
- PPE is as follows:
 - protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information);
 - protective coverall (at least type 3 or 4, EN 14605) which is impermeable for the biocidal product shall be worn (coverall material to be specified by the authorisation holder within the product information);
 - Eye protection;
 - Substance/task appropriate respirator if ventilation is inadequate.
- Use product only in premises that are connected to a STP.

4.13.3. *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.

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

See general directions for use.

4.13.5. *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**

- The duration of the effect is dependent on the performance requirements of the customer for their preserved material and on the specific ingredients composition and pH of the preserved product.
- Always read the label or leaflet before use and follow all the instructions provided.
- Respect the conditions of use of the product (concentration, contact time, temperature, pH, etc.)

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

PRECAUTIONARY MEASURES DURING STORAGE AND TRANSPORT:

Keep in a well-ventilated place. The product as supplied may evolve gas (largely carbon dioxide) slowly. To prevent the buildup of pressure the product is packaged in specially vented containers, where necessary. Keep this product in the original container when not in use. Container must be stored and transported in an upright position to prevent spilling the contents through the vent, where fitted.

5.2. Risk mitigation measures

-

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

- Skin contact: Remove contaminated clothing and shoes. Wash contaminated skin with water. Contact poison treatment specialist if symptoms occur.
- Eye contact: Immediately flush with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses if easy to do. Continue to rinse with tepid water for at least 30 minutes. Call 112/ambulance for medical assistance.
- Ingestion: Wash out mouth with water. Contact poison treatment specialist. Seek medical advice immediately if symptoms occur and/or large quantities have been ingested. Do not give fluids or induce vomiting.
- Inhalation (of spray mist): Remove victim to fresh air and keep at rest in a position comfortable for breathing. Seek medical advice immediately if symptoms occur and/or large quantities have been inhaled.
- In case of impaired consciousness place in recovery position and seek medical advice immediately.
- Keep the container or label available.

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

- Do not discharge unused product on the ground, into water courses, into pipes (e.g. sink, toilets) nor down the drains.
- Dispose of unused product, its packaging and all other waste, in accordance with local regulations.

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

Conditions for safe storage, including any incompatibilities: Keep in a dry, cool and well-ventilated place, in the original container.

Shelf-life: 12 months

Protect from sunlight.

Recommendation: If a metal packaging is used, a varnish layer should be applied.

6. OTHER INFORMATION

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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)	Spectrum™ RX6804 MICROBIOCIDE		Market area: EU		
Authorisation number	EU-0025678-0001 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Mixture of 5-chloro-2-methyl-2H- isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H- isothiazol-3-one (EINECS 220-239-6) (Mixture of CMIT/MIT)		Active Substance	55965-84-9		5,9

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

Trade name(s)	Spectrum™ PR3126 PRESERVATIVE		Market area: EU		
	Spectrum™ RX8560 MICROBIOCIDE		Market area: EU		
	Spectrum™ RX7827 MICROBIOCIDE		Market area: EU		
Authorisation number	EU-0025678-0002 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Mixture of 5-chloro-2-methyl-2H- isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H- isothiazol-3-one (EINECS 220-239-6) (Mixture of CMIT/MIT)		Active Substance	55965-84-9		3,2

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

Trade name(s)	Biosperse™ 250 MICROBIOCIDE		Market area: EU		
	Biosperse™ 251 MICROBIOCIDE		Market area: EU		
	Biosperse™ 850 MICROBIOCIDE		Market area: EU		
	Biosperse™ 851 MICROBIOCIDE		Market area: EU		
	Spectrum™ RX6810 MICROBIOCIDE		Market area: EU		
	Spectrum™ RX6820 MICROBIOCIDE		Market area: EU		
Authorisation number	EU-0025678-0003 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Mixture of 5-chloro-2-methyl-2H- isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H- isothiazol-3-one (EINECS 220-239-6) (Mixture of CMIT/MIT)		Active Substance	55965-84-9		2,3

COMMISSION IMPLEMENTING REGULATION (EU) 2023/754**of 12 April 2023****granting a Union authorisation for the single biocidal product ‘Arche Chlorine’ in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council****(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), first subparagraph, thereof,

Whereas:

- (1) On 7 December 2018, Arche Consortia submitted to the European Chemicals Agency (‘the Agency’) an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 for Union authorisation of a single biocidal product named ‘Arche Chlorine’ of product-types 2 and 5, as described in Annex V to that Regulation, providing written confirmation that the competent authority of Belgium had agreed to evaluate the application. The application was recorded under case number BC-UQ045679-98 in the Register for Biocidal Products.
- (2) ‘Arche Chlorine’ contains active chlorine released from chlorine as the active substance included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012 for product-types 2 and 5.
- (3) On 27 November 2020, the evaluating competent authority submitted, in accordance with Article 44(1) of Regulation (EU) No 528/2012, an assessment report and the conclusions of its evaluation to the Agency.
- (4) On 5 July 2021, the Agency submitted to the Commission its opinion ⁽²⁾, the draft summary of the biocidal product characteristics (‘SPC’) of ‘Arche Chlorine’ and the final assessment report on the single biocidal product, in accordance with Article 44(3) of Regulation (EU) No 528/2012.
- (5) The opinion concludes that ‘Arche Chlorine’ is a single biocidal product within the meaning of Article 3(1), point (r), 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, it meets the conditions laid down in Article 19(1) of that Regulation.
- (6) On 30 July 2021, 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.
- (7) On 7 March 2022, Germany requested the Commission to adjust the terms and conditions of the Union authorisation of the single biocidal product ‘Arche Chlorine’ for its territory in accordance with Article 44(5), second subparagraph, of Regulation (EU) No 528/2012 on the grounds of public policy referred to in Article 37(1), point (b), and the protection of health and life of humans referred to in Article 37(1), point (c), of that Regulation. In their request, the German authorities referred to the national rules of the German Drinking Water Ordinance (TrinkwV) ⁽³⁾ establishing a systematic set of rules to ensure healthy and clean drinking water by regulating the required quality of water, and the substances, methods and procedures to be used for the treatment of drinking water; imposing obligations on water treatment plants and setting rules on the enforcement of those obligations. Based on the rules established by the TrinkwV, certain norms and common practices have developed which are well established in the sector of drinking water treatment in Germany.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ ECHA opinion of 16 June 2021 on the Union authorisation of the single biocidal product ‘Arche Chlorine’ (ECHA/BPC/281/2021), <https://echa.europa.eu/it/opinions-on-union-authorisation>.

⁽³⁾ Trinkwasserverordnung in der Fassung der Bekanntmachung vom 10. März 2016 (Bundesgesetzblatt I S. 459), zuletzt geändert durch Artikel 1 der Verordnung vom 22. September 2021 (Bundesgesetzblatt I S. 4343). TrinkwV.pdf (gesetze-im-internet.de)

- (8) Germany explained in more detail that parts of the description of use 2 (disinfection of drinking water at drinking water suppliers), use 3 (disinfection of water in reservoirs) and use 4 (disinfection of water in collective systems) of the SPC do not fully correspond to the rules of the TrinkwV. In particular, the application methods and application rates and frequency for those uses would need to be adapted to meet the requirements of the list of treatment substances and disinfection processes according to paragraph 11 of the TrinkwV.
- (9) The Commission, having regard to Article 2(7) of Regulation (EU) No 528/2012, considers that the request made by Germany to adjust the conditions of the Union authorisation of the single biocidal product 'Arche Chlorine' for its territory in accordance with Article 44(5), second subparagraph, of Regulation (EU) No 528/2012 is justified on the grounds of public policy in the supply of drinking water and the protection of health and life of humans pursuant to Article 37(1), points (b) and (c), respectively, of that Regulation. The TrinkwV implements in Germany Council Directive 98/83/EC⁽⁴⁾, which sets a legal framework to protect human health from the adverse effects of any contamination of water intended for human consumption by ensuring that it is wholesome and clean. That Directive sets essential quality standards at Union level and allows Member States to implement additional requirements and higher standards when transposing it into their national laws. The particular rules chosen by Germany to transpose the provisions of Directive 98/83/EC into national law are in place since 2001 and are implemented and relied upon by the drinking water treatment sector in Germany. Products for the disinfection of drinking water made available on the German market should therefore not interfere with that system and should comply with the rules established in the TrinkwV.
- (10) The Commission concurs with the opinion of the Agency and considers it therefore appropriate to grant a Union authorisation for 'Arche Chlorine' with the adjustments of the SPC as requested by Germany for its territory for the uses 2, 3 and 4 in accordance with Article 44(5), second subparagraph, of Regulation (EU) No 528/2012.
- (11) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation with authorisation number EU-0026816-0000 is granted to Arche Consortia for the making available on the market and use of the single biocidal product 'Arche Chlorine' in accordance with the summary of the biocidal product characteristics set out in the Annex.

For the territory of the Federal Republic of Germany, adjustments to the terms and conditions apply for the uses 2, 3 and 4 of 'Arche Chlorine' as laid down in the summary of product characteristics in the Annex.

The Union authorisation is valid from 3 May 2023 to 30 April 2033.

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*.

⁽⁴⁾ Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption (OJ L 330, 5.12.1998, p. 32).

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

Done at Brussels, 12 April 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Summary of product characteristics for a biocidal product

Arche Chlorine

Product type 2 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)

Product type 5 – Drinking water (Disinfectants)

Authorisation number: EU-0026816-0000

R4BP asset number: EU-0026816-0000

1. ADMINISTRATIVE INFORMATION**1.1. Trade name(s) of the product**

Trade name(s)	Arche Chlorine
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1.2. Authorisation holder

Name and address of the authorisation holder	Name	ARCHE Consortia
	Address	Liefkensstraat 35D, 9032 Wondelgem Belgium
Authorisation number	EU-0026816-0000	
<i>R4BP asset number</i>	EU-0026816-0000	
Date of the authorisation	3 May 2023	
Expiry date of the authorisation	30 April 2033	

1.3. Manufacturer(s) of the product

Name of manufacturer	PCC Rokita SA
Address of manufacturer	Sienkiewicza 4, 56-120 Brzeg Dolny Poland
Location of manufacturing sites	Sienkiewicza 4, 56-120 Brzeg Dolny Poland

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

Active substance	Active chlorine released from chlorine
Name of manufacturer	PCC Rokita SA
Address of manufacturer	Sienkiewicza 4, 56-120 Brzeg Dolny Poland
Location of manufacturing sites	Sienkiewicza 4, 56-120 Brzeg Dolny Poland

2. PRODUCT COMPOSITION AND FORMULATION

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Active chlorine released from chlorine		Active Substance			100,0
chlorine	chlorine	Non-active substance	7782-50-5	231-959-5	100,0

2.2. Type of formulation

GA – Gas

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	May cause or intensify fire; oxidiser Causes skin irritation. Causes serious eye irritation. Toxic if inhaled. May cause respiratory irritation. Very toxic to aquatic life. Contains gas under pressure; may explode if heated
Precautionary statements	Keep away from clothing and other combustible materials. Do not breathe gas. Avoid release to the environment. Wear protective gloves. Wear protective clothing. Wear eye protection. Wear face protection. IF INHALED: Remove person to fresh air and keep comfortable for breathing. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Collect spillage. Store in a well-ventilated place. Keep container tightly closed. Store locked up. Protect from sunlight. Store in a well-ventilated place. In case of fire: Stop leak if safe to do so. Dispose of contents to local regulation. Keep valves and fittings free from oil and grease. Call a doctor if you feel unwell. Avoid breathing gas. Wash hands thoroughly after handling. Use only outdoors or in a well-ventilated area. IF ON SKIN: Wash with plenty of water. Call a Poison center/doctor. Specific treatment (see reference to supplemental first aid instruction on this label). If skin irritation occurs: Get medical attention. If eye irritation persists: Get medical attention. Take off contaminated clothing. And wash it before reuse.

4. AUTHORISED USE(S)

4.1. Use description

Table 1

Use # 1 – Disinfection of waste water after the waste water plant

Product type	PT02 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	/
Target organism(s) (including development stage)	Scientific name: bacteria Common name: Bacteria Development stage: Scientific name: viruses Common name: Viruses Development stage:
Field(s) of use	Indoor Outdoor Disinfection of waste water after the waste water plant, by shock dosing (in case of contamination).
Application method(s)	Method: Closed system Detailed description: Automated dosing system.
Application rate(s) and frequency	Application Rate: Shock dosing: 477 mg/l active chlorine (AC) under dirty conditions. Dilution (%): - Number and timing of application: Contact time: 30 minutes
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	Cylinder: 4,8-140 l (6-175 kg Cl ₂) Drum: 400-1 000 l (500-1 250 kg Cl ₂) Railway tanks: 43 000-44 000 l (53 750-55 000 kg Cl ₂) Carbon/stainless steel

4.1.1. Use-specific instructions for use

Connect the chlorine cylinder or drum to the automated dosing system, closed dosing system. Set up the parameters of the system to obtain an active chlorine concentration in the water according to the application rate indicated above.

4.1.2. Use-specific risk mitigation measures

Reduce residual concentrations of active chlorine by active carbon filtration or addition of reducing agents (e.g. ascorbic acid or sodium ascorbate) before discharging the waste water to surface water. Alternatively, water can be retained in a buffer before discharge.

Regular water quality assessments should be performed to assure the effluent meets all required quality standards.

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 Section 5 General directions for use

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

See Section 5 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 Section 5 General directions for use

4.2. **Use description**

Table 2

Use # 2 – Disinfection of drinking water at drinking water suppliers

Product type	PT05 – Drinking water (Disinfectants)
Where relevant, an exact description of the authorised use	/
Target organism(s) (including development stage)	Scientific name: bacteria Common name: Bacteria Development stage: Scientific name: viruses Common name: Viruses Development stage:
Field(s) of use	Indoor Outdoor Disinfection at the drinking water suppliers and their water distribution systems, by continuous dosing.
Application method(s)	Method: Closed system Detailed description: Automated dosing system Adjustment applicable in the territory of the Federal Republic of Germany in accordance with Article 44(5) of Regulation (EU) No 528/2012: In accordance with the list of treatment substances and disinfection processes of paragraph 11 of the German Drinking Water Ordinance¹, the technical rules for dosing set out in the Deutscher Verein des Gas Wasserfaches e.V.²-working sheets W 229, W 296, W 623 and the minimum contact time of W 229 apply³. (See section 6 for further references)

Application rate(s) and frequency	Application Rate: 0,5 mg/l active chlorine (AC) as residual concentration in the system Dilution (%): - Number and timing of application: Frequency: continuous dosing Adjustment applicable in the territory of the Federal Republic of Germany in accordance with Article 44(5) of Regulation (EU) No 528/2012: In accordance with the list of treatment substances and disinfection processes of paragraph 11 of the German Drinking Water Ordinance (See section 6 for further reference)⁴ Application rate: Maximum addition 1,2 mg/l free Cl₂; Concentration range after completion of treatment: maximum 0,3 mg/l free Cl₂, minimum 0,1 mg/l free Cl₂ (including the amounts before treatment and from other treatments) as residual concentration in the system In exceptional cases an addition of up to 6 mg/l free Cl₂ and concentration of up to 0,6 mg/l free Cl₂ after treatment is acceptable as residual concentration in the system, if disinfection cannot be ensured by other means or if disinfection is temporarily impaired by ammonium.
Category(ies) of users	Professional
Pack sizes and packaging material	Cylinder: 4,8-140 l (6-175 kg Cl₂) Drum: 400-1 000 l (500-1 250 kg Cl₂) Railway tanks: 43 000-44 000 l (53 750-55 000 kg Cl₂) Carbon/stainless steel

4.2.1. Use-specific instructions for use

Connect the chlorine cylinder or drum to the automated, closed dosing system. Set up the parameters of the system to obtain an active chlorine concentration in the water according to the application rate indicated above.

Please note that some Member States after primary disinfection, request to maintain a residual level of available chlorine in drinking water in the pipes as a precautionary measure. This additional amount, claimed by the applicant as 'Secondary disinfection: 0,1 to 0,5 mg/l available chlorine (residual)' has been considered as covered by the primary disinfection.

4.2.2. Use-specific risk mitigation measures

Ensure that the concentration of chlorine in the drinking water does not exceed national chlorine limits before consumption.

Ensure that the concentration of chlorate present in the drinking water does not exceed the parametric values set in Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (recast) (OJ L 435, 23.12.2020, p. 1).

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 Section 5 General directions for use

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

See Section 5 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 Section 5 General directions for use

4.3. **Use description**

Table 3

Use # 3 – Disinfection of water in reservoirs

Product type	PT05 – Drinking water (Disinfectants)
Where relevant, an exact description of the authorised use	/
Target organism(s) (including development stage)	Scientific name: bacteria Common name: Bacteria Development stage: Scientific name: viruses Common name: Viruses Development stage:
Field(s) of use	Indoor Outdoor Disinfection of water (with water coming from tap water network), in reservoirs/tanks, by continuous dosing.
Application method(s)	Method: Closed system Detailed description: Automated dosing system. The disinfection is carried out in the inlet of the reservoir, in order to assure proper distribution of the disinfectant in the water. Adjustment applicable in the territory of the Federal Republic of Germany in accordance with Article 44(5) of Regulation (EU) No 528/2012: In accordance with the list of treatment substances and disinfection processes of paragraph 11 of the German Drinking Water Ordinance¹, the technical rules for dosing set out in the Deutscher Verein des Gas Wasserfaches e.V.²-working sheets W 229, W 296, W 623 and the minimum contact time of W 229 apply³. (See section 6 for further references)

Application rate(s) and frequency	Application Rate: 0,5 mg/l Active Chlorine (AC) as residual concentration in the system. Dilution (%): - Number and timing of application: Frequency: continuous dosing Adjustment applicable in the territory of the Federal Republic of Germany in accordance with Article 44(5) of Regulation (EU) No 528/2012: In accordance with the list of treatment substances and disinfection processes of paragraph 11 of the German Drinking Water Ordinance¹. (See section 6 for further reference)⁴. Application rate: maximum addition 1,2 mg/l free Cl₂; Concentration range after completion of treatment: maximum 0,3 mg/l free Cl₂, min 0,1 mg/L free Cl₂ (including the amounts before treatment and from other treatments) In exceptional cases an addition of up to 6 mg/l free Cl₂ and concentration up to 0,6 mg/l free Cl₂ after treatment is acceptable, if disinfection cannot be ensured by other means or if disinfection is temporarily impaired by the presence of ammonium.
Category(ies) of users	Professional
Pack sizes and packaging material	Cylinder: 4,8-140 l (6-175 kg Cl₂) Drum: 400-1 000 l (500-1 250 kg Cl₂) Railway tanks: 43 000-44 000 l (53 750-55 000 kg Cl₂) Carbon/stainless steel

4.3.1. Use-specific instructions for use

Connect the chlorine cylinder or drum to the automated, closed dosing system. Set up the parameters of the system to obtain a continuous active chlorine concentration in the water according to the application rate indicated above.

4.3.2. Use-specific risk mitigation measures

Ensure that the concentration of chlorine in the drinking water does not exceed national chlorine limit before consumption.

Ensure that the concentration of chlorate present in the drinking water does not exceed the parametric values set in (EU) Directive 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (recast) (OJ L 435, 23.12.2020, p. 1).

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 Section 5 General directions for use

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

See Section 5 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 Section 5 General directions for use

4.4. **Use description**

Table 4

Use # 4 – Disinfection of water in collective systems

Product type	PT05 – Drinking water (Disinfectants)
Where relevant, an exact description of the authorised use	/
Target organism(s) (including development stage)	Scientific name: bacteria Common name: Bacteria Development stage: Scientific name: viruses Common name: Viruses Development stage: Scientific name: legionella pneumophila Common name: Bacteria Development stage:
Field(s) of use	Indoor Outdoor In Public institutions, healthcare facilities Disinfection of drinking water in collective drinking water systems by continuous dosing
Application method(s)	Method: Closed system Detailed description: Automated dosing system Adjustment applicable in the territory of the Federal Republic of Germany in accordance with Article 44(5) of Regulation (EU) No 528/2012: In accordance with the list of treatment substances and disinfection processes of paragraph 11 of the German Drinking Water Ordinance, the requirements set out in the Deutscher Verein des Gas Wasserfaches e.V.² -working sheets W 229, W 296, W 623 and the minimum contact time of W 229 apply³. (See section 6 for further references)

Application rate(s) and frequency	Application Rate: 1 mg/l active chlorine (AC) as residual concentration in the system Dilution (%): - Number and timing of application: Frequency: continuous dosing Adjustment applicable in the territory of the Federal Republic of Germany in accordance with Article 44(5) of Regulation (EU) No 528/2012: In accordance with the list of treatment substances and disinfection processes of paragraph 11 of the German Drinking Water Ordinance¹. (See section 6 for further reference)⁴ Application rate: maximum addition 1,2 mg/l free Cl₂; Concentration range after completion of treatment: maximum 0,3 mg/l free Cl₂, min 0,1 mg/L free Cl₂ (including the amounts before treatment and from other treatments) In exceptional cases an addition of up to 6 mg/l free Cl₂ and concentration up to 0,6 mg/l free Cl₂ after treatment is acceptable, if disinfection cannot be ensured by other means or if disinfection is temporarily impaired by the presence of ammonium.
Category(ies) of users	Professional
Pack sizes and packaging material	Cylinder: 4,8-140 l (6-175 kg Cl₂) Drum: 400-1 000 l (500-1 250 kg Cl₂) Railway tanks: 43 000-44 000 l (53 750-55 000 kg Cl₂) Carbon/stainless steel

4.4.1. Use-specific instructions for use

Connect the chlorine cylinder or drum to the automated, closed dosing system. Set up the parameters of the system to obtain a continuous active chlorine concentration in the water according to the application rate indicated above.

4.4.2. Use-specific risk mitigation measures

Ensure that the concentration of chlorine in the drinking water does not exceed national chlorine limit before consumption.

Ensure that the concentration of chlorate present in the drinking water does not exceed the parametric values set in (EU) Directive 2020/2184 of 16 December 2020 on the quality of water intended for human consumption (recast) (OJ L 435, 23.12.2020, p. 1).

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 Section 5 General directions for use

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

See Section 5 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 Section 5 General directions for use

4.5. **Use description**

Table 5

Use # 5 – Disinfection of drinking water for animals

Product type	PT05 – Drinking water (Disinfectants)
Where relevant, an exact description of the authorised use	/
Target organism(s) (including development stage)	Scientific name: bacteria Common name: Bacteria Development stage: Scientific name: viruses Common name: Viruses Development stage:
Field(s) of use	Indoor Outdoor Disinfection of drinking water for animals (with water coming from tap water network) in agricultural areas, by continuous dosing.
Application method(s)	Method: Closed system Detailed description: Automated dosing system
Application rate(s) and frequency	Application Rate: 0,5 mg/l active chlorine (AC) as residual concentration in the system. Dilution (%): - Number and timing of application: Frequency: continuous dosing
Category(ies) of users	Professional
Pack sizes and packaging material	Cylinder: 4,8-140 l (6-175 kg Cl ₂) Drum: 400-1 000 l (500-1 250 kg Cl ₂) Railway tanks: 43 000-44 000 l (53 750-55 000 kg Cl ₂) Carbon/stainless steel

4.5.1. *Use-specific instructions for use*

Connect the chlorine cylinder or drum to the automated, closed dosing system. Set up the parameters of the system to obtain a continuous active chlorine concentration in the water according to the application rate indicated above.

4.5.2. *Use-specific risk mitigation measures*

For food commodities, ensure that the concentration of chlorate present in food does not exceed the MRL values set in Commission Regulation (EU) 2020/749 of 4 June 2020 amending Annex III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for chlorate in or on certain products (OJ L 178, 8.6.2020, p. 7).

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 Section 5 General directions for use

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

See Section 5 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 Section 5 General directions for use

5. **GENERAL DIRECTIONS FOR USE ⁽¹⁾**

5.1. **Instructions for use**

-

5.2. **Risk mitigation measures**

For connecting or disconnecting the product containers as well as for maintenance or repair of the gas pipe system, the following risk mitigation measures (RMMs) are mandatory:

- an alarm system (trigger value corresponding to the acute exposure concentration (AEC): 0,5 mg active chlorine/m³ (or lower according to national legislation) which initiates safety procedures like wearing respiratory protective equipment (RPE) according to CEN standard EN14387: Respiratory protective devices – Gas filter(s) and combined filter(s) – Requirements, testing, marking (or equivalent);
- application of local exhaust ventilation (LEV) (according to the national legislation) and low-pressure/vacuum are in place to avoid chlorine emission;
- the electrochemical sensors used for measurements to detect various chlorinated species in addition to chlorine itself;
- sensors to measure exposure also when the operators are using RPE according to CEN standard EN141 or equivalent.

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

Avoid breathing this toxic gas as much as possible. IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. Immediately call 112/ambulance for medical assistance.

Information for healthcare personnel/doctor:

Immediately initiate life support measures, thereafter call a POISON CENTRE.

IF SWALLOWED: Not applicable.

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

IF ON SKIN: Take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation occurs: Get medical advice.

IF IN EYES: Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing for 5 minutes. Call a POISON CENTRE or a doctor.

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

At the end of the treatment, dispose of unused product and the packaging in accordance with local requirements.

Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets...) or down the drains.

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

Storage conditions:

Airtight pressure tanks: Due to its chemical and physical properties, chlorine gas is always stored in dedicated carbon/steel recipients with special, dedicated valves. Chlorine packages for use within the EU should be constructed and labelled according to Directive 2010/35/EU of the European Parliament and of the Council⁵ and the Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) done at Geneva on 30 September 1957. See section 6 for further reference. Maximum filling 1,25 kg/l (80 % of volume approx.).

Keep containers with chlorine tightly closed and store in a cool, dry and well-ventilated place. Tightly screw on the valve outlet protection seal and the valve protection cap when storing. Prevent cylinders from falling over. Protect from heat and direct sunlight, the temperature of the container should never be below 15 °C or above 50 °C.

Chlorine should be kept away from reactive products (materials to avoid: reducing agents, combustible materials, metals in powder, acetylene, hydrogen, ammonia, hydrocarbons and organic materials).

6. OTHER INFORMATION

With respect to the 'Category(ies) of users' note:

Professionals (including industrial users) means trained professionals if this is required by national legislation.

¹ German Drinking Water Ordinance: Trinkwasserverordnung in der Fassung der Bekanntmachung vom 10. März 2016 (BGBl. I S. 459), die zuletzt durch Artikel 1 der Verordnung vom 22. September 2021 (BGBl. I S. 4343) geändert worden ist; list of treatment substances and disinfection processes of paragraph 11 of the German Drinking Water Ordinance: Bekanntmachung des Umweltbundesamtes der Liste der Aufbereitungsstoffe und Desinfektionsverfahren gemäß § 11 der Trinkwasserverordnung – 21. Änderung – (Stand: Dezember 2019).

² Deutscher Verein des Gas- und Wasserfaches e.V. (German Technical and Scientific Association for Gas and Water).

³ Part II, Lfd. Nr.4 of the list of treatment substances and disinfection processes of paragraph 11 of the German Drinking Water Ordinance.

⁴ Part I c, Lfd. Nr.2 of the list of treatment substances and disinfection processes of paragraph 11 of the German Drinking Water Ordinance.

⁵ Directive 2010/35/EU of the European Parliament and of the Council of 16 June 2010 on transportable pressure equipment and repealing Council Directives 76/767/EEC, 84/525/EEC, 84/526/EEC, 84/527/EEC and 1999/36/EC (OJ L 165, 30.6.2010, p. 1).

CORRIGENDA**Corrigendum to Council Decision (CFSP) 2023/432 of 25 February 2023 amending Decision 2014/145/CFSP concerning restrictive measures in respect of actions undermining or threatening the territorial integrity, sovereignty and independence of Ukraine**

(Official Journal of the European Union L 59 I of 25 February 2023)

On pages 533 to 582, in the Annex, in the table under the heading 'Entities', entries 175 to 208 are renumbered as entries 176 to 209.

**Corrigendum to Council Implementing Regulation (EU) 2023/429 of 25 February 2023
implementing Regulation (EU) No 269/2014 concerning restrictive measures in respect of actions
undermining or threatening the territorial integrity, sovereignty and independence of Ukraine**

(Official Journal of the European Union L 59 I of 25 February 2023)

On pages 373 to 422, in the Annex, in the table under the heading 'Entities', entries 175 to 208 are renumbered as entries 176 to 209.

Corrigendum to Commission Implementing Regulation (EU) 2023/453 of 2 March 2023 extending the definitive anti-dumping duty imposed by Implementing Regulation (EU) 2017/141 on imports of certain stainless steel tube and pipe butt-welding fittings, whether or not finished, originating in the People's Republic of China to imports of certain stainless steel tube and pipe butt-welding fittings, whether or not finished, consigned from Malaysia, whether declared as originating in Malaysia or not

(Official Journal of the European Union L 67 of 3 March 2023)

On page 35, in Article 1(2):

for:

‘The extension of the duty mentioned in paragraph 1 does not apply to the companies listed below:

Country	Company	TARIC additional code
Malaysia	Pantech Stainless And Alloy Industries Sdn. Bhd	A021
Malaysia	SPI United Sdn. Bhd	A022’

read:

‘The extension of the duty mentioned in paragraph 1 does not apply to the companies listed below:

Country	Company	TARIC additional code
Malaysia	Pantech Stainless And Alloy Industries Sdn. Bhd.	A021
Malaysia	SP United Industry Sdn. Bhd.	A022’

**Corrigendum to Commission Implementing Regulation (EU) 2023/254 of 6 February 2023 amending
Implementing Regulation (EU) 2020/761 as regards certain technical rules on the management of
tariff rate quotas**

(Official Journal of the European Union L 35 of 7 February 2023)

On page 6, in Article 2, third paragraph, point (a):

- for:* '(a) Article 1(2), points (3)(b)(i) and (ii), and (3)(c)(i) and (ii), and point (6) of the Annex shall apply as from the first day of 90-day period after the publication of this Regulation in the *Official Journal of the European Union* or, where applicable, to the first application period opening after that period;'
- read:* '(a) Article 1(2), points (3)(b)(i) and (ii), and (3)(c)(i) and (ii), and point (6) of the Annex shall apply as from the first day after the 90-day period that follows the publication of this Regulation in the *Official Journal of the European Union* or, where applicable, to the first application period opening after that period;'
-

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