Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)

YODICAMP ORDEÑO

Product type(s) 3

PVP IODINE as included in the Union list of approved active substances

Case Number in R4BP: **BC-TY019734-97**

Evaluating Competent Authority: SPAIN

Date: October 2023

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1 CONCLUSION

Physical-chemical properties and Analytical Methods

The product YODICAMP ORDEÑO is an aqueous soluble liquid (SL) based on PVP-Iodine for cleaning, disinfection and sealing of the udder and teat hole before and after dairy cows, ewes, goats and other lactating females. It is a brown liquid with a very weak characteristic odour. It has a pH between 3.0-5.0.

This product is stable at low-temperature storage (0ºC for 7 days), at high-tempeature storage conditions (54ºC for 2 weeks) and room temperature storage, thus a self-life of 2 year is granted.

Furthermore, it does not need to be classified regarding physical and chemical hazards as it is not flammable, not oxidising or explosive and does not self-ignite.

Regarding analytical methods, volumetric thiosulfate method for the determination of available iodine in the biocidal product is acceptable.

Efficacy against target organisms

The assessment concludes that the product is efficacious at 8% (v/v) dilution in water for pre-milking teat disinfection, at clean conditions, and from 20% (v/v) dilution for post-milking teat disinfection.

Label instructions should state that cleaning prior to disinfection is necessary on pre-milking application.

The users should inform if the treatment is ineffective and report straightforward to the registration holder.

Human health

Yodicamp Ordeño contains Iodine (CAS 7553-56-2) that is used in biocidal products for the disinfection of animals' teats/udder and animal houses. In the products type 3, iodine is complexed with Polyvinylpyrrolidone (iodophor type 2).

The following substances of concern (SoC) were identified in this product:

- Alkyl alcohol C9-C11, ethoxylated (CAS 68439-46-3) <> Ethoxylated fatty alcohol
- 2-(2-butoxyethoxy) ethanol (CAS 112-34-5) <> Butyldiglycol

A human health risk assessment has been carried out for professional use of the product for all intended uses taken into account both the active substance and the identified SoCs.

In accordance with Article 15(2) of Regulation (EU) No 528/2012 of the European Parliament and of the Council 22 May 2012 concerning the making available on the market and use of biocidal products, the Biocidal Products Committee (BPC) has adopted this opinion on the review of approval of the active substance iodine and polyvinylpyrrolidone iodine. These substances are identified as having endocrine-disrupting properties.

Therefore, the active substance iodine (including PVP-iodine) does meet the exclusion criteria according to Article 5(1 d) BPR, the following exclusion criteria met; has endocrine

disrupting properties. According to article 23 BPR, the evaluating competent authority (ES), will perform a comparative assessment as part of the evaluation of an application for authorisation of a biocidal product.

The **risk assessment for human health** takes into account HEAdhoc recommendation 13, and agreements from working group and WebEx meetings on iodine based union authorisation applications.

Professional user risk assessment

Due to local effects of the active substance and the SoCs, a qualitative local risk assessment has been performed. In addition, for the active substance and the SoC butyldiglycol the quantitative inhalation exposure has been assessed.

When only exposure arising from the biocidal use is considered, acceptable systemic exposure is identified for manual dipping without PPE. However, from local effects assessment, due to the classification of the product as H318 (Causes serious eye damage), the use of eye protection during handling of the product is mandatory.

When exposure arising from biocidal use and total dietary intake are considered, acceptable risks are identified for two post-milking disinfection per day by manual dipping or three post-milking disinfection by automated dipping.
Note: expected iodine residues in milk from two milking events per day for manual milking and from three events per day for automatic milking are considered comparable (conclusion reached at Secure Webex meeting 3-10-2017 for exposure to residues from iodine based union authorisation applications).

From the risk assessment approach, the safe use of the product does not require the use of gloves at any time, however, according to the CAR and the codes of good practice, for hygienic reasons it is standard practice to use at least gloves (in order to reduce the risk of possible cross contamination) and protective clothing.

Consumer risk assessment

Based on the risk assessment of consumers, taking into account only the effect from the use of the product, safe use is identified (adult 10.07% UL and toddler 30.88% of UL). However, when taken into account all iodine sources (i.e. including background values from milk and other dietary sources), the UL for toddlers is exceeded (i.e. 124.88% UL). In any case, the iodine intake that can be attributed to the use of the product is only a minor part of the total iodine intake. Exceedances of the UL are reported when worst case consumption values are used in the human health risk assessment, but these exceedances can for the larger part be attributed to the iodine intakes arising from background levels. The additional burden arising from teat disinfection is considered of no significant impact.
Considering the above, ES CA considers the exceedance of the UL for toddlers (i.e. 124.88%) taking into account teat disinfection and dietary intake acceptable.
Note: a more detailed argument has been developed in the section "Risk for consumers via residues in food", through the ES CA decision.

Explanatory note (only for Spain authorisation):

According to national legislation, in Spain there are three user categories:

• Trained professional users (TP): pest control operators, having received specific training in biocidal product uses according to the national legislation in force.
• Professional users (P): professionals that use the biocidal products in the context of their profession, that is not pest control operator, and that are unlikely to have received any specific training in biocidal product use according to the national legislation in force. It can be expected that they have some knowledge and skills handling chemicals (if they must use it in their job) and they are able to use correctly some kind of PPE if necessary.
• Non-professional users (NP): users who are not professionals and that apply the biocidal product in the context of their private life. (Note: this user has not been claimed by the applicant for this product).

The conclusions reached in this PAR, which affect the intermediate category of "Professional", will only be applicable at the Spanish level.

Environmental risk

Based on the available information related to the use of the product YODICAMP ORDEÑO, the environmental assessment is acceptable.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

Identifier of the product

Identifier	Country (if relevant)
YODICAMP ORDEÑO	SPAIN

Authorisation holder

Name and address of the authorisation holder	**Name**	PRODUCTOS QP S.A.
	Address	Ctra. Logroño, Km 10'2 50180 – UTEBO (Zaragoza) SPAIN
Authorisation number	ES/APP(NA)-2023-03-00894	
Date of the authorisation	20/10/2023	
Expiry date of the authorisation	20/10/2028	

Manufacturer(s) of the product

Name of manufacturer	PRODUCTOS QP S.A.
Address of manufacturer	Ctra. Logroño, Km 10'2 50180 – UTEBO (Zaragoza) SPAIN
Location of manufacturing sites	Ctra. Logroño, Km 10'2 50180 – UTEBO (Zaragoza) SPAIN

Manufacturer(s) of the active substance(s)

Active substance	POLYVINYLPYRROLIDONE IODINE (PVP-IODINE)
Name of manufacturer	Laboratorios Montplet, SLU
Address of manufacturer	Vía Trajana, 53-55 08020 - BARCELONA SPAIN
Location of manufacturing sites 1	ISP CHEMICALS LLC AFFILIATE OF ASHLAND 455 N. MAIN ST. (HWY 95) CALVERT CITY KY 42029 – USA Plant: 455 N. MAIN ST. (HWY 95), CALVERT CITY KY 42029 USA
Location of manufacturing sites 2	BASF Corporation P. O. Box 457 Geismar, LA 70734-0457 Plant:8404 River Road Geismar, LA 70734 - USA

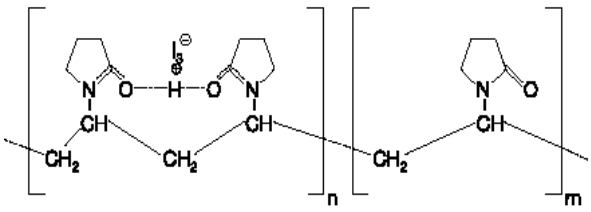
2.1.2 Product composition and formulation

NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

Yes ☐
No ☒X

Identity of the active substance

Main constituent(s)	
ISO name	Iodine
IUPAC or EC name	Iodine
EC number	231-442-4
CAS number	7553-56-2
Index number in Annex VI of CLP	053-001-00-3
Minimum purity / content	995 g/kg
Structural formula	I-I
Iodine is formulated as PVP-Iodine in the product.	
IUPAC Name	Polyvinylpyrrolidone iodine (common name PVP-iodine)
EC number	607-771-8
CAS number	25655-41-8
Minimum purity / content	For polyvinylpyrrolidone iodine: the iodine content shall have a purity of 995 g/kg
Structural formula	

Candidate(s) for substitution

In accordance with Article 15(2) of Regulation (EU) No 528/2012 of the European Parliament and of the Council 22 May 2012 concerning the making available on the market and use of biocidal products (BPR), in September 2022 the Biocidal Products Committee (BPC) concluded that iodine and polyvinylpyrrolidone iodine are considered as having endocrine-disrupting properties. However, the Commission has not yet adopted an Implementing Regulation amending the conditions of approval of the active substance. This is needed in accordance the second paragraph of art 15(1) of the BPR.
Therefore, the active substance iodine (including PVP-iodine) does meet the exclusion criteria according to Article 5(1 d) BPR having endocrine disrupting properties. According to

article 23 BPR, the evaluating competent authority (ES), will perform a comparative assessment as part of the evaluation of an application for authorisation of a biocidal product. In this way, since no alternative products are available in the Spanish market and the lack of products for teat disinfection may cause a danger to public health and/or animal health these products are authorised.

Qualitative and quantitative information on the composition of the biocidal product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
PVP Iodine Iodine	Polyvinylpyrrolidone Iodine	Active substance	25655-41-8	607-771-8	2.2% 0.20-0.25% *
Ethoxylated fatty alcohol	Alkyl alcohol, C9-C11, ethoxylated	Non-Active substance	68439-46-3	614-482-0	1,8%
Butyl diglycol	2-(2-butoxyethoxy)ethanol	Non-Active substance	112-34-5	203-961-6	3.5%

Details of the full product composition and **information on the co-formulants are confidential** and are presented in the confidential part of the dossier.

*The manufacturer of BP (applicant) declares that enough PVP-Iodine is added to the product formulation to have available iodine in the range of 0,20-0,25%.

Taking into account the above and the results of the analysis of available iodine in the last 10 manufactured batches of YODICAMP ORDEÑO (see confidential annex), the product contains an average of 0,22% of free iodine that corresponds to an average of 2.2% of PVP-Iodine added to the formulation

Information on technical equivalence

All sources, except two, of Iodine (including PVP-iodine) are the same as evaluated for inclusion in the Union list of approved substances.
The sources of Iodine described in Location manufacturing sites 5 and 6 are Technical Equivalences:

(1)– Source of Location manufacturing 5 – Asset number: EU-0012901-0000
(2)– Source of Location manufacturing 6 – Asset number: EU-0012442-0000

Information on the substance(s) of concern

The following substances of concern (SoC) were identificated:

- **Alkyl alcohol, C9-C11, ethoxylated (CAS: 68439-46-3)**

Identification is based on the classification of the substance of concern; Eye Dam. 1, its concentration in the biocidal product and its contribution to the classification of the biocidal products as Eye Dam. 1.
This Substances of Concern together with the active substance, trigger the classification of the product for Eye Damage Category 1 (H318).
According to the guidance on the Identification and evaluation of substances of concern (SoCs) in relation to human health (toxicological) endpoints, CA-Nov14-Doc.5.11, this SoC contained in the product should be allocated in Band B. Associated evaluation and risk management requirements according to the SoC banding approach for Band B are limited to a "Qualitative exposure and risk assessment to determine whether S-phrases/P-

statements normally associated with concerned R-phrases/H statements are sufficient or whether other risk mitigation measures should be applied". This has been accounted for and addressed in the respective parts of this PAR.

- **2-(2-butoxyethoxy)ethanol (CAS: 112-34-5) <>Butyldiglycol**

The CLP harmonised classification of this substance of concern is Eye Irrit. 2 (causes serious eye irritation), a category that could be considered covered by the final classification of the product.
However, according to the Guidance on the Biocidal Product Regulation (Volume III Human Health–Part B and C Risk Assessment–Version 4.0–December2017), butyldiglycol should be considered as a Substance of Concern (SoC), as there is available European Union-agreed Occupational Exposure Limit (OEL). The long-term (8 hours) occupational exposure limit (LTEL) of butyldiglycol is 67.5 mg/m^3 <> 10 ppm and the short-term occupational exposure limit (STEL) is 101.2 mg/m^3 <> 15 ppm. There is no skin notation.

Type of formulation

SL – Soluble Liquid

2.1.3 Hazard and precautionary statements

Classification and labelling of the product according to the Regulation (EC) 1272/2008

Classification	
Hazard category	Eye Dam. 1, Aquatic Chronic 3
Hazard statement	H318, H412
Labelling	
Signal words	Danger
Pictograms	 GHS05
Hazard statements	H318: Causes serious eye damage H412: Harmful to aquatic life with long lasting effects
Precautionary statements	P280 Wear protective gloves/protective clothing/eye protection. P273: Avoid release to the environment. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing P310 Immediately call a POISON CENTER or doctor/physician. P501: Dispose of contents/container as hazardous waste to a registered establishment or undertaking, in accordance with current regulations.

*ES CA will apply article 37 according to BPR in the authorisation of this product including in this section the P statements that are recommended and highly recommended according to the result of the risk assessment of the product and considering the Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008 (Version 4.2 March 2021).

2.1.4 Authorised use(s)

Use description

Table 1. Use # 1 – Teats disinfection

Product Type	PT03 – Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	BP for external topic use for cleaning, disinfecting and sealing of the udder/teat hole **before and after milking**, providing a protective barrier against the entry of germs into the udder through the teat hole, protecting and softening the skin and mucous membranes. Indicated for topical use in dairy cows, ewes, goats and other lactating females.
Target organism (including development stage)	Bacteria Yeast
Field of use	Indoor
Application method(s)	Manual or automatic by **dipping** with a 8% BP dilution for cleaning and disinfecting teats/udder before milking and manual or automatic by dipping with pure BP after milking
Application rate(s) and frequency	For daily cows: 4 ml/cow/event of 8% (v/v) dilution of BP in water **before milking** and 4 ml/cow/event of pure BP **after milking** (1 ml per teat/cow/event x 4 teat/cow) For goats and ewes: 2 ml/animal/event of 8% (v/v) dilution of BP in water **before milking** and 2 ml/animal/event of pure BP **after milking** (1 ml per teat/animal/event x 2 teat/animal) The frequency of application is: 2 events/day for manual milking and 3 events/day for milking systems for dairy cows, and 1 application per day for ewes or goats.
Category(ies) of users	Professional and trained professional
Pack sizes and packaging material	Jerry can; 5, 10, 20 and 25 L. Plastic HDPE Drum; 60 and 200L. Plastic HDPE, with tap. IBC / intermediate bulk container; 1000L. Plastic HDPE, with tap.

2.1.4.1 Use-specific instructions for use

See section 2.1.5.1.

2.1.4.2 Use-specific risk mitigation measures

See section 2.1.5.2.

2.1.4.3 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 2.1.5.3.

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

See section 2.1.5.4.

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

See section 2.1.5.5.

2.1.5 General directions for use

2.1.5.1 Instructions for use

This BP is specially formulated to be applied for cleaning, disinfection and sealing of the udder/teat hole before and after milking. It is indicated for dairy cow, ewes, goats and other lactating females.

Apply the product by dipping, before and after milking.

The frequency of application is:
- For daily cows: 2 events/day for manual milking and 3 events/day for milking systems
- For goats and ewes, 1 application/day for ewes or goats (that only have 2 teats).

Codes of good practice should be followed. In this sense, for hygienic reasons it is standard practice to use at least gloves (in order to reduce the risk of possible cross contamination) and protective clothing.

Before milking. If the udder is cleaned with water before milking to remove dirty scabs, the teat must be neat and dry with a cloth or paper towel before pre-milking treatment.

Pre-milking Teat Dipping: cleaning the teat and then disinfect them by dipping with dip cup containing 20-25 ml of 8% (v/v) BP dilution (one cup with 20-25 ml is used for approximately 5-6 cows, or 10-12 goats or ewes). Contact time of 30 seconds is needed for effective disinfection. Then, dry the teat hole with an individual cloth or paper towel before milking, and stripping 4-5 squirts of milk from each udder before attach milking units to cow, to remove foremilk which may have high iodine content and also may serve as the primary stimulus for milk let-down.

After milking, remove with a paper or cloth towel all organic debris from teats before applying post-milking teat dipping. Teat dipping is the single most effective practice for reducing infections, especially by contagious bacteria. Dipping all teats after each milking in a sanitizing solution has a greater impact on reduction of milk somatic cell counts and increased milk yields than any other milking practice. Effective teat dips should destroy microorganisms present on teats at the end of milking. This prevents bacteria from establishing a colony at the teat end or in teat lesions where they could penetrate the

teat canal and infect it. In addition, a good teat dip should leave a residue on the teat so the antimicrobial action is still present when the cow lies down in a free stall or any other place where sanitary conditions are less than ideal. Effective teat dips reduce new udder infections by 50 to 90%. As soon as the milking units are removed, dip teats in the BP solution that is intended for teat dipping.

Post-milking Teat Dipping: Cover the entire teat with dip cup containing 20-25 ml of pure BP (one cup with 20-25 ml is used for approximately 5-6 cows, or 10-12 goats and ewes). Once the teats are dipped, the operator slightly moves the teats to allow the formation of a droplet on the sphincter at the basis of the teat. This is the crucial place to be protected since it is the entry point of the contaminants.
Keep the cows in the milking parlour and let the product dry on the udder, making sure that the animal does not lie down until the product has dried, at least 5 min. (contact time)
The **frequency of application is**:
- For daily cows: 2 events/day for manual milking and 3 events/day for milking systems
- For goats and ewes, 1 application/day for ewes or goats (that only have 2 teats).
Leave the product until next milking. Keep the cows standing until the product has dried (at least 5 min).

2.1.5.2 Risk mitigation measures

Avoid eye and skin contact.
The use of eye protection during handling of the product is mandatory.
the safe use of the product does not require the use of gloves at any time, however, according to the CAR, for hygienic reasons it is standard practice to use at least gloves (in order to reduce the risk of possible cross contamination) and protective clothing.
Wash hands thoroughly after use.
Do not eat, drink or smoke when using this product.
Avoid release to the environment.

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

IF INHALED: if symptoms occur call a POISON CENTRE or a doctor.
IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow.Do NOT induce vomiting. Call 112/ambulance for medical assistance
IF ON SKIN: Immediately wash skin with plenty of water.Thereafter take off all contaminated cloting and wash it before reuse. Continue to wash the skin with water for 15 minutes, Call a POISON CENTRE or a doctor.
IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rising for least 15 minutes. Call 112/ambulance for medical assistance.

Information to Healthcare personnel/doctor:
The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid

Environmental precautions:
Absorb the spillage using sand or inert absorbent and move it to a safe place. Do not absorb in sawdust or other combustible absorbents.

Avoid spillage into an aqueous medium as it contains substances potentially dangerous for this. Contain the product absorbed in hermetically sealed containers. In the case of serious spillage into an aqueous medium notify the relevant authorities.

2.1.5.4 Instructions for safe disposal of the product and its packaging

In Spain:
Empty containers, unused product, washing water, containers and other waste generated during the treatment are considered hazardous waste. Deliver those wastes to a registered establishment or undertaking, in accordance with current regulations.

Code the waste according to Decision 2014/955 / EU.

Do not release to soil, ground, surface water or any kind of sewer.

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

Store it protected from direct sunlightand in a dry, cool and ventilated place. Avoid contact with food or feed.
Keep container tightly closed. Store in the original containers and away from incompatible or reactive products.
Shelf life: 2 years

2.1.6 Other information

Definitions:

Professional: User applying biocidal products in the workplace. This user has some knowledge and skills in the handling of chemicals, and is able to correctly use personal protective equipment (PPE) if necessary.
Trained professional: pest control operators, having received specific training in disinfectants according to the national legislation in force.

2.1.7 Packaging of the biocidal product

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
Jerry can	5L, 10L, 20L,25L	Plastic: HDPE	Plastic: HDPE	Professional and trained professional	yes
Drum	60L, 200L	Plastic: HDPE	Plastic: HDPE (with tap)	Professional and trained professional	yes
IBC / (intermediate bulk container)	1000L	Plastic: HDPE	Plastic: HDPE (with tap)	Professional and trained professional	yes

Description and safety of the packaging: opaque HDPE that does not let pass light, homologated for ADR/IMDG/IATA transport

2.1.8 Documentation

Data submitted in relation to product application

The reference list (including updates) for the studies submitted have been included in Annex 3 whilst the reference list for the studies considered confidential has been included in the PAR confidential.

Access to documentation

Productos QP, S.A. has submitted a Letter of access from Laboratorios Montplet S.L.U. (former Alcoholes Montplet S.A.) to Iodine (including PVP Iodine) Data, as participant for Iodine under the review programme of Directive 98/8/EC.
The sources of Iodine used and included in PVP-Iodine for the production of biocidal product YODICAMP ORDEÑO has been declared by Alcoholes Montplet S.L.U.

2.2. Assessment of the biocidal product

2.2.1 Intended use(s) as applied for by the applicant

Table 1. Use # 1 – Pre-milking and post-milking teat disinfection by dipping

Product Type(s)	PT03 – Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	BP for external topic use for cleaning, disinfecting and sealing of the udder/teat hole before and after milking, providing a protective barrier against the entry of germs into the udder through the teat hole, protecting and softening the skin and mucous membranes. Indicated for topical use in dairy cows, ewes, goats and other lactating females.
Target organism (including development stage)	Bacteria aerobic gram-positive and gram-negative, and yeasts
Field of use	Indoor
Application method(s)	Manual or automatic by dipping with a 8% BP dilution for cleaning and disinfecting teats/udder before milking and manual or automatic with pure BP in dipping cups after milking
Application rate(s) and frequency	For daily cows: 4 ml/cow/event of 8% (v/v) dilution of BP in water before milking and 4 ml/cow/event of pure BP after milking (1 ml per teat/cow/event x 4 teat/cow), and 2 events/day For goats and ewes: 2 ml/animal/event of 8% (v/v) dilution of BP in water before milking and 2 ml/animal/event of pure BP after milking (1 ml per teat/cow/event x 2 teat/animal), and 1 events/day
Category(ies) of user(s)	Professional and trained professional

Pack sizes and packaging material	Jerry can 5L,10L, 20L y 25L Drum 60L y 200L IBC / (intermediate bulk container) 1000L

2.2.2 Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual	-	Liquid	-
Colour at 20 °C and 101.3 kPa	Visual	-	Brown	-
Odour at 20 °C and 101.3 kPa	Visual	-	Characteristic iodine odour	-
pH Acidity / alkalinity	CIPAC MT 75.3 CIPAC MT 191	0.2**5**% Iodine	pH (100%) = 4.24 pH (1%) = 4.97 Acidity: 0.034% as H_2SO_4	2.2.2 15-4885-02
Relative density / bulk density	CIPAC MT 41.1	0.25% Iodine	1.0154 g/mL	15-4885-02
Storage stability test – **accelerated storage**	CIPAC MT.46	0.25% Iodine	$[C]_0$ = 0.215% $[C]_f$ = 0.202% Δ[C] = -6.04% Stable after storing it 14 days at 54°C.	2.2.2 15-4885-02
Storage stability test – **long term storage at ambient temperature**		0.25% Iodine	$[C]_0$ = 0.253% $[C]_{3m}$ = 0.245% Δ[C] = -3.16% $[C]_{6m}$ = 0.247% Δ[C] = -2.37% $[C]_{12m}$ = 0.229% Δ[C] = -9.49% $[C]_{18m}$ = 0.223% Δ[C] = -11.86% $[C]_{24m}$ = 0.228% Δ[C] = -9.88% Regarding to the appearance is a brown liquid and no separation is observed. Acceptable results after 2 years of storing at room temperature.	2.2.2 16-4885-01 (24 months report)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Storage stability test – **low temperature stability test for liquids**	CIPAC MT 39.3	0.25% Iodine	Temperature: 0°C Time: 7 days The sample is homogeneous. There is not separation of phases or crystalized material.	2.2.2 15-4885-02
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	-	-	The PVP Iodine is a complex which stabilizes the iodo, therefore it is considered more stable to the effect of light. On the other hand, according to the Assesment report of Iodo/PVP Iodine, in water solution coexist, I_2 , I^- and IO_3^-, being able to form photolitically I_2 from I^- and IO_3^- so it can be considered that the effect of light could be positive. However, as a precaution, it is going to be included in the label the sentence "Store it protected from direct sunlight"	-
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**		0.25% Iodine	Temperature: After evaluating the results obtained in the accelerated storage stability test it can be conclude that the temperature does not produce a negative effect in the active substance. Humidity: It is a water solution therefore, humidity is not going to influence in the physico-chemical characteristics of the biocidal product.	2.2.2 15-4885-02

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	GIFAP monograph 17 (Coprofile 2009)	Batch: 220216 0.25% Iodine	No changes were observed in the orginal container after storing it for 24 months at 25°C	2.2.2 16-4885-01 (Long-term stability test – 24 months report)
Wettability	-	-	Not applicable ((the product is an aqueous solution, SL)	
Suspensibility, spontaneity and dispersion stability			Not applicable ((the product is an aqueous solution, SL)	
Wet sieve analysis and dry sieve test			Not applicable ((the product is an aqueous solution, SL)	
Emulsifiability, re-emulsifiability and emulsion stability			Not applicable ((the product is an aqueous solution, SL)	
Disintegration time			Not applicable ((the product is an aqueous solution, SL)	
Particle size distribution, content of dust/fines, attrition, friability			Not applicable ((the product is an aqueous solution, SL)	
Persistent foaming	CIPAC MT 47.2	Batch: 101115 0.25% Iodine	Water D Rep 1 after 1 min: 98 mL Rep 2 after 1 min: 97 mL The biocidal product contains 1.8% of surfactant as adjuvant of the formulation. It helps the wettability of the biocidal product and therefore favours the cleaning of the udders. So, the presence of this surfactant explains the foam in the test (>60 ml after 1 min). However, it is really applied directly on the udders by dipping. The product won't be stirred or sprayed so the possibility of	2.2.2 15-4885-02

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			forming foam that could cause risk to the operator or animal is very low.	
Flowability/Pourability /Dustability	-	-	Not applicable (the product is an aqueous solution, SL)	-
Burning rate — smoke generators	-	-	Not applicable	-
Burning completeness — smoke generators	-	-	Not applicable	-
Composition of smoke — smoke generators	-	-	Not applicable	-
Spraying pattern — aerosols	-	-	Not applicable	-
Physical compatibility	-	-	This product is not intended to be used with other chemicals products	-
Chemical compatibility	-	-	Incompatible with reducing agents and alkaline metals.	-
Degree of dissolution and dilution stability	CIPAC MT 41.1	Batch: 101115 0.25% Iodine	Completely soluble and dilution stable at use dilution of 3% Rep 1 and Rep 2 after 24 h: Clear solution. There is not separated material	2.2.2 15-4885-02
Surface tension	Ring method EEC A5	Batch: 101115 0.25% Iodine	28.9 mN/m	2.2.2 15-4885-02
Dynamic Viscosity (at 20ºC)	CIPAC MT 192 OECD 114	Lote: 101115 Iodine: 0.25% Iodine	2.83 mPa.s (at 200 rpm)	2.2.2 15-4885-02
Dynamic Viscosity (at 20ºC and 40ºC)	OECD 114 with a capillary viscosimeter	Lote: 030222 Iodine: 0.25%	2.1 mPa.s (at 20ºC) 1.5 mPa.s (at 40ºC)	2.2.2 Cert 013-22

Table 2.2.2-1 Physical-Chemical properties and Accelerated storage data (Batch: 101115)

	Method	Initial	After 14 days at 54ºC
Active Substance content as Iodine (I_2)	CIPAC 44/TC/M/3.2 *(Volumetric Thiosulphate Method)*	0.215 % w/w (Lote: 101115)	0.202 % w/w

Appearance	Visual	Brown liquid with a very weak characteristic odour	Brown liquid with a very weak characteristic odour
Density (at 20ºC)	CIPAC MT 3	1.0154 g/ml	1.0152 g/ml
Acidity	CIPAC MT 191	0.034% as H2SO4	0.043% as H2SO4
pH (100%, at 22.6ºC)	CIPAC MT 75.3	4.24	3.34
pH (1%, at 22.8ºC)	CIPAC MT 75.3	4.97	4.63
Dilution Stability (*at máx. use dilution of 3% in CIPAC D water)*	CIPAC MT 41.1	no separation observed	no separation observed
Persistent foaming (*at máx. use dilution of 3% in CIPAC D water)*	CIPAC MT 47.2	96-98 ml foam after 3 min and 12 min (*100 ml foam after 10s)*	98-100 ml foam after 3 min and 75-94 ml foam after 12 min (*100 ml foam after 10s)*
Surface tension (at 20ºC)	Ring method EEC A5	28.9 mN/m	-
Dynamic Viscosity (at 20ºC)	CIPAC MT 192 OECD 114	2.83 mPa.s (at 200 rpm)	-

Table 2.2.2-2 Stability to low temperature storage (Batch: 101115)

	Method	**Initial**	**After 7 days at 0ºC**
SL stability	CIPAC MT 39.3	-	no phase separation or crystallization is observed

Table 2.2.2-3 Stability to long term storage at ambient temperature (Batch: 220216)

	Active Substance content as Iodine (I_2)	**Appearance**	**Density (at 20ºC)**	**pH (100%)**	**pH (1%)**
Method	CIPAC 44/TC/M/3.2 *(Volumetric Thiosulphate Method)*	Visual	CIPAC MT 3	CIPAC MT 75.3	CIPAC MT 75.3
Initial 0 months at 25ºC	0.253 % w/w	Brown liquid with no separation observed	1.0164 g/ml	4.65	5.93
After 3 months at 25ºC	0.245 % w/w	Brown liquid with no separation observed	1.0162 g/ml	3.87	5.36
After 6 months at 25ºC	0.247 % w/w	Brown liquid with no separation observed	1.0164 g/ml	3.57	5.23
After 12 months at 25ºC	0.229 % w/w	Brown liquid with no separation observed	1.0163 g/ml	3.53	5.42
After 18 months at 25ºC	0.223 % w/w	Brown liquid with no separation observed	1.0161 g/ml	3.32	5.48
After 24 months at 25ºC	0.228 % w/w	Brown liquid with no separation observed	1.0162 g/ml	3.358	5.42

Conclusion on the physical, chemical and technical properties of the product

The product YODICAMP ORDEÑO is an aqueous soluble liquid (SL) based on PVP-Iodine (2.2% w/w pure active, equivalent to 0.20-0.25% w/w as iodine) for cleaning, disinfection and sealing of the udder and teat hole before and after dairy cows, ewes, goats and other lactating females. It is a brown liquid with a very weak characteristic odour and foaming.

The pH 4.24 (100%) and 4.97 (1%).

This product is stable at low-temperature storage (0ºC for 7 days), at high tempeature accelerate storage conditions (54ºC for 2 weeks) and room temperature storage, thus a self-life storage stability of 2 year is granted (% loss AS <10%).

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	-	-	None of the components of the product are explosive. Therefore, it is safe to assume the product itself will not be explosive.	-
Flammable gases	-	-	The product is water based; therefore, it is not expected to release flammable gas	-
Flammable aerosols	-	-	Not applicable	-
Oxidising gases	-	-	Not applicable	-
Gases under pressure	-	-	Not applicable	-
Flammable liquids	-	-	None of the components of the product are classified as flammable. Therefore, it is safe to assume the product itself will not be flammable.	-
Flammable solids	-	-	Not applicable	-
Self-reactive substances and mixtures	-	-	Not applicable	-
Pyrophoric liquids	-	-	The product is water based, therefore it is not expected to have pyrophoric properties.	-
Pyrophoric solids	-	-	Not applicable	-
Self-heating substances and mixtures	-	-	Not applicable	-
Substances and mixtures which in contact with water emit flammable gases	-	-	The product is water based, therefore it is not expected that in contact with water, release flammable gas.	-
Oxidising liquids	-	-	None of the components of the product are oxidising. Therefore, it is safe to assume the product itself will not be oxidising.	-
Oxidising solids	-	-	Not applicable	-
Organic peroxides	-	-	Not applicable	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Corrosive to metals	Exemption of UN Test C.1 (By extrapo-lation of the results of the UN Test C.1. of a similar product)	MAMICAMP SELLADOR Lote: 090222 PVP-Iodine: 2.5%	This test was already carried out for the product MAMICAMP SELLADOR, which has a higher concentration of available iodine than YODICAMP ORDEÑO, and with co-formulants of a similar chemical nature (non-corrosive to metals). Said corrosivity test for metals, showed that the MAMICAP SELLADOR product is not corrosive for metals according to the method UN Test C.1 at 7 days, being the worst case due to having a higher concentration of available Iodine, and so, it is foreseeable that YODICAMP ORDEÑO turns out to be non-corrosive to metals too. Therefore, taking into account the concentrations and similar chemical nature of the components that are part of both biocidal products, the conclusions from MAMICAMP SELLADOR can be extrapolate to this BP, and it is concluded that YODICAMP ORDEÑO is not corrosive to metals. Not corrosive to steel (max weight loss 4.0% in 7 days) nor aluminium (max weight loss 0.5% in 7 days).	2.2.2 Report nº S3016011253R1 (2022)
Auto-ignition temperatures of products (liquids and gases)	-	-	None of the components of the product is self-igniting. Therefore, it safe to assume the product itself will not be self igniting.	-
Relative self-ignition temperature for solids	-	-	Not applicable	-
Dust explosion hazard	-	-	Not applicable	-

Conclusion on the physical hazards and respective characteristics of the product
The biocidal product does not need to be classified regarding physical and chemical hazards as it is not corrosive to metal, not flammable, not oxidising or explosive and does not self-ignite.

2.2.4 Methods for detection and identification

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Active Substance (as available iodine)	Volumetric thiosulphate method	30-200% (6 measurements)	y = 0.0441 + 0.9693x (R^2=0.9999)	Not specific for I_2	98-102 %	100 %	1 %		IUCLID 5

Principle of method and LOQ:
El PVP-Iodine content is not directly determined but calculated from total available Iodine (I_2). Total available iodine content can be determined by various well-known methods such as volumetric thiosulphate method (European Pharmacopeia, 5th Edition).
Samples are diluted with water and hydrochloric acid, and the available iodine obtained is volumetrically determined with sodium thiosulfate 0.1N. This method was validated according to SANCO/3030/99 rev.4.

Conclusion on the methods for detection and identificationof the product
Adequate methodology exists for the determination of the active substance, as available Iodine (I_2), in the biocidal product: The volumetric thiosulfate method for the determination of available iodine in the biocidal product is validated.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

It is declared that the biocide product contains PVP-Iodine to have available iodine in the range of 0,20-0,25%.

Field of use:
MG01: Disinfectants.
PT3: Veterinary hygiene - Teat disinfection of milk producing animals
Indoor use
This product is used by professional users for disinfecting the udder/teat hole before and after milking, providing a protective barrier against the entry of germs (bacteria and yeast) into the udder through the teat hole.
Indicated for topical use in dairy cows, ewes, goats and other lactating females.

The BP can be applied by dipping (manually or automatically) with an 8% v/v BP dilution in pre-milking or/and dipping (manually or automatically) with the pure BP in post-milking.
For manual dipping special dip cups are used.

2.2.5.2 Organisms to be controlled and products, organisms or objects to be protected

The product is used to control bacteria, such as *Escherichia coli, Staphylococcus aureus* and *Streptococcus uberis,* and yeast as *Candida albicans* in the pre or post-milking process of lactating animals.

2.2.5.3 Effects on target organisms, including unacceptable suffering

The product is intended to produce a reduction in the number of viable bacterial cells (bactericidal activity) and of yeast cells (yeasticidal activity) of relevant test organisms under defined conditions according to the EN 14885.

The unacceptable suffering has not been possible to assess.

2.2.5.4 Mode of action, including time delay

Available iodine is the active form. It has a high germicidal power, even at low concentrations. The action of iodine is rapid and lasts several hours. It is combined with carbohydrates and bacterial lipids and oxidizes them (binds to C = C bonds of fatty acids). Also precipitates bacterial proteins and nucleic acids, thus killing the microorganism. In proteins binds to N-H, S-H bonds and phenols, being the oxidation of S-H bonds very fast and irreversible.
The mode of action of iodine is non-selective and is based on the following mechanisms:

- Iodine rapidly penetrates into microorganisms showing a high affinity pattern of adsorption.
- Iodine combines with protein substances in the bacterial cell; these could be peptidoglycans in the cell walls or enzymes in the cytoplasm. This results in irreversible coagulation of the protein and consequent loss of function.
- Iodine is known to act on thiol groups in the cell, if a thiol enzyme is part of a metabolic chain then metabolic inhibition will result.
- Iodine reacts with key groups of proteins, in particular the free-sulphur amino acids cysteine and methionine, nucleotides and fatty acids.
- Iodine interferes at the level of the respiratory chain of the aerobic microorganisms by blocking the transport of electrons through electrophilic reactions with the enzymes of the respiratory chain.

The rapid penetration of iodine into microorganisms and its mode of action indicate that the time-delay i.e. contact time required for sufficient efficacy depends on the tolerance of the organism to iodine and the concentration of iodine used for treatment. Iodine is more effective at higher temperatures.

2.2.5.5 Efficacy data

Pre-milking - Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Bactericide	Teat disinfection pre-milking (PT3) Indoor	YODICAMP ORDEÑO (0.220% Iodine)	Bacteria*:* *Escherichia coli* CECT 405 *Staphylococcus aureus* CECT 239 *Streptococcus uberis* CECT 994	EN 1656: 2020	Phase 2 step 1 test (suspension test) Concentration tested: 20%, 8% and 4% v/v Temperature: 30°C Contact time: 30 seconds Clean/Dirty conditions 3 g/L bovine albumin Criteria: at least a 5 log reduction	Bactericidal activity demonstrated at 8% (v/v)	2.2.5./ 210026965
Bactericide	Teat disinfection pre-milking (PT3) Indoor	YODICAMP ORDEÑO (0.220% Iodine)	Bacteria*:* *Escherichia coli* CECT 405, *Staphylococcus aureus* CECT 239 *Streptococcus uberis* CECT 994	PR NF-EN 17422: 2019	Phase 2 step 2 test (carrier test) Concentration tested: 20%, 8% and 0.1% v/v Temperature: 30°C Contact time: 30 seconds Clean/Dirty conditions 3 g/L bovine albumin Test surface: VitroSkin® (human synthetic skin) Criteria: at least a 3 log reduction	Bactericidal activity demonstrated at 8% v/v	2.2.5./ D/21/B0237
Levuricide	Teat disinfection pre-milking (PT3) Indoor	YODICAMP ORDEÑO (0.220% Iodine)	Yeast*:* *Candida albicans* CECT 1394	EN 1657: 2016	Phase 2 step 1 test (suspension test) Concentration tested: 8%, 4% and 2% v/v Temperature: 30°C Contact time: 30 seconds Clean/Dirty conditions 3 g/L bovine albumin Criteria: at least a 4 log reduction	Yeasticidal activity demonstrated at 4% (v/v)	2.2.5./ 210026963
Levuricide	Teat disinfection pre-milking (PT3) Indoor	YODICAMP ORDEÑO (0.220% Iodine)	Yeast*:* *Candida albicans* CECT 1394	PR NF-EN 17422: 2019	Phase 2 step 2 test (carrier test) Concentration tested: 8%, 4% and 0.1% v/v Temperature: 30°C Contact time: 30 seconds Clean/Dirty conditions 3 g/L bovine albumin Test surface: VitroSkin® (human synthetic skin) Criteria: at least a 2 log reduction	Yeasticidal activity demonstrated at 4% (v/v)	2.2.5./ D/21/B025238
Levuricide	Teat disinfection	YODICAMP ORDEÑO	Yeast*:* *Candida albicans* CECT 1394	EN 1657: 2016	Phase 2 step 1 test (suspension test) Concentration tested: 80%, 10% and 6% v/v	Yeasticidal activity demonstrate	2.2.5./ 150095848

	pre-milking (PT3) Indoor	(0.220% Iodine)			Temperature: 30°C Contact time: 30 minutes Clean/Dirty conditions 3 g/L bovine albumin Criteria: at least a 4 log reduction	d at 10% (v/v)	

Post-milking - Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Bactericide	Teat disinfection post-milking (PT3) Indoor	YODICAMP ORDEÑO (1.9% PVP-Iodine)	Bacteria*: Escherichia coli CECT405, Staphylococcus aureus CECT 239 Streptococcus uberis CECT 994*	EN 1656: 2010	Phase 2 step 1 test (suspension test) Concentration tested: 80%, 10% and 6% v/v Temperature: 30°C Contact time: 5 minutes Clean/Dirty conditions 10 g/L skimmed milk Criteria: at least a 5 log reduction	Bactericidal activity demonstrated at 10% (v/v)	2.2.5./ 150095858
Bactericide	Teat disinfection post-milking (PT3) Indoor	YODICAMP ORDEÑO (0.220% Iodine)	Bacteria*: Escherichia coli CECT405, Staphylococcus aureus CECT 239 Streptococcus uberis CECT 994*	PR NF-EN 17422: 2019	Phase 2 step 2 test (carrier test) Concentration tested: 50%, 8% and 0.1% v/v Temperature: 30°C Contact time: 5 minutes Clean/Dirty conditions 10 g/L skimmed milk Test surface: VitroSkin® (human synthetic skin) Criteria: at least a 4 log reduction	Bactericidal activity demonstrated at 8% v/v	2.2.5./ D/21/B0235
Levuricide	Teat disinfection post-milking (PT3) Indoor	YODICAMP ORDEÑO (0.220% Iodine)	Yeast*: Candida albicans* CECT 1394	EN 1657: 2016	Phase 2 step 1 test (suspension test) Concentration tested: 8%, 4% and 2% v/v Temperature: 30°C Contact time: 5 minutes Clean/Dirty conditions 10 g/L skimmed milk Criteria: at least a 4 log reduction	Yeasticidal activity demonstrated at 4% (v/v)	2.2.5./ 210026964
Levuricide	Teat disinfection post-milking (PT3) Indoor	YODICAMP ORDEÑO (0.220% Iodine)	Yeast*: Candida albicans* CECT 1394	PR NF-EN 17422: 2019	Phase 2 step 2 test (carrier test) Concentration tested: 20%, 4% and 0.1% v/v Temperature: 30°C Contact time: 5 minutes Clean/Dirty conditions 10 g/L skimmed milk Test surface: VitroSkin® (human synthetic skin) Criteria: at least a 3 log reduction	Yeasticidal activity demonstrated at 20% (v/v)	2.2.5./ D/21/B0236

Conclusion on the efficacy of the product

For efficacy testing of the Yodicamp Ordeño disinfectant product a tiered approach has been provided according to the Guidance on the Biocidal Products Regulation Volume II Efficacy - Assessment and Evaluation (Parts B+C), to the Technical Agreements for Biocides Efficacy (EFF) and to the Minutes of Efficacy Working Group.
The biocidal disinfectant has a bactericidal and yeasticidal activity, that has been demonstrated according to the international European Standards EN 1656 and EN 1657 (phase 2, step 1), under specific test conditions for pre- and post-milking teat disinfectants.

Since there is still no established a specific standard for teat disinfection in phase 2, step 2, the quantitative bactericidal and yeasticidal carrier test with artificial skin has been carried out according to the PR NF-EN 17422:2019 pre-standard (Chemical disinfectants and antiseptics. Quantitative surface test for the evaluation of teat disinfectants used in the veterinary area. Test method and requirements, phase 2/stage 2), under conditions suitable for pre- and post-milking disinfection, and similar to those used for the EN 1656 and EN 1657 standards, as agreed with the eCA.

The test method described by the draft standard PR NF EN 17422:2019 is based on the standard EN 16437 (Quantitative surface test for the evaluation of the bactericidal activity of disinfectants and chemical antiseptics used in the veterinary area on porous surfaces without action mechanics -Test method and requirements, phase 2/ stage 2), but takes into account the practical conditions of application of teat disinfectants, adapting the test conditions that may influence their activity in practical application, including the test surface, contact time and temperature.
Both the recommended pre-milking and post-milking modes of application are by dipping (without mechanical action).

Yodicamp Ordeño has been shown to be effective diluted at 8% against bacteria Escherichia coli CECT405, Streptococcus uberis CECT 994 and Staphylococcus aureus CECT 239, according to the UNE-EN 1656:2020 (phase 2, step1), and at 4% against the yeast Candida albicans CECT 1394, according to the UNE-EN 1657:2016 (phase 2, step1), in the assay conditions stablished for pre-milking teat disinfection, and also when is carried out the quantitative carrier tests according to PR NF-EN 17422:2019 (phase 2, step 2) with artificial skin, in the same conditions (at 30ºC, 30 seconds of contact time and with 3 g/l bovine albumin as interferent substance).

This biocidal product has also been shown to be effective diluated at 10% against the bacteria Escherichia coli CECT405, Streptococcus uberis CECT 994 and Staphylococcus aureus CECT 239, according to the UNE-EN 1656:2010 standard (phase 2, step 1), and at 4% against Candida albicans CECT 1394 yeast according to UNE-EN 1657:2016 (phase 2, step 1) under the test conditions established for post-milking teat disinfection. As well as when quantitative carrier tests are performed according to PR NF- EN 17422:2019 (phase 2, step 2) with artificial skin, it has demonstrated its bactericidal activity diluated at 8% and yeasticidal activity diluated at 20% under the same conditions (at 30ºC, 5 minutes contact time and with 10 g/L of skimmed milk as interfering substance).
Test methods followed for the evaluation of bactericidal and yeasticidal activity have been without mechanical action, therefore, the product cannot be used with mechanica action.

On this basis, the assessment, therefore, concludes that the product is efficacious at 8% (v/v) dilution in water for pre-milking teat disinfection, at clean conditions, and from 20% (v/v) dilution for post-milking teat disinfection. Label instructions should state that cleaning prior to disinfection is necessary on pre-milking application. The users should inform if the treatment is ineffective and report straightforward to the registration holder.

2.2.5.6 Occurrence of resistance and resistance management

Taking into account the mode of action of iodine which is non-selective, development of resistance against iodine is unlikely. Iodine / iodophors have been used for over 170 years as disinfectants for a variety of applications. Such applications include disinfection of skin in the human hygiene and medical area but also skin of animals using teat dips as well as surfaces such as milk tanks.

No reduction in efficacy was reported to the producers of iodine/iodophor-based products for such applications indicating that no development of resistant microorganisms or viruses has occurred, and therefore no resistance management strategies has been developed.

2.2.5.7 Known limitations

Not available.

2.2.5.8 Evaluation of the label claims

Iodine-containing product to veterinary area to teat disinfection of dairy animals.

The Yodicamp Ordeño product has shown a sufficient efficacy against bacteria and yeasts at 8% (v/v) dilution in water for pre-milking teat disinfection and at RTU for post-milking teat disinfection.

For pre-milking teat disinfection only at clean conditions.

Application method by dipping without mechanical action.

2.2.5.9 Relevant information if the product is intended to be authorised for use with other biocidal product(s)

Yodicamp Ordeño product is not intended to be use with other biocidal products.

2.2.6 Risk assessment for human health

Data of the active substance (a.s.) iodine were evaluated by the Rapporteur Member State (RMS) Sweden (RMS SE, 2013). No new data have been required. The following data on active substance issued from Iodine Assessment Report, Sweden, December 2013 (Iodine CAR) will be used for human health risk assessment:

Endpoint	Values
AEL	0.01 mg/kg bw/d
AEC inhalation	1 mg/m^3 (0.1 ppm)
Vapour Pressure (Pa) at 25°C	40.7 Pa at 25°C
Molecular weight (g/mol)	253.81 g/mol

Yodicamp Ordeño contains Iodine (CAS 7553-56-2) that is used in biocidal products for the disinfection of animals' teats/udder and animal houses. In the products type 3, iodine is complexed with Polyvinylpyrrolidone (iodophor type 2).

An iodophor is a preparation containing iodine complexed with a carrier and/or a solubilizing agent, such as polycarbonic acids, surfactants or polymers as povidone (PVP, Polyvinylpyrrolidone). In this way, a controlled release of iodine is accomplished.
Iodine is an essential dietary trace element for mammals. It is required for the synthesis of the thyroid hormones, which control metabolism and play an important role in reproduction, growth and development.

2.2.6.1 Assessment of effects on Human Health

Not acute toxicity studies (oral, dermal, inhalation toxicity, skin and eye irritation/corrosion and skin sensitisation) have been performed for the biocidal product.

The classification of the product has been carried out according the classification of the components and the Regulation (CE) 1272/2012 on classification, labelling and packaging of substances and mixtures (CLP)

Skin corrosion and irritation

Data waiving	
Information requirement	Skin corrosion and irritation
Justification	The BP does not contain any component classified as skin corrosive, and contains 2.2% of PVP-Iodine, the only substance classified as Skin Irritant 2, with not specific concentration limit and, according the CLP Regulation criteria for classification of mixtures with the addition method, this BP is not classified as skin irritant because contains less than the generic concentration limit (10%). No classification is triggered for skin irritation.

Eye irritation

Data waiving	
Information requirement	Eye irritation
Justification	The BP is classified according the CLP Regulation criteria, from components data, applying the additivity approach. The mixture has 3 components classified by their eye effects and 2 classified eye irritation Cat.1 - Polyvinylpyrrolidone Iodine **Eye Dam. 1** 2.2% - Alcohol ethoxylate (C9-C11) **Eye Dam. 1** 1.8% - Butyldiglycol Eye irrit. 2 3.5% ∑ Eye Effects Category 1 + ∑ Skin Corrosive **Category 1** ≥ 3% 2.2% + 1.8% = 4% > 3% Therefore, the BP is **classified it as Eye Dam. 1**.**H318**

Respiratory tract irritation

Data waiving	
Information requirement	Respiratory tract irritation
Justification	Regarding the content of a.s and co-formulants, and according to the classification rules laid down in the CLP regulation, **no classification is required** for respiratory tract irritation.

Skin sensitization

Data waiving	
Information requirement	Skin sensitization
Justification	Regarding the content of a.s and co-formulants, and according to the classification rules laid down in the CLP regulation, **no classification is required** for skin sensitization.

Respiratory sensitization (ADS)

Data waiving	
Information requirement	Respiratory sensitization
Justification	Regarding the content of a.s and co-formulants, and according to the classification rules laid down in the CLP regulation, no classification is required for respiratory sensitization.

Acute toxicity

Acute toxicity by oral route

The mixture has only 1 component classified as Acute Tox. 4 (oral), with DL50(oral) known and < 2000 mg/kg:

- Alcohol ethoxylate (C9-C11) (DL50 oral: 1400 mg/kg), at 1.8%

The Acute Toxicity Estimation for the mixture (ATE_{mix}) is calculated according to the formula:

$$\frac{100}{\mathbf{ATE}_{\mathbf{mix}}} = \sum_{\mathbf{n}} \frac{C_i}{ATE_i} \rightarrow \frac{100}{\mathbf{ATE}_{\mathbf{mix}}} = \frac{1.8\%}{1400}$$

Were:

C_i = concentration of component i (% w/w o % v/v)

i = individual component, varying i from 1 to n (number of components in mixture)

ATE_i = Acute Toxicity Estimation of component i.

ATE_{mix} = Acute Toxicity Estimation of the mixture.

And Result: ATE_{mix} = 77778 > 2000 → the BP is NOT classified for oral acute toxicity

Data waiving	
Information requirement	Oral acute toxicity
Justification	Not necessary. The BP is not classified as Oral Acute Toxic, according the addition method of CLP Regulatory for mixtures, from components data, because the ATE_{mix} > 2000. The mixture has only 1 component (Alcohol ethoxylate (C9-C11) classified as Acute Tox. 4 (oral), with DL50(oral) known and < 2000 mg/kg

Acute toxicity by inhalation

Data waiving	
Information requirement	Inhalation acute toxicity
Justification	Regarding the content of a.s and co-formulants, and according to the classification rules laid down in the CLP regulation, no classification is required for inhalation acute toxicity

Acute toxicity by dermal route

Data waiving	
Information requirement	Dermal acute toxicity
Justification	Regarding the content of a.s and co-formulants, and according to the classification rules laid down in the CLP regulation, no classification is required for dermal acute toxicity.

Information on dermal absorption

An in vitro skin penetration study, in order to obtain the percutaneous absorption rate of total iodine from one biocide formulation, PE 305-1, a ready-to-use solution containing PVP-iodine, with a 0.26% total iodine content, similar to YODICAMP ORDEÑO, through human (split-thickness) skin membranes was presented by the Iodine Registration Group for the approval of this AS (see LoA).

This study concludes that the mean total absorption was 12% total iodine of the dose applied for the biocidal formulations tested considering the amounts of iodine found in the receptor fluid, the receptor compartment wash, the skin membranes, and levels 3-15 of the tape strips.

Based on these results, a dermal penetration rate of 12% could be used for the human health exposure assessment and the subsequent risk characterisation, and it is considered unnecessary to perform the dermal absorption assay with the BP.

Value(s) used in the Risk Assessment – Dermal absorption	
Substances	Iodine
Value(s)	12%
Justification for the selected value(s)	According to the Swedish CAR for the active substance Iodine (including PVP-I), using the data obtained in the dermal absoption studies, the dermal absoption was estimated to 12%.

Data waiving	
Information requirement	Dermal absorption study
Justification	No study on dermal absorption has been provided for YODICAMP ORDEÑO. The active substance dossier on iodine (incl. PVP-iodine) (Sweden 2013), includes a human skin *in-vitro* dermal absorption study (De Ligt, 2009), in which two iodine-based biocidal products have been investigated. Both products are different from the compositional point of view and contain a different iodine concentration. The results of the two dermal absorption studies demonstrated that regardless of iodophor type (i.e. alcohol ethoxylate-complexed iodine or PVP-iodine) and type and concentration of co-formulants, the dermal absorption of total iodine was ca. 12%. On the other hand, although the formulation contains one co-formulant that is irritating or corrosive to the skin, it is below its specific classification limit, so YODICAMP ORDEÑO is not classified with regards to skin irritation properties. Therefore, no impact on the skin integrity and on the dermal absorption of iodine from the biocidal product is expected. In addition, only alcohol etoxylate is classified for eye damaging effect which causes the classification of YODICAMP ORDEÑO as H318, however, it is present at lower level compared to the tested formulation in the CAR. For these reasons, a dermal absorption of 12% will be used for the calculation of human health exposure.

Endocrine Disruption

In accordance with Article 15(2) of Regulation (EU) No 528/2012 of the European Parliament and of the Council 22 May 2012 concerning the making available on the market and use of biocidal products, the Biocidal Products Committee (BPC) has adopted this opinion on the review of approval of the active substance iodine and polyvinylpyrrolidone iodine.

According to the Commission Delegated Regulation (EU) No 2017/2100, a substance is identified as having endocrine-disrupting properties with respect to humans if it meets the following three criteria
(a) it shows an adverse effect in an intact organism or its progeny;
(b) it has an endocrine mode of action, i.e., it alters the function(s) of the endocrine system; and
(c) the adverse effect is a consequence of the endocrine mode of action.

Iodine, in excess of physiological needs, meets all the above three criteria – it shows adverse effects (thyroid disorders) in humans; it has an endocrine mode of action (disruption of thyroid hormones metabolism and hypothalamic-pituitary-thyroid axis); and the adverse effects are a consequence of the endocrine mode of action. Therefore, the biocidal active substances, iodine and PVP-iodine, are identified as having endocrine-disrupting properties with respect to humans.

Assessment of the ED properties of non-active substances (co-formulants):

After reviewing the potential ED properties of co-formulants (please refer to the Confidential Annex), none of them are subject to an on-going evaluation or a decision regarding their ED properties. Based on the available information, ES CA considers that there is no concern regarding the ED properties of these co-formulants.

According to the document agreed at the CG-49 meeting on Criteria – significant indications of ED properties for non-active substances at present, non-active substances contained in the biocidal product YODICAMP ORDEÑO should not be considered as having significant indication of ED properties.

Overall conclusion on the biocidal product regarding ED properties:

The biocidal product contains an active substance with endocrine disrupting properties.

Available toxicological data relating to non active substance(s) (i.e. substance(s) of concern)

According to the definition of a substance of concern laid down in the Guidance on the BPR Volume III Human Health- Assessment & Evaluation– Part B and C Risk Assessment (Version 4.0 December 2017), two substances of concern (SoC) were identificated:

- **Alkyl alcohol, C9-C11, ethoxylated (CAS: 68439-46-3)**

Identification is based on the classification of the substance of concern; Eye Dam. 1, your concentration in the biocidal product and your contribution to the classification of the biocidal products as Eye Dam. 1
This SoC contained in the product are included in Band B. Associated evaluation and risk management requirements according to the SoC banding approach for Band B are limited to determine whether P-statements normally associated with concerned H statements are sufficient or whether other risk mitigation measures should be applied.
For more information see confidential annex.

- **2-(2-butoxyethoxy)ethanol (CAS: 112-34-5) <>Butyldiglycol**

The CLP harmonised classification for this substance of concern is Eye Irrit. 2 (causes serious eye irritation). Therefore, this SoC is included in Band A. Associated evaluation and risk management requirements according to the SoC banding approach for Band A could be considered covered by the final classification of the product as Eye Dam 1.

However, according to the Guidance on the Biocidal Product Regulation (Volume III Human Health–Part B and C Risk Assessment–Version 4.0–December2017), butyldiglycol should be considered as a Substance of Concern (SoC), as there is available European Union-agreed Occupational Exposure Limit (OEL). The long-term (8 hours) occupational exposure limit (LTEL) of butyldiglycol is 67.5 mg/m^3 <> 10 ppm and the short-term occupational exposure limit (STEL) is 101.2 mg/m^3 <> 15 ppm. There is no skin notation.

Available toxicological data relating to a mixture

Not relevant.

Other

Specific target organ toxicity, repeated exposure (STOT RE)

Value used in the Risk Assessment – STOT RE	
Justification	For Iodine a concern for specific target organ toxicity was identified. According to database of registered substances under REACH in ECHA website, the Iodine REACH consortium has proposed a classification for Iodine with STOT RE (thyroid gland), category 1 (H372). In line with other biocides dossier evaluations, this classification and the generic concentration limit for mixture classification (if the concentration is ≥1% →STOT RE 2
Classification of the product according to CLP	Regarding the content of Iodine, and according to the classification rules laid down in the CLP regulation, **no classification is required** for Specific target organ toxicity, repeated exposure (STOT RE).

2.2.6.2 Exposure assessment

YODICAMP ORDEÑO is a concentrated liquid soluble (SL), containing 2.2% w/w PVP-Iodine, equivalent to 0.20-0.25% w/w of available Iodine (I_2) quelated with Polyvinylpyrrolidone, with relative density of 1.0154 g/ml, it is intended to be used by professionals to disinfect teats of cows, ewes and goats (PT3) in:

- **Pre-milking** by manual or automatic application with dipping-cups containing an 8% (v/v) dilution of BP, and at an application dose of 1 ml/teat/event
- **Post-milking** with the pure BP in dipping cups, and at an application dose of 1 ml/teat/event:

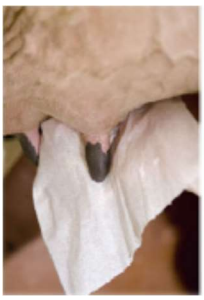
According with the **good milking practices manuals**, before milking it must clean the udders of animals with soapy water to remove traces of dirty scabs, excrement, straw, etc., and dry with disposable paper or towels. Then, it must do a **pre-milking teat disinfection** with diluted disinfectant solution (8% BP), let at least 30 seconds of contact time for effective disinfection and dry the teat hole with an individual cloth or paper towel a before milking.

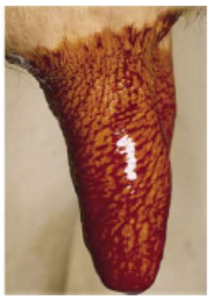
After the pre-milking disinfection treatment, stripping 4-5 squirts of milk from each udder before attach milking units to cow, to remove foremilk which may have high iodine content and also may serve as the primary stimulus for milk let-down.

After milking, remove all organic debris from teats with a disposable paper or towel before the **post-milking teat dipping disinfection**: Cover the entire teat with dip cup containing 20-25 ml of pure BP (according to the professional users, one cup with 20-25 ml is needed to approximately 5-6 cows). Once the teats are dipped, the operator slightly moves the teats to allow the formation of a droplet on the sphincter at the basis of the teat. This is the crucial place to be protected since it is the entry point of the contaminants. It is needed keep the cows in the milking parlour and let the product dry on the udder, making sure that the animal does not lie down until the product has dried, at least 5 min (contact time), or more if possible.

The container of the cup of aprox. 500 ml is filled with about 400 ml of BP, the cap or cup is screwed and the cup is filled with aprox. 20-25 ml of BP by manual pressure, as the cup is emptied.

See below photos of both phases of disinfection





Introductory note on the transferability of the following exposure assessment to buffaloes, ewes and goats

The following exposure assessment is performed for the use in dairy cows. The teat disinfection of dairy cows is an important use of the product, but not limited to this use. The products can also be used for the disinfection of the teats of buffaloes, sheep and goats.

The following exposure assessment for cows also covers the use in buffaloes, ewes and goats because:

- Buffaloes: equal to dairy cows, buffaloes have four teats. The application rates per animal and milking are equal to dairy cows. Buffaloes are only milked two times a day. Consequently, the exposure of the milker to iodine teat disinfectants per day is equal or even lower in the case of buffaloes than for cows (assuming a herd with the same number of animals and the same milking techniques).
- Ewes and goats: these animals have only two teats per animal and they are only milked 1-2 times per day.

It is therefore concluded that the exposure of a milker of dairy cows covers the exposure of a milker of buffaloes, sheep and goats.

General considerations:

The exposure assessment has been performed considering 0.25% of available iodine.

The exposure assessments are based on model calculations using models and default values from the HEAdhoc Recommendation no. 13 (Jan. 2017) – "Exposure Assessment of Teat Disinfection Products for Veterinary Hygiene (PT3)".

As a first step, exposure assessments are performed for all individual scenarios (work tasks: loading of the product, application by dipping cups or robot, and cleaning) which are relevant for teat disinfection (see table "list of scenarios" below). In a second step, the exposure calculated for the individual work tasks are combined.

In line with HEAdhoc Recommendation no. 13 (Jan. 2017), it is considered that the default value for a dairy cow herd size is 100 animals (ESD for PT3, Jan. 2012) and that dairy cows are regularly milked twice per day. Taking into account the lactation period for dairy cows (i.e. 270-300 days), 82 milk producing cows from a herd size of 100 dairy cows are milked per day (100 cows x 300/365 = 82 cows). **For higher animal numbers or more milkings per day, an additional milker is needed.**

Farmers are likely to apply the product themselves and are considered to be professional users for this type of product i.e. they are used to handling these product types regularly, they have access to relevant safety information and they can be expected to wear personal

protective equipment (PPE) when handling the products. The protection factors for personal protective equipment (PPE) used for the exposure assessments are defaults from the HEEG opinion 9, agreed in TM I 2010 "Default protection factors for protective clothing and gloves".

Explanatory note:
According to national legislation, in Spain there are three user categories:

- Trained professional users (TP): pest control operators, having received specific training in biocidal product uses according to the national legislation in force.
- Professional users (P): professionals that use the biocidal products in the context of his profession, that is not pest control operator, and that are unlikely to have received any specific training in biocidal product use according to the national legislation in force. It can be expected that they have some knowledge and skills handling chemicals (if they must use it in their job) and they are able to use correctly some kind of PPE if necessary.
- Non-professional users (NP): users who are not professionals and that apply the biocidal product is in his private life. (Note: this user has not been claimed by the applicant for this product).

The conclusions reached in this PAR, which affect the intermediate category of "Professional", will only be applicable at the Spanish level.

Identification of main paths of human exposure towards active substance(s) and substances of concern from its use in biocidal product

Summary table: relevant paths of human exposure							
Exposure path	**Primary (direct) exposure**			**Secondary (indirect) exposure**			
	Industrial use	**Professional use**	**Non-professional use**	**Industrial use**	**Professional use**	**General public**	**Via food**
Inhalation	n.a.	Yes	n.a.	n.a.	No	No	No
Dermal	n.a.	Yes	n.a.	n.a.	No	No	No
Oral	n.a.	No	n.a.	n.a.	No	No	Yes

"n.a." (not applicable)

Whilst elemental iodine has a high vapour pressure of 40.7 Pa at 20ºC, the iodine CAR informs us that evaporation of iodine from water based products is assumed to be very low: "Iodine is supposed to react immediately with organic matter (microorganisms, protein substances etc.), also by formation of different iodine species (iodide etc.).
For these reasons and in respect of the natural background values in the air, iodine evaporation and – consequently - contamination of the air is regarded as negligible".
In addition, inhalation exposure is not assessed since, due to the application method, aerosol formation is not expected.
Therefore, according to the agreed in HH-WG IV-2017, as the active substance is complex-bound, evaporation is not considered relevant.

However, according to the Guidance on the Biocidal Product Regulation (Volume III Human Health–Part B and C Risk Assessment–Version 4.0–December2017), butyldiglycol should be considered as a Substance of Concern (SoC), as it is a volatile substance and there is available European Union-agreed Occupational Exposure Limit (OEL) for it. The long-term (8 hours) occupational exposure limit of butyldiglycol is 67.5 mg/m^3 and the short-term occupational exposure limit (STEL) 101.2 mg/m^3 <> 15 ppm. There is no skin notation.

According to the BPR Guidance (p. 424), *for SoCs for which Community workplace exposure limits (IOELVs – Indicative Occupational Exposure Limit Values) have been set, a quantitative inhalation risk assessment for the professional operator against the IOELV should always be conducted*. In this case, the IOELV is not associated with a "skin notation" and, therefore, a dermal quantitative risk assessment for the professional operator will not be performed and only an inhalation quantitative risk assessment has been undertaken for the co-formulant butyldiglycol.
The ConsExpo Web model describes inhalation of volatiles into the breathing zone of the user, and therefore, this model (version 1.1.0) will be used to calculate the inhalation exposure due to evaporation.

Primary oral exposure is ruled out for professional users.

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario**	**Primary or secondary exposure Description of scenario**	**Exposed group**
1.	Mixing and loading for pre-milking dipping.	Primary exposure generated when a quantity of pure product is manually poured into a container and diluted with water, to obtain an 8% v/v solution. Automatic dilution (drawning of pure product) is covered by the manual dilution step	Trained professionals & Professionals
2.	Pre-milking application by manual dipping	Primary exposure due to manual pre-milking application of 8% diluted BP with a dipping cup. Automatic dipping (robot) is covered by manual dipping.	
3.	Cleaning of teats before milking	Primary exposure due to cleaning of teats: removal of freshly applied 8% diluted product. Automatic cleaning (robot) is covered by manual.	
4.	Cleaning of pre-milking equipment	Primary exposure due to cleaning of the pre-milking dip cup. With robotic system, no exposure is expected in this scenario.	
5.	Mixing and loading for post-milking dipping.	Primary exposure generated when a quantity of RTU pure product is manually poured into the dipping cup reservoir. Automatic process is covered by the manual M&L.	
6.	Post-milking application by manual dipping	Primary exposure due to manual post-milking application of ready to use BP with a dipping cup. Automatic dipping (robot) is covered by manual dipping.	
7.	Removal of dried disisnfectant residues from post-milking	Primary exposure. It is negligible, because the disinfectant is expected to have completely dried up and either fallen off or rubbed off the next milking event.	
8.	Cleaning of post-milking equipment	Primary exposure due to cleaning of the post-milking dip cup. With robotic system, no exposure is expected in this scenario	

Industrial exposure

No industrial use is foreseen for the product YODICAMP ORDEÑO. Therefore, the assessment of industrial exposure is not relevant.

Professional exposure

Scenario [1]. Manual mixing and loading of concentrated product for pre-milking. Dilution (pouring) step.

Description of Scenario [1]
Primary exposure (dermal and inhalation) generated when a quantity of pure product is manually poured into a container and diluted with water, to obtain an 8% v/v solution that will be applied in the pre-milking treatment. The guidance informs us that the re-filling of equipment with the diluted product will be covered within this mixing and loading step and does not need to be assessed separately. This is because the model covers all relevant mixing and loading tasks performed by a worker on an 8 hour working day. *Dermal exposure* Mixing and loading the biocidal product into dipping equipment will result in exposure to iodine via the dermal route. In line with HEAdhoc recommendation no. 13: Exposure Assessment of Teat Disinfection Products for Veterinary Hygiene (PT3) (Agreed at the Human Health Working Group I on 19 January 2017), for mixing and loading of concentrated product for dermal exposure, **mixing and loading model 4** is used. Mixing and loading model 4 provides indicative hand exposure values of 0.01 ml/treatment for 1 L containers, 0.2 ml/treatment for 5 L containers and 0.5 ml/treatment for 10 & 20 L containers. The guidance recommends that the indicative value should be used in line with the total amount of required solution/day. For dermal exposure, the total amount of the required solution that is needed per day is of importance. Manually, cows are milked twice a day, however, for robotic milking, cows can be milked three times a day. The concentrated product is diluted at 8%v/v and then, it can be used pre-milking. The max amount of diluted product used per cow is 4 ml for one event. Therefore, as worst case the amount needed for one day is: 4 ml diluted product x 3 times a day = 12 ml. As the product is used at 8% (v/v) dilutions, max 12 ml x 8% = 0.96 ml concentrated product per cow/day is used. Considering 82 cows, this results in a total amount of product per day of 0.96 ml x 82 cows = 78.72 ml = 0.07872 liter product/day. Therefore the amount of concentrated product handled by user will be < 1 litre and as such the indicative exposure value of 0.01 ml is most appropriate. In case of loading of dipping robotic milking device (for automated dipping) the sucking lance of the robotic milking device is inserted in a can containing the diluted product. Therefore, the exposure for the manual scenario is considered worst-case, and therefore used in the exposure calculation. *Inhalation exposure* As iodine in the product is complex-bound in the formulation, no evaporation is expected and therefore no inhalation exposure is assessed for it. However, exposure to vapour occurs during the loading phase due to the vapour pressure of the SoC butyldiglycol (Pv= 2.92 Pa at 25ºC). A calculation of the nearfield (1 m^3)

exposure of the worker to the butyldiglicol is calculated using the consumer model ConsExpo web model (version 1.1.0) "Exposure to vapour: evaporation – constant release" which is applicable to assess the volatile part of this substance.

Exposure to the eyes
Exposure to the eyes may occur during the loading phase. Eye contact in consequence of splashes during filling of the product into the reservoir of the dipping cup cannot be excluded.

	Parameters	Value
Tier 1	Available iodine in the product	0.25%
	Dermal penetration	12%
	Body weight	60 kg
	Indicative dermal exposure value (mixing and loading model 4)	0.01 ml/event
	No PPE (penetration)	100%
	ConsExpo web parameters for mixing & loading phase	
	Concentration of butyldiglycol in b.p.	3.5%
	Room volume[1]	1 m^3
	Exposure duration[1]	0.75 min
	Application duration[1]	0.25 min
	Product amount[1]	5000 g
	Ventilation rate[1]	4/h
	Release area[1]	20 cm^2
	Mass transfer rate[1]	Thibodeaux
Tier 2	Gloves (penetration)	10% (protection 90%)

[1] Recommendation no. 13 of the BPC Ad hoc WG-HH

Calculations for Scenario [1]

The calculation sheets are provided in Annexo 3.2.
In the following, the results of the calculations are provided for scenario 1

Summary table: estimated exposure to iodine from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [1]	1/No PPE	-	5.08E-05	-	5.08E-05
	2/Gloves	-	5.08E-06	-	5.08E-06

Summary table: estimated exposure to butyldiglycol from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated external inhalation exposure (mg/m³)**	**Estimated external dermal exposure (mg/m³)**	**Estimated external oral exposure (mg/m³)**	**Estimated external total exposure (mg/m³)**
Scenario [1]	1/No PPE	7.5E-05	-	-	7.5E-05
	2/Gloves	7.5E-05	-	-	7.5E-05

Further information and considerations on scenario [1]

As we will see, the cuantitative risk for this scenario is acceptable without PPE.
The classification of the b.p. requires additional assessment of local risks. This local risk assessment has indicated a risk for serious eye irritiation, thus eye protection is required.

Combined scenarios

See the combined exposure for pre-milking treatement in the scenario 4.

Scenario [2]. Pre-Milking application of 8% diluted BP with a dipping cup.

Description of Scenario [2]
The scenario describes a professional user who cover the entire teat with a dipping cup containing 8% (v/v) dilution of BP with an application rate of 1 ml/teat, 4 teats/cow and 2 events/day. According to Model 4 of Recommendation 13 of BPC HEAd hoc WG (2017) of Teat Disinfection Products (PT3) the exposure during the use of dipping cups is considered covered by the dermal exposure as calculated by the scenario of mixing and loading (Scenario [1]). Furthermore, it is assumed that dipping cups are designed specifically for this task, that has an upper compartment for application of the dip and a lower compartment as reservoir for the dipping solution, and during the application the worker holds the cup at the lower department, so direct hand exposure to the biocide product or treated teat is avoided. According to this Recommendation no. 13, inhalation exposure is also covered by cleaning of teats phase, as this presents the exposure inhalation from evaporation from all treated cows. As such, no further consideration of cow teat disinfection through dipping is required. Furthermore, according to HEAdhoc Recommendation no. 13 (Jan. 2017), no exposure estimate is required for automated applications (by robot).

Scenario [3]: Pre-Milking post-dipping. Cleaning of teats: removal of freshly applied 8% diluted product.

Description of Scenario [3]

The scenario describes a professional user who, after the required contact time has elapsed, cleans and removes the freshly applied BP dilution, with a single service dry paper/towel/cloth, immediately before milking.

In the CAR, the TNsG 2002 model "surface disinfection model 2" was used for assessing the cleaning of teats during pre-milking disinfection, but this model does not adequately describe the task "cleaning of teats", since it refers to "washing and wiping floors with mob, bucket and wringer", a scenario for wich considerably higher exposure is expected than for cleaning of teats.

To cover this scenario, exposure estimates were made according to model no. 8 of the Recommendation 13 of BPC HEAd hoc WG (2017) of Teat Disinfection Products (PT3). Thus, to estimate dermal exposure during cleaning of teats and removal of freshly pre-milking applied product, based on the Disinfectant Product Fact Sheet (RIVM report 320005003/2006), it is assumed that 0.1% of the amount of in-use product on the surface area (here: the teats and a part of the udder of the cow with 44 cm^2/teat and 176 cm^2/cow) contacts the palm of the hands.
To calculate the amount of biocidal product on surface area, the HEEG opinion 16 inform us that the estimated thickness of the liquid layer on the skin is 0.01 cm (this approach has been assumed in the Recommendation no. 13).
Therefore: 0.1% x 44 cm^2/teat x 0.01 cm x 4 teats/cow, for treating 82 daily cows twice per day.

Inhalation exposure.
Aerosol formation is not expected. In addition, as iodine is complex-bound in the formulation, no evaporation is expected and therefore an inhalation exposure estimate is not required for the active substance.
However, exposure to vapour occurs during this phase due to the vapour pressure of the SoC butyldiglycol. As worst case and although it is not real, this scenario will be evaluated assuming that the product is applied pure in 4 milking events. According to Recommendation no. 13, the consumer model ConsExpo web model (version 1.1.0) "Exposure to vapour: evaporation – constant release" will be used to calculate it.

	Parameters	Value
Tier 1	In-use concentration iodine	0.02%
	Surface area of cow teat[1]	44 cm^2
	Percentage of applied in-use product in contact with hands (palms)[1]	0.1%
	Thickness of liquid layer on teat[1]	0.01 cm
	Dermal penetration	12 %
	Adult body weight	60 kg
	No PPE	0% protection (100 % penetration)
	ConsExpo web parameters for cleaning of teats phase	
	Concentration of butyldiglycol in b.p.	3.5%
	Room volume[1]	168 m^3
	Exposure duration[1]	180 min

	Application duration[1]	180 min
	Product amount[2]	1332.2 g
	Ventilation rate[1]	4/h
	Release area[1]	14432 cm^2
	Mass transfer rate[1]	Thibodeaux
	Molecular weight matrix	18
Tier 2	Protection afforded by gloves	90 % protection (10 % penetration)

[1] Recommendation no. 13 of BPC Ad hoc WG on HH
[2] Although it is not real, it is assumed a worst case in which the product is applied pure in the 4 milking events. Therefore: 1 mL/teat x 4 teats/cow x 82 cows x 4 milking events = 1312 mL of pure product x 1.0154 g/mL = 1332.2 g of pure product

Calculations for Scenario [3]

The calculation sheets are provided in Annexo 3.2.

The maximum I_2 concentration an operator is exposed to in this scenario is:
8 mL x 1.0154 g/mL = 8.1232 g
0.25% x 8.1232/100 = 0.0203%
Rounded: 0.02% (content of iodine in the 8% v/v diluted product)

The total amount of biocidal product on a herd of cows can be calculated as:
44 cm^2/teat x 4 teats x 0.01 cm x 82 cows = 144.32 cm^3 =
=144.32 g of in-use solution (assuming a density of 1g/cm^3).
Assuming that there are two pre-milking applications/day, hands are exposed to 0.1% of the amount of product on cow teats for each application and the highest in-use dilution for pre-milking is 0.02% w/w (I_2), the external dose on hands during removal of freshly applied product pre-milking can be calculated as:
144.32 g x 2 x 0.1% x 0.02% = 5.77E-05 g iodine/day =
= 0.058 mg iodine/day.

The systemic exposure, when no PPE is considered, is then calculated taking into account a dermal absorption value of 12% and an adult bodyweight of 60 kg:
0.058 x 12% / 60 kg = 1.15E-04 mg/kg bw/day.

Summary table: estimated exposure to iodine from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [3]	1 / No PPE	-	1.15E-04	-	1.15E-04
	2/ Gloves	-	1.15E-05	-	1.15E-05

Summary table: estimated exposure to butyldiglycol from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated external inhalation exposure (mg/m³)**	**Estimated external dermal exposure (mg/m³)**	**Estimated external oral exposure (mg/m³)**	**Estimated external total exposure (mg/m³)**
Scenario [3]	1/No PPE	2.1E-02	-	-	2.1E-02
	2/Gloves	2.1E-02	-	-	2.1E-02

Further information and considerations on scenario [3]

As we will see, the cuantitative risk for this scenario is acceptable without PPE.

Combined scenarios

See the combined exposure for pre-milking treatement in the scenario 4.

Scenario [4]. Cleaning of the pre-milking equipment (dip cups)

Description of Scenario [4]		
After disinfection, the reservoir is emptied and the entire dip is cleaned with water. A small amount of product will remain in the application equipment; however this will be highly diluted by the wash-water. Therefore it is concluded that exposure during cleaning of application equipment is lower in comparison to the exposure during mixing and loading and application operations. Due to the lack of appropriate exposure model for the scenario "cleaning of equipment", the model RISKOFDERM toolkit, Connecting lines is used as a surrogate model according to the HEAdhoc Recommendation no. 13 (Jan. 2017) using indicative model value for hand exposure of 0.92 mg/min. Inhalation exposure is not assessed, since aerosol formation is not expected. In addition, as the active substance is complex-bound, evaporation is not considered relevant. In any case, it is assumed that exposure to vapour in this phase is assessed to be negligible in relation to the loading and application phase. The duration of this task is considered to be 5 min. On the one hand, it is expected that this operation will be carried out only once a day but, as a worse case, it is assumed that the cleaning step is performed after each milking event (twice per day). On the other hand, it is assumed that two dip cup are used: one for pre-milking treatement and the other for post-milking treatement.		
	Parameters	Value
Tier 1	Total iodine (active substance in diluted product)	0.02%
	Dermal penetration	12%
	Body weight	60 kg

	Indicative value for dermal exposure	0.92 mg/min
	Exposure duration per event	5 min/event
	Events per day (automated milking)	2 events/d
	No PPE (Penetration)	100%
Tier 2	PPE (Gloves penetration)	10%

Calculations for Scenario [4]

Tier 1 assessment
It is assumed that no protective equipment is worn.
Based on the assumption, as a worse case, that a user cleaning equipment is exposed 9.2 mg diluted product/day (i.e. 0.92 mg x 5 minutes/event x 2 event/day) and assuming that the diluted product contains 0.02% w/w iodine, systemic exposure can be calculated as follows (based on a default adult bodyweight of 60 kg and a dermal absorption value of 12%):

9.2 mg x 0.02% x 12% / 60 kg = 3.68E-06 mg iodine/kg bw/day

Tier 2 assessment
The 'Tier 1' exposure assessment is refined by including in the calculations:

- The protection afforded by gloves. HEEG opinion 9 (2010) informs us that suitable protective gloves will provide 90 % protection (equivalent to 10% penetration) Therefore:
  10% x 9.2 mg x 0.02% x 12% / 60 kg = 3.68E-07 mg iodine/kg bw/day

The calculation sheets are provided in Annexo 3.2.

Summary table: estimated exposure to iodine from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [4]	1/No PPE	negligible	3.68E-06	-	3.68E-06
	2/Gloves	negligible	3.68E-07	-	3.68E-07

Further information and considerations on scenario [4]

As we will see, the cuantitative risk for this scenario is acceptable without PPE.

Combined scenarios

It is possible that a professional user may carry out a number of scenarios across one day. The ES CA considers a professional user may mix/load or decant the product, apply the product to cow teats through dipping, remove freshly applied product (pre-milking) and clean equipment. Combined exposures from these scenarios are considered in the table below for pre-milking only:

Summary table: combined systemic exposure to iodine from professional uses for PRE-MILKING only				
Scenarios combined	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenarios [1+2+3+4] /Tier 1: No PPE	Negligible	1.7E-04	-	1.7E-04
Scenarios [1+2+3+4] /Tier 2: gloves	Negligible	1.7E-5	-	1.7E-05

Also, as will be seen later, the exposure due to the pre-milking treatment will be combined with the exposure due to the post-milking treatment.

Summary table: combined estimated exposure to butyldiglycol from professional uses for PRE-MILKING					
Exposure scenario	**Tier/PPE**	**Estimated external inhalation exposure (mg/m^3)**	**Estimated external dermal exposure (mg/m^3)**	**Estimated external oral exposure (mg/m^3)**	**Estimated external total exposure (mg/m^3)**
Scenario [1+2+3+4]	1/No PPE	$2.1075x10^{-2}$	-	-	$2.1075x10^{-2}$
	2/Gloves	$2.1075x10^{-2}$	-	-	$2.1075x10^{-2}$

During the PRE-Milking stage, the exposure to vapour generated jointly in the teat cleaning phase (scenario 3) and in the mixing and loading phase of the concentrated product (scenario 1), the latter to a very small extent, constitutes the majority exposure, compared to which the rest of the scenarios, including those at the POST-milking stage, represent negligible exposure to vapour.

Scenario [5].Manual mixing and loading of ready to use (RTU) product for post-milking

Description of Scenario [5]
Primary exposure (dermal and inhalation) generated when the ready to use product is manually decanting into dipping equipment used for post-milking treatment. This will result in exposure to iodine via the dermal route. In line with HEAdhoc recommendation no. 13: Exposure Assessment of Teat Disinfection Products for Veterinary Hygiene (PT3) (Agreed at the Human Health Working Group I on 19 January 2017), for mixing and loading of RTU product for dermal exposure, **mixing and loading model 4** is used. Mixing and loading model 4 provides indicative hand exposure values of 0.01 ml/treatment for 1 L containers, 0.2 ml/treatment for 5 L containers and 0.5 ml/treatment for 10 & 20 L containers. The guidance recommends that the indicative value should be used in line with the total amount of required solution/day.

For dermal exposure, the total amount of the required product that is needed per day is of importance. Manually, cows are milked twice a day, however, for robotic milking, cows can be milked three times a day.
The max amount of RTU product used per cow is 4 ml for one event. Therefore, as worst case the amount needed for one day is: 4 ml diluted product x 3 times a day = 12 ml.
Considering 82 cows, this results in a total amount of product per day of 12 ml x 82 cows = 984 ml = 0.984 liter product/day.
Therefore the amount of product handled by user will be < 1 litre and as such the indicative exposure value of 0.01 ml is most appropriate.

In case of loading of dipping robotic milking device (for automated dipping) the sucking lance of the robotic milking device is inserted in a can containing the diluted product. Therefore, the exposure for the manual scenario is considered worst-case, and therefore used in the exposure calculation.

As iodine in the product is complex-bound in the formulation, no evaporation is expected and therefore no inhalation exposure is assessed.

The guidance informs us that the re-filling of equipment with the product will be covered within this mixing and loading step and does not need to be assessed separately. This is because the model covers all relevant mixing and loading tasks performed by a worker on an 8 hour working day.

	Parameters	Value
Tier 1	Available iodine in the product (w/w)	0.25%
	Dermal penetration	12%
	Body weight	60 kg
	Indicative dermal exposure value[1]	0.01 ml/event
	No PPE (penetration)	100%
Tier 2	Gloves (penetration)	10% (protection 90%)

[1] *Mixing and loading model 4, according to Recommendation no. 13*

Calculations for Scenario [5]

The calculation sheets are provided in Annexo 3.2.
In the following, the results of the calculations are provided for scenario 5

Summary table: estimated exposure to iodine from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [5]	1/No PPE	-	5.08E-05	-	5.08E-05
	2/Gloves	-	5.08E-06	-	5.08E-06

Further information and considerations on scenario [5]

As we will see, the cuantitative risk for this scenario is acceptable without PPE.

Combined scenarios

See the combined exposure for post-milking treatement in the scenario 8.

Scenario [6. POST-Milking application of RTU product with a dipping cup

Description of Scenario [6]
The product (RTU) is filled undiluted into the reservoir of a dip cup. By squeezing the reservoir, the disinfectant is pumped into the dip cup above the reservoir which is then ready for dipping. After milking, the dip cup prepared as described above, is put over each teat from below making sure that the full length of each teat is immersed into the disinfectant. Dermal exposure during use of the cup is not expected based on the design of the dipping cup. This kind of cup has an upper compartment for application of the dip cup and a lower compartment as a reservoir for the dipping solution. During the application, the worker holds the cup at the lower compartment. Thus, direct hand exposure to the product or treated teat is avoided. Based on the HEAdhoc Recommendation no. 13 (Jan. 2017), any possible spillage is considered covered by the dermal exposure as calculated by the scenario of mixing and loading (please refer to scenario 5 above). As such, no further consideration of cow teat disinfection through dipping is required. Furthermore, according to HEAdhoc Recommendation no. 13 (Jan. 2017), no exposure estimate is required for automated applications (by robot).

Calculations for Scenario [6]

No exposure is expected in this scenario.

Scenario [7]. Removal of dried disisnfectant residues from post-milking treatment

Description of Scenario [7]
This work step was not considered in the CAR. According to the HEAdhoc Recommendation no 13, after a post-milking treatment, the disinfectant is expected to have completely dried up and either fallen off or rubbed off during the time span between treatment and cleaning. Therefore, any exposure to remains of the disinfectant on the teats is considered to be negligible.

Calculations for Scenario [7]

No exposure is expected in this scenario.

Scenario [8]. Cleaning of the post-milking equipment (dip cup)

Description of Scenario [8]

After disinfection, the reservoir is emptied and the entire dip is cleaned with water. A small amount of product will remain in the application equipment; however this will be highly diluted by the wash-water. Therefore it is concluded that exposure during cleaning of application equipment is lower in comparison to the exposure during mixing and loading and application operations.

Due to the lack of appropriate exposure model for the scenario "cleaning of equipment", the model RISKOFDERM toolkit, Connecting lines is used as a surrogate model according to the HEAdhoc Recommendation no. 13 (Jan. 2017) using indicative model value for hand exposure of 0.92 mg/min.

Inhalation exposure is not assessed, since aerosol formation is not expected. In addition, as the active substance is complex-bound, evaporation is not considered relevant.

The duration of this task is considered to be 5 min.

On the one hand, it is expected that this operation will be carried out only once a day but, as a worse case, it is assumed that the cleaning step is performed after each milking event (twice per day). On the other hand, as we have seen, it is assumed that two dip cup are used: one for pre-milking treatement and the other for post-milking treatement.

	Parameters	Value
Tier 1	Total iodine (active substance in the RTU pure product)	0.25%
	Dermal penetration	12%
	Body weight	60 kg
	Indicative value for dermal exposure	0.92 mg/min
	Exposure duration per event	5 min/event
	Events per day (automated milking)	2 events/d
	No PPE (Penetration)	100%
Tier 2	PPE (Gloves penetration)	10%

Calculations for Scenario [8]

Tier 1 assessment
It is assumed that no protective equipment is worn.
Based on the assumption, as a worse case, that a user cleaning equipment is exposed 9.2 mg product/day (i.e. 0.92 mg x 5 minutes/event x 2 event/day) and assuming that the product contains 0.25% w/w iodine, systemic exposure can be calculated as follows (based on a default adult body weight of 60 kg and a dermal absorption value of 12%):

9.2 mg x 0.25% x 12% / 60 kg = 4.6E-05 mg iodine/kg bw/day

Tier 2 assessment
The 'Tier 1' exposure assessment is refined by including in the calculations:

- The protection afforded by gloves. HEEG opinion 9 (2010) informs us that suitable protective gloves will provide 90 % protection (equivalent to 10% penetration) Therefore:

10% x 9.2 mg x 0.25% x 12% / 60 kg = 4.6E-06 mg iodine/kg bw/day

The calculation sheets are provided in Annexo 3.2.

Summary table: estimated exposure to iodine from professional uses (mg/kg bw/d)					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [8]	Tier 1/ No PPE	-	4.6E-05	-	4.6E-05
Scenario [8]	Tier 2/ Gloves	-	4.6E-06	-	4.6E-06

The calculation sheets are provided in Annexo 3.2.

Further information and considerations on scenario [8]

As we will see, the cuantitative risk for this scenario is acceptable without PPE.

Combined scenarios

It is possible that a professional user may carry out a number of scenarios across one day. The ES CA considers a professional user may mix/load or decant the product, apply the product to cow teats through dipping, remove freshly applied product (pre-milking) and clean equipment. Combined exposures from these scenarios are considered in the table below for post-milking only and pre- and post- milking.

Summary table: combined systemic exposure to iodine from professional uses for POST-MILKING only (mg/kg bw/d)				
Combined scenarios	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenarios [5+6+7+8] /Tier 1: No PPE	Negligible	9.68E-05	-	9.68E-05
Scenarios [5+6+7+8] /Tier 2: gloves	Negligible	9.68E-06	-	9.68E-06

Summary table: combined systemic exposure to iodine from professional uses for PRE-MILKING and POST-MILKING (mg/kg bw/d)				
Combined scenarios	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenarios [1+2+3+4+5+6+7+8] /Tier 1: No PPE	Negligible	2.67E-04	-	2.67E-04
Scenarios [1+2+3+4+5+6+7+8] /Tier 2: gloves	Negligible	2.67E-05	-	2.67E-05

Non-professional exposure

The product is intended for professional use only, and no non-professional exposure is foreseen. Therefore, the assessment of non-professional exposure is not relevant.

Exposure of the general public

The general public does not have access to the milking parlour. Therefore, no general public primary or secondary exposure is foreseen.

Monitoring data

There is no monitoring data available for this product.

Dietary exposure

Iodine is essential for life and it can be consumed from many different sources. Although it is recognised that both insufficient and excessive iodine intakes can cause diseases, it is generally considered that the benefits of the prevention of diseases from iodine deficiency far outweighs possible side-effects of oversupply. For this reason the mean exposure to iodine from the rest of the diet has also been presented.
The actual amount of iodine intake in the EU is highly variable and difficult to estimate, as levels of iodine intake depend on the geographical location, the soil, people's diet, the season, farming practices, iodine fortification of feed for dairy cattle, iodine supplementation programs and other factors. The iodine intake that can be attributed to the use of iodine-containing teat disinfectants is only a minor part of the total iodine intake. According to the European Scientific Committee on Food, the most important sources of iodine in industrialised countries are dairy products. More recently, calculations by EFSA confirm that for both adults and toddlers, milk is by far the main source of iodine, but the total iodine level in milk vary greatly between different regions in Europe.

Dietary exposure is discussed in various human health working group meetings and WebEx meetings for evaluating various iodine based union authorisations application. For the exposure to residues, the O'Brien study can be used. The assumptions that could be considered for the exposure to residues via milk were that needs to be considered are included below:

- Exposure in accordance to intended use (WGIII 2017).
- For exposure to residues the following was concluded by eCAs from iodine based union authorisation applications (Secure Webex meeting (3-10-2017)): "The expected iodine residues in milk from two milking events per day for manual milking and from three events per day for automatic milking are considered comparable".
- Take into account a density of 1.03 kg/L for whole milk (Ullmanns's Food and Feed, 3 Volume set. (Elvers, B. (2017). 1st ed. Weinhem, Germany: Wiley-VCH, page 344).
- 50% reduction due to bulking of milk is not allowed (WGII 2017).
- 27% reduction due to pasteurisation of the milk is not allowed. (WGII 2017)
- At WGIV 2017 it was agreed that for daily milk consumption to use **0.45 L/day for adults** (EFSA PRIMo version 2, based on highest mean for Dutch populations) and **0.46 L/day for infant/toddlers** (EFSA PRIMo version 2, based on highest mean for French population).
- For the calculations, information from the O'Brien study was used. The O'Brien study assessed the effect of a teat disinfection product is used, based on 0.5% available iodine on the total iodine content in milk. Therefore, the measured residues in milk are from the O'Brien study need to be corrected for our case (0.02% available iodine for pre-milking and 0.25% available iodine for post-milking), which is included below.
- **Background in milk** is variable due to differences in iodine concentrations in natural sources (drinking water and grass) and due to feed (supplemented with various amounts of iodine). The background was discussed in the Secure Webex meeting (3-10-2017), in which was concluded by eCAs from iodine based union authorisation applications: "General support was given to the derivation of an EU harmonised value. The value of **200 µg/L iodine** in milk was considered appropriate as an EU harmonised value, based on the monitoring data from EFSA 2013 (EFSA Journal 2013;11(2):3101) and the O'Brien study." (See WG V 2017).
- Iodine dietary intake from **other sources** than milk was also discussed in the Secure WebEx meeting (3-10-2017), in which was concluded by eCAs from iodine based union authorisation applications: "The values from the UK survey were considered adequate to represent the EU iodine dietary intake from sources other than milk. Rounding of the values to **185 µg/day for adults** and **96 µg/day for toddler** was agreed." It should be noted that these values excluded iodine intake from milk. Furthermore, within this UK study (UK retail survey of iodine in UK produced dairy foods, FSIS 02/08, 16 June 2008) 350 samples of dairy and seaweed products were purchased from eight areas of the UK. Levels of iodine found were generally in similar ranges to those reported from previous surveys (MAFF iodine in milk). Furthermore, the reported values are in agreement with an EFSA scientific opinion on the use of iodine in feeding stuffs. It is noted that in the UK study report for the calculations for body weights 76 for adults and 14.5 kg for infants are considered, whereas 70 kg and 12 kg are used in the consumption calculations. Moreover, during the discussion at the Secure WebEx meeting it was noted that comparable values could be obtained from French and German monitoring studies. (See WG V 2017).
- Consumers are exposed to residues of iodine due to various sources. The inclusion from other sources in the consumer risk assessment was discussed at WGIV, and the following was concluded: Iodine exposure from all sources will be included in the assessment.

Based on the details above the following three theoretical intakes will be calculated and evaluated:

- Iodine intakes resulting from only the proposed teat treatment.

- Iodine intakes from milk (sum of; the proposed teat treatment + background levels in milk (200 µg/L)).
- Iodine intakes from all dietary sources (sum of; the proposed teat treatment + background levels in milk (200 µg/L) + mean intake associated with other dietary sources (adult = 185 µg/day, infant = 96 µg/day)).

The estimated dietary intakes of iodine have been compared to the relevant UL for adults (600 µg/day) and infants (200 µg/day)

List of scenarios

Summary table of main representative dietary exposure scenarios		
Scenario number	**Description of scenario**	**Subject of exposure**
9.	Residual exposure from teat treatment	Adults Toddlers
10.	Exposure from total milk intake	Adults Toddlers
11.	Exposure from total dietary intake	Adults Toddlers

Scenario 9. Residual exposure from teat treatment

The residual level of iodine due to teat disinfection was investigated by O'Brien study et al (2013). The effect of milk iodine concentrations of a teat disinfectant containing 0.5 % iodine and applied post- or pre- and post-milking were investigated in this survey. Another objective of this study was to quantify combined effects of teat disinfection and dietary supplementation of iodine. Feed fortification levels tested were 30 mg and 70 mg per cow per day. In this evaluation, only the results of the teat disinfection without considering the influence of iodine supplementation by feed are presented. The results of the study have been presented in following Table:

Study	Iodine (%)	Applications	Mean treated residue (µg/kg)	Mean control residue (µg/kg)	Difference (additional iodine residues in milk) (µg/kg)
*O'Brien 2013**	0.5	2x post milking	461	217	244
*O'Brien 2013**	0.5	2x pre and 2x post milking	670	217	453
*O'Brien 2013***	0.5	2x pre milking	-	-	209

** O`Brien, B., Gleeson, D. and Jordan, K. (2013): Iodine concentrations in milk. Irish Journal of Agricultural and Food Research 52*

*** In the study by O'Brian, treatment only pre-milking was not considered, but it could be estimated as:"Pre &post milking" –"post milking estimates". It is to sa: 453 –244= 209*

For the control group, in which cows were treated with non-iodine teat disinfectant and 0 mg iodine/day feed supplementation, a 'baseline' of 217 µg/kg iodine in milk was established. This is equivalent to 224 µg/L based on the density of whole milk (1030 g/L).

Therefore, from data of O´Brien, 244 µg/kg is the theoretical additional residues after post-milking teat disinfection; this value has been calculated by subtracting the iodine level of the control group (217 µg/kg) from the residue level after post-milking treatment (461 µg/kg). The value 244 µg/kg is used as a starting point for extrapolation to the product concentration of 0.25%:

Additional iodine residues in milk due to treatment with pure YODICAMP ORDEÑO:
244 µg/Kg x (0.25/0.5) = 122 µg I/Kg milk
Based on the density of whole milk (1.03 Kg/L):
122 µg/Kg x 1.03 Kg/L = 125.66 µg I/L milk
The daily milk consumption is 0.45 L/day for adults and 0.46 L/day for infant/toddlers.
Therefore, the iodine intakes resulting from only the proposed teat treatment are:
Adults: 125.66 µg I/L x 0.45 L/d = **56.547 µg I/d**
Toddlers: 125.66 µg I/L x 0.46 L/d = **57.804 µg I/d**

Considering the Upper Intake Level (UL): 600 µg/d for adults and 200 µg/d for toddlers:
Percentage UL = (56.547/600) x 100 = **9.42% adult**
Percentage UL = (57.804/200) x 100 = **28.90% toddler**

Estimated from data of O´Brien, 209 µg/kg is the theoretical additional residues after pre-milking teat disinfection; this value has been calculated by subtracting the iodine level of the "post-milking" (244 µg/kg) from the residue level after "pre and post-milking treatment" (453 µg/kg). The value 209 µg/kg is used as a starting point for extrapolation to the product concentration of 0.02%:

Additional iodine residues in milk due to treatment with diluted Yodicamp Ordeño:
209 µg/Kg x (0.02/0.5) = 8.36 µg I/Kg milk
Based on the density of whole milk (1.03 Kg/L):
8.36 µg/Kg x 1.03 Kg/L = 8.61 µg I/L milk
The daily milk consumption is 0.45 L/day for adults and 0.46 L/day for infant/toddlers.
Therefore, the iodine intakes resulting from only the proposed teat treatment are:
Adults: 8.61 µg I/L x 0.45 L/d = **3.875 µg I/d**
Toddlers: 8.61 µg I/L x 0.46 L/d = **3.961 µg I/d**

Considering the Upper Intake Level (UL): 600 µg/d for adults and 200 µg/d for toddlers:
Percentage UL = (3.875/600) x 100 = **0.65% adult**
Percentage UL = (3.961/200) x 100 = **1.98% toddler**

The theoretical additional iodine residues in milk due to treatment pre- and post- milking teat disinfection, is the result of the sum of the iodine residues from the pre-milking plus those from the post-milking : 8.36 + 122 = 130.36 µg I/Kg milk.
Based on the density of whole milk (1.03 Kg/L):
130.36 µg/Kg x 1.03 Kg/L = 134.27 µg I/L milk
The daily milk consumption is 0.45 L/day for adults and 0.46 L/day for infant/toddlers.
Therefore, the iodine intakes resulting from only the proposed teat treatment are:
Adults: 134.27 µg I/L x 0.45 L/d = **60.42 µg I/d**
Toddlers: 134.27 µg I/L x 0.46 L/d = **61.76 µg I/d**

Considering the Upper Intake Level (UL): 600 µg/d for adults and 200 µg/d for toddlers:
Percentage UL = (60.42/600) x 100 = **10.07% adult**
Percentage UL = (61.76/200) x 100 = **30.88% toddler**

Scenario 10. Exposure from total milk intake

The value of 200 µg/L iodine in milk is the background milk:

Adult: 200 µg/L x 0.45 L/d = 90 µg I/d
Toddler: 200 µg/L x 0.46 L/d = 92 µg I/d

Total iodine intakes from milk is the sum of the residual exposure from teat treatment + background levels in milk. Therefore:

Pre-milking:

Adults: 3.875 µg I/d + 90 µg I/d = **93.875 µg I/d**
Toddlers: 3.961 µg I/d + 92 µg I/d **= 95.961 µg I/d**

Post-milking:

Adults: 56.547 µg I/d + 90 µg I/d = **146.547 µg I/d**
Toddlers: 57.804 µg I/d + 92 µg I/d **= 149.804 µg I/d**

Pre- and post-milking:

Adults: 60.42 µg I/d + 90 µg I/d = **150.42 µg I/d**
Toddlers: 61.76 µg I/d + 92 µg I/d **= 153.76 µg I/d**

Considering the Upper Intake Level (UL): 600 µg/d for adults and 200 µg/d for toddlers:

Pre-milking:

Percentage UL = (93.875/600) x 100 = **15.65 % adult**
Percentage UL = (95.961/200) x 100 = **47.98 % toddler**

Post-milking:

Percentage UL = (146.547/600) x 100 = **24.42 % adult**
Percentage UL = (149.804/200) x 100 = **74.90 % toddler**

Pre- and post-milking:

Percentage UL = (150.42/600) x 100 = **25.07 % adult**
Percentage UL = (153.76/200) x 100 = **76.88 % toddler**

Scenario 11. Exposure from total diary intake

Iodine dietary intake from other sources than milk was set:

185 µg/day for adults
96 µg/day for toddler.

Total iodine intakes from all dietary sources is the sum of the proposed teat treatment + background levels in milk (200 µg/L) + mean intake associated with other dietary sources. Therefore:

Pre-milking:

Adults: (3.875 + 90 + 185) µg I/d = **278.87 µg I/d**
Toddlers: (3.961 + 92 + 96) µg I/d **= 191.96 µg I/d**

Post-milking:

Adults: (56.547 + 90 + 185) µg I/d = **331.55 µg I/d**
Toddlers: (57.804 + 92 + 96) µg I/d **= 245.80 µg I/d**

Pre- and post-milking:

Adults: (60.42 + 90 + 185) µg I/d = **335.42 µg I/d**
Toddlers: (61.76 + 92 + 96) µg I/d **= 249.76 µg I/d**

Considering the Upper Intake Level (UL): 600 µg/d for adults and 200 µg/d for toddlers:

Pre-milking:

Percentage UL = (278.87/600) x 100 = **46.48 % adult**
Percentage UL = (191.96/200) x 100 = **95.98 % toddler**

Post-milking:

Percentage UL = (331.55/600) x 100 = **55.26 % adult**
Percentage UL = (245.8/200) x 100 = **122.90 % toddler**

Pre- and post-milking:

Percentage UL = (335.42/600) x 100 = **55.90 % adult**
Percentage UL = (249.76/200) x 100 = **124.88 % toddler**

As we can see, the total daily intake for toddlers exceeds the upper limit value, representing 122.9% (post-milking) and 124.88% (pre and post-milking).

Information of non-biocidal use of the active substance

Summary table of other (non-biocidal) uses			
	Sector of use	**Intended use**	**Reference value(s)**
1.	Veterinary use	Veterinary medicine as antiseptics and sanitisers (reduction of mastitis, prevention of infections in wounded, etc)	"No MRL required" for all target tissues according to Commission Regulation (EU) No 37/2010. (EMA)[1]
2.	Food additives	Fortification of food (iodised salt)	The amount of iodine added varies from 10-75 mg/kg salt with a majority of values in the range of 15-30 mg/kg, according to EFSA NDA Panel, 2014, Scientific Opinion on Dietary Reference Values for iodine, EFSA Journal 2014; 12(5);3660 (doi:10.2903/j.efsa.2014.3660)
3.	Feed additives	Supplementation of animal feed	Dairy cows: 5 mg I/kg of complete feeding stuff according to Commission Regulation (EC) No 1459/2005 of 8 Sept. 2005 2 mg I/kg recommended according to EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), Scientific opinion on the safety and efficacy of iodine compounds (E2) as feed additives for all animal species […], EFSA Journal 2013; 11(2):3099 (doi:10.2903/j.efsa.2013.3099)

[1] European Agency for the Evaluation of Medical Products (EMA). Iodine report from Committee for Veterinary Medical Products

Note regarding need to set MRLs: Since the direct treatments of cows with iodine-containing veterinary hygiene products may lead to residues in milk, the need to set new maximum residue limits (MRLs) should be investigated according to the "Proposed decision for Iodine" of 31 January 2014. However, it should be acknowledged that iodine-based teat dips have a long history as veterinary medicines for the prevention of mastitis all over Europe and worldwide and that veterinary and biocidal uses are quite similar (if not identical) with respect to application frequency, iodine use concentration and product composition. The European Agency for the Evaluation of Medicinal Products (EMA) concluded in their summary report on iodine that it would be inappropriate to elaborate maximum residue levels (MRLs) for iodine. Therefore, iodine was included in Annex II of Council Regulation (EEC) 2377/90 (now repealed by Regulation (EC) No 470/2009) comprising the list of substances not subject to maximum residue limits. Commission Regulation (EU) No 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin lists iodine (including inorganic compounds) in Table 1 "Allowed substances" of the Annex with a "no MRL required" entry for all food producing species and all target tissues (including milk).

Estimating Livestock Exposure to Active Substances used in Biocidal Products

A direct exposure of animals is determined for Yodicamp Ordeño, since it is a topical product applied to the teats.
According to the EMEA (European Agency for the Evaluation of Medicinal Products) summary report on iodine-containing products used for veterinary medicine, only small increases in serum iodine concentration have been found after teat dipping indicating that the procedure has a negligible effect on tissue iodine concentrations. These results suggest limited livestock exposure and no-detailed risk assessment was therefore performed for animal health. This is supported by the EFSA 2013 opinion on the safety and efficacy of iodine compounds (E2) as feed additives, in which it was concluded that the iodine level in edible tissues/products is generally found to be highest in milk and not in meat. Calculations on residues in milk presented in the dietary assessment are therefore covering potential residues in meat and considered as sufficient for the product.

Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s)

Yodicamp Ordeño is not used in a manner which may cause direct contact with food. Calculations for estimating dietary exposure via residues in milk have been provided above.

Estimating transfer of biocidal active substances into foods as a result of non-professional use

Not required since Yodicamp Ordeño is not intended to be used by non-professionals.

Exposure associated with production, formulation and disposal of the biocidal product

Exposure during production and formulation of a biocidal product is not assessed under the requirements of the BPR (Regulation No. 528/2012).

Aggregated exposure

Although iodine is released from multiple sources, aggregated exposure is not assessed since a respective methodology is not available yet.

Summary of exposure assessment

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group**	**Tier (PPE)**	**Estimated total uptake** (mg a.s./kg bw/day)
Scenario 1: mixing/loading (Pre-milking)	Professionals & Trained professionals	1 (no PPE)	5.08E-05
		2 (gloves)	5.08E-06
Scenario 2: application by dipping cup Pre-milking)	Professionals & Trained professionals	Covered by scenario 1	
Scenario 3: cleaning of teats (Pre-milking)	Professionals & Trained professionals	1 (no PPE)	1.15E-04
		2 (gloves)	1.15E-05
Scenario 4: cleaning of equipment (Pre-milking)	Professionals & Trained professionals	1 (no PPE)	3.68E-06
		2 (gloves)	3.68E-07
Scenario 5: M&L (decanting) (Post-milking)	Professionals & Trained professionals	1 (no PPE)	5.08E-05
		2 (gloves)	5.08E-06
Scenario 6: application by dipping cup (Post-milking)	Professionals & Trained professionals	Covered by scenario 5	
Scenario 7: cleaning of teats (Post milking)	Professionals & Trained professionals	No exposure expected	
Scenario 8: cleaning of equipment(Post-milking)	Professionals & Trained professionals	1 (no PPE)	4.60E-05
		2 (gloves)	4.60E-06
Combined scenarios 1+2+3+4: (Pre-Milking)	Professionals & Trained professionals	1 (no PPE)	1.70E-04
		2 (gloves)	1.70E-05
Combined scenarios 5+6+7+8: (Post-Milking)	Professionals & Trained professionals	1 (no PPE)	9.68E-05
		2 (gloves)	9.68E-06
Combined scenarios 1+2+3+4+5+6+7+8: (Pre & Post Milking)	Professionals & Trained professionals	1 (no PPE)	2.67E-04
		2 (gloves)	2.67E-05

2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation for iodine

Reference	**Study**	**NOAEL (LOAEL)**	**AF**	**Correction for oral absorption**	**Value**

$AEL_{short-term}$	Not derived in the CAR and not relevant for HHRA				
$AEL_{medium-term}$	Not derived in the CAR and not relevant for HHRA				
$AEL_{long-term}$ = Upper Intake Level (UL)	EU Scientific Committee on Food (SCF, 2002)[1] Human data				600 µg/day (0.01 mg/kg bw/d) for adults and 200 µg/day for toddlers
ARfD	According to CAR, not applicable. Substance is not acute toxic or harmful.				
ADI	Not derived in the CAR and not relevant for HHRA. Instead of an ADI, a Recommended daily intake of 150-200 µg/day is given in the CAR.				
AEC = OEL (Occupational exposure limit)	Human data				0.1 ppm / 1 mg/m^3

[1] The SCF (2002) established an Upper Intake Level (UL) of 600 µg/day for adults and 200-450 µg/day for children and school pupils. The UL is equal to the AEL. These values are as given in the AR for iodine.

The reference values for iodine of 600 µg/d for adults and 200 µg/d for children are not toxicological reference values but upper intake levels. These values have been derived with the aim of setting recommendations for intake and do not represent toxicological cut-off values for risk assessment. For trace elements like iodine, generally no toxicologically cut-off values are set. Therefore, it was agreed at Human Health Working Group II-2017 to use the upper intake levels as reference values. Furthermore, it is noted that effects that were taken into account for the derivation of the limit values were considered marginal and not associated with clinical effects. Moreover, the assessment factor taken into account is relatively high for a nutrient. It is further noted that WHO derived a value of 1000 µg/d for people in general but not for children specifically. Therefore, the limit values used in this assessment are considered conservative.

Maximum residue limits or equivalent

No MRL required for all target tissues according to Commission Regulation (EU) No 37/2010 of 22 Dec. 2009.

Risk for industrial users

Industrial exposure is not relevant.

Risk for professional users

Systemic effects

The total uptakes for adult users (professionals), as indicated in the corresponding scenarios have been summarized in the following table:

Scenario	Tier	Upper intake Level (UL) mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ UL (%)	Acceptable (yes/no)
Scenario 1	1(No PPE)	0.01	5.08E-05	0.51	Yes
	2(Gloves)	0.01	5.088E-06	0.05	Yes

Scenario 2	Covered by scenario 1				
Scenario 3	1(No PPE)	0.01	1.15E-04	1.15	Yes
	2 (gloves)	0.01	1.15E-05	0.1	Yes
Scenario 4	1(No PPE)	0.01	3.68E-06	0*	Yes
	2 (gloves)	0.01	3.68E-07	0*	Yes
Scenario 5	1(No PPE)	0.01	5.08E-05	0.51	Yes
	2 (gloves)	0.01	5.08E-06	0.05	Yes
Scenario 6	Exposure is covered by scenario 5				
Scenario 7	No exposure is expected				
Scenario 8	1(No PPE)	0.01	4.60E-5	0.46	Yes
	2(Gloves)	0.01	4.60E-6	0*	Yes
Combined task					
1+2+3+4 Pre-milking	1(No PPE)	0.01	1.70E-4	1.69	Yes
	2 (gloves)	0.01	1.70E-5	0.17	Yes
5+6+7+8 Post-milking	1(No PPE)	0.01	9.68E-05	0.97	Yes
	2 (gloves)	0.01	9.68E-06	0.1	Yes
1+2+3+4+5+6+7+8 Pre-&Post-milking	1(No PPE)	0.01	2.67E-04	2.667	Yes
	2 (gloves)	0.01	2.67E-05	0.267	Yes
Dietary exposure (adults)					
		Upper intake level (UL) µg/d	**Estimated uptake µg/d**		
Scenario 9	Pre-milking	600	3.875	0.65	Yes
	Post-milking	600	56.547	9.42	Yes
	Pre&Post-milking	600	60.42	10.07	Yes
Scenario 10	Pre-milking	600	93.875	15.65	Yes
	Post-milking	600	146.547	24.42	Yes
	Pre&Post-milking	600	150.42	25.07	Yes
Scenario 11	Pre-milking	600	278.87	46.48	Yes
	Post-milking	600	331.55	55.26	Yes
	Pre&Post-milking	600	335.42	55.90	Yes

**Negligible exposure*

As a worst-case, the estimated daily iodine intakes by dietary exposure have been added to the individual worker exposure tasks/scenarios.

PRE-MILKING						
Task/ Scenario	**Tier/ PPE**	**Estimated total systemic uptake (mg/kg bw/d)**	**% UL (0.01 mg/kg bw/day) due to biocidal use**	**% UL (0.01 mg/kg bw/day) due to biocidal use + iodine from milk due to teat treatment[1]**	**% UL (0.01 mg/kg bw/day) due to biocidal use + total milk intake[2]**	**% UL (0.01 mg/kg bw/day) due to biocidal use + total dietary intake[3]**
Mixing and loading / [Scen 1]	1/ none	5.08E-05	0,51	1,15	16,15	46,99
	2/ gloves	5.08E-06	0,05	0,70	15,70	46,53
Application by dipping cup / [Scen 2]	Covered by scenario 1					
Cleaning of teats / [Scen 3]	1/ none	1.15E-04	1,15	1,80	15,65	47,63
	2/ gloves	1.15E-05	0,115	0,76	15,76	46,59
Cleaning of equipment / [Scen 4]	1/ none	3.68E-06	0,037	0,68	15,68	46,52
	2/ gloves	3.68E-07	0,004	0,65	15,65	46,48
Combined scenarios [1+2+3+4]	1/ none	1.70E-04	1,699	2,34	17,34	48,18
	2/ gloves	1.70E-05	0,170	0,82	15,82	46,65

POST-MILKING						
Task/ Scenario	**Tier/ PPE**	**Estimated total systemic uptake (mg/kg bw/d)**	**% UL (0.01 mg/kg bw/day) due to biocidal use**	**% UL (0.01 mg/kg bw/day) due to biocidal use + iodine from milk due to teat treatment[1]**	**% UL (0.01 mg/kg bw/day) due to biocidal use + total milk intake[2]**	**% UL (0.01 mg/kg bw/day) due to biocidal use + total dietary intake[3]**
Mixing and loading (decanting) / [Scen 5]	1/ none	5.08E-05	0,51	9,93	24,93	55,77
	2/ gloves	5.08E-06	0,051	9,48	24,48	55,31
Application by dipping cup / [Scen 6]	Covered by scenario 5					

POST-MILKING						
Task/ Scenario	**Tier/ PPE**	**Estimated total systemic uptake (mg/kg bw/d)**	**% UL (0.01 mg/kg bw/day) due to biocidal use**	**% UL (0.01 mg/kg bw/day) due to biocidal use + iodine from milk due to teat treatment[1]**	**% UL (0.01 mg/kg bw/day) due to biocidal use + total milk intake[2]**	**% UL (0.01 mg/kg bw/day) due to biocidal use + total dietary intake[3]**
Cleaning of teats / [Scen 7]	No exposure expected					
Cleaning of equipment / [Scen 8]	1/ none	4.60E-05	0,46	9,88	24,88	55,72
	2/ gloves	4.60E-06	0,046	9,47	24,47	55,30
Combined scenarios [5+6+7+8]	1/ none	9.68E-05	0,97	10,39	25,39	56,23
	2/ gloves	9.68E-06	0,10	9,52	24,52	55,35

PRE & POST-MILKING						
Task/ Scenario	**Tier/ PPE**	**Estimated total systemic uptake (mg/kg bw/d)**	**% UL (0.01 mg/kg bw/day) due to biocidal use**	**% UL (0.01 mg/kg bw/day) due to biocidal use + iodine from milk due to teat treatment[1]**	**% UL (0.01 mg/kg bw/day) due to biocidal use + total milk intake[2]**	**% UL (0.01 mg/kg bw/day) due to biocidal use + total dietary intake[3]**
Combined scenarios [1+2+3+4+5+6+7+8]	1/ none	2.67E-04	2,667	12,74	27,74	58,57
	2/ gloves	2.67E-05	0,267	10,34	25,34	56,17

Local effects

The biocidal product YODICAMP ORDEÑO is classified for eye damage (H318: Causes serious eye damage). This is categorised as hazard cat. "high" for local effects according to the Guidance for human health risk assessment:

Summary table: estimated local exposure from professional uses							
Hazard category	**Effects in terms of C&L**	**Who is exposed**	**Taskes, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Relevant RMMM & PPE**	**Conclusion on risk**

High	Eye dam. Cat 1, H318	Professional	Loading the product in dipping cups, application by dipping the product, cleaning of dipping cups	Skin Eye (splashes, hand to eye transfer)	Few minutes during mixing and loading, and cleaning of equipment For application, an hour per day	P280 Wear eye protection Avoid contact with eyes or skin	Acceptable

During the mixing and loading process, it is necessary to handle the concentrated product, which can cause serious damage to the eyes (it is H318). Therefore, the use of protective googles is mandatory.
During application by manual dipping, the worker holds the cup at the lower compartment, so direct hand exposure to the biocide product or a treated teat is avoided. The cup has an upper compartment for application of the dip and a lower compartment as reservoir for the dipping solution. The correct quantity of liquid to cover a teat is pushed in the top of the dip by pressure on the flexible reserve flask containing YODICAMP ORDEÑO. In addition, given the design of the cup, splashes and spills can be avoided.
No exposure of professionals occurs during automated dipping.
Even so, at least wear chemical googles will be recommended during application.

A quantitative local risk characterisation for butyldiglycol has also been carried out. This means that the IOELV of this substance is compared with quantitative exposure estimates. According to the available European Union-agreed Occupational Exposure Limit (OEL), the long-term (8 hours) occupational exposure limit of butyldiglycol is 67.5 mg/m^3 and the short-term occupational exposure limit (STEL) is 101.2 mg/m^3.
The exposure to butyldiglycol via inhalation is estimated using the consumer ConsExpo web model (version 1.1.0) "Exposure to vapour: evaporation – constant release" for the exposure to vapour generate jointly in the scenario 3 (teat cleaning phase) and in the scenario 1 (mixing and loading phase of the concentrated product), the latter with a very small contribution. Compared to scenario 3, the rest of the scenarios, including those at the POST-milking stage, represent negligible exposure to vapour.

This results in a mean event concentration and peak concentration of 2.1075 × 10^{-2} mg/m³ which is below the 8-hour-TWA of 67.5 mg/m^3, and short-term exposure level STEL (15 mins) of 101.2 mg/m^3.

The concentration of butyldiglycol in air is calculated to be 0.021075 mg/m^3 and the resulting risk index is 0.03% (0.021075/67.5) for a 8 hours TWA. The estimated exposure is thus lower than the available IOELV value for butylglycol. Taking this into account, the butyldiglycol evaporation vapours exposure to is considered acceptable.

Altogether the exposure to butyldiglycol is not considered to cause adverse health effects to the professional users when using Yodicamp Ordeño in accordance to the use instructions. Due to its volatility butyldiglycol evaporates quickly after application. Therefore, secondary exposure to butyldiglycol is considered negligible.

Conclusion

It is mandatory wear eye protection, at least during the mixing and loading of the product.

From the risk assessment approach, the safe use of the product does not require the use of gloves at any time, however, according to the CAR, for hygienic reasons it is standard practice to use at least gloves (in order to reduce the risk of possible cross contamination) and protective clothing.

Risk for non-professional users

Non-professional exposure is not relevant.

Risk for the general public

Exposure of the general public is not relevant.

Risk for consumers via residues in food

The risk for consumers via residues in food concerns both professionals and general public (secondary exposure).
Some scenarios are theoretically envisageable but not relevant because not realistic or covered by the main scenario of residues in milk following teat disinfection. Indeed the exposure to residues in meat following use of teat disinfectants is covered by the exposure to residues in milk following the same use according to the CAR of iodine.
Dietary risk via iodine residues in milk has been assessed for both adults and children. For more details please refer to the exposure section "Dietary exposure" above.
Based on a worst case assumption of two manual milking's per day, the estimated daily iodine intakes and % UL for adults and toddler are presented in the following table:

	Adults (0.45 L/day)	**Toddler (0.46 L/day)**
	Estimated daily intake (µg/day) [% of UL]	**Estimated daily intake (µg/day) [% of UL]**
PRE-milking teat-disinfection, 8% diluted product (0.02% available iodine)		
Intake from milk due to teat treatment	3.875 (0.65%)	3.96 (1.98%)
Total milk intake	93.87 (15.65%)	95.96 (47.98%)
Total dietary intake	278.87 (46.48%)	191.96 (95.98%)
POST-milking teat-disinfection, RTU product (0.25% available iodine)		
Intake from milk due to teat treatment	56.547 (9.42%)	57.80 (28.90%)
Total milk intake	146.55 (24.42%)	149.8 (74.90%)
Total dietary intake	331.55 (55.26%)	245.8 (**122.9%**)
PRE & POST-milking teat-disinfection		
Intake from milk due to teat treatment	60.422 (10.07%)	61.76 (30.88%)
Total milk intake	150.42 (25.07%)	153.76 (76.88%)
Total dietary intake	335.42 (55.9%)	249.76 (**124.88%**)

Considering the worst case (pre & post-milking treatement), for adults, the estimated daily iodine residue in milk resulting from use of the product is in maximum 10.07% of the UL. When adding background values for iodine in milk, daily iodine intake is in maximum 25.07% of the UL. Finally, the total dietary intake of iodine resulting from milk consumption and from other dietary sources is in maximum 55.9% of the UL.

For toddler, the estimated daily iodine residue in milk resulting from the use of the product is at maximum 30.88% of the UL. When adding background values for iodine in milk, daily iodine intake is at maximum 76.88% of the UL. Finally, the total dietary intake of iodine resulting from milk consumption and from other dietary sources at in maximum 124.88% of the UL.

ES CA decision:
Human health risk is acceptable for all milking applications based on estimated intakes, except for toddlers, where total daily intake considerably exceeds (124.88%) the UL. Iodine from toddler dietary intake, arising from every other source except from iodine containing teat disinfection product residues, takes up almost the whole fraction of the UL if current EU data is used.
Considering the above, the following elements have been taken into account to make the decision to authorize the product YODICAMP ORDEÑO:
- The reference values for iodine of 600 µg/d for adults and 200 µg/d for children are not toxicological reference values but upper intake levels. These values have been derived with the aim of setting recommendations for intake and do not represent toxicological cut-off values for risk assessment. For trace elements like iodine, generally no toxicologically cut-off values are set. Therefore, it was agreed at Human Health Working Group II-2017 to use the upper intake levels as reference values. Furthermore, it is noted that effects that were taken into account for the derivation of the limit values were considered marginal and not associated with clinical effects. Moreover, the assessment factor taken into account is relatively high for a nutrient. It is further noted that WHO derived a value of 1000 µg/d for people in general but not for children specifically. Therefore, the limit values used in this assessment are considered conservative.
- The estimated intakes are based on theoretical worst case levels of iodine in milk and were calculated based on a chronic exposure, which was considered to be the most appropriate based on how the UL was derived. Furthermore, it is noted that the SCF (from which the UL for adult and toddler are included in the CAR for iodine) also reports adapted UL values for older children. As the estimated residue levels of iodine in milk are based on a worst case assessment and the data are based on short term consumption studies, then the intakes seen in reality may not be of concern if the lifelong exposures from varying sources of food were considered.
- Within Europe iodine deficiency is considered a major public health problem and iodine supplementation programs are ongoing nationally and internationally to improve the iodine intake and thereby to prevent consequences for public health, e.g. by the addition of iodine in food or salt (e.g. The Netherlands) or the advice to use iodine containing dietary supplements. Other EU countries (e.g. United Kingdom, Czech Republic) regulate adequate iodine intake through addition of iodine to cattle feed. Although it is recognised that both insufficient and excessive iodine intakes can cause diseases, it is generally considered that the benefits of the prevention of diseases from iodine deficiency far outweighs possible side-effects of oversupply.
- The actual amount of iodine intake in the EU is highly variable and difficult to estimate, as levels of iodine intake depend on the geographical location, the soil, people's diet, the

season, farming practices, iodine fortification of feed for dairy animals, iodine supplementation programs and other factors. From iodine supplementation programs, monitoring data on iodine nutrition will become available and a clearer picture of the iodine status across Europe will emerge. It has been discussed in the CA-meeting whether the generation of additional data on residue levels from teat disinfection in milk should be requested from applicants for post-authorisation. However, in the September 2017 CA meeting it was agreed that such a requirement cannot be imposed to the applicants for product authorisation.

- In the specific case of Spain, the study by Serra et al (2003)[1] shows that children in Spain have lower milk consumption than the Dutch children population, used as a default value for the risk assessment. The study was done by a representative sample of the Spanish population (n = 3.534 individuals, 1.905 female and 1.629 male). Both a 24-hours recall and a general questionnaire with socio-economic, demographic and lifestyle items were administered. The results show that the daily intake of milk is 0.37 L/day for boys and 0.35 L/day for girls (aged 2-5 years). A median of 0.36 L/day can be used to re-assess the calculations.

The daily products consumption is also lower than in The Netherlands: according to Serra et al study, is 514 g for boys and 496 g/day for girls. The iodine content in daily products is estimated as 35 µg/100 g (Public Health England, 2015); therefore, the intake by other foods would be estimated as 48 µg/day, far from the assumed 96 µg/day for the calculations above.

A recent study (Vila et al, 2020)[2] reviews the iodine nutrition in Spain and concludes that "Although iodine nutrition in Spain has improved in recent years, the problem is not completely resolved. It is necessary that health institutions establish measures to ensure an adequate iodine nutrition of the population, especially among the highest risk groups (children and adolescents, women of childbearing age, pregnant women and nursing mothers)."

It can be inferred that the iodine intake in Spain may be of concern due to the low levels rather than excessive levels. Therefore, the contribution of milk intake to iodine nutrition is welcomed and does not represent a risk.

References:

1 L. Serra Majem, L. Ribas Barba, C. Pérez Rodrigo, B. Roman Viñas, J. Aranceta BartrinaDietary habits and food consumption in Spanish children and adolescents (1998–2000): socioeconomic and demographic factor Med Clin (Barc), 121 (2003), pp. 126-131

2 Public Health England, 2015. McCance and Widdowson's composition of foods integrateddataset. Available from: https://www.gov.uk/government/publications/composition-of-foodsintegrated- dataset-cofid. (Accessed 13 November 2015).

3 Lluís Vila, Anna Lucas, Sergio Donnay, Antonio de la Vieja, Silvia Wengrovicz, Piedad Santiago, Orosia Bandrés, Inés Velasco, Eduardo Garcia-Fuentes, Susana Ares, José Carlos Moreno Navarro, Mercedes Espada, Antonio Muñoz, Juan Carlos Galofré, Manel Puig-Domingo La nutrición de yodo en España. Necesidades para el futuro. Endocrinología, Diabetes y Nutrición, Volume 67, Issue 1, January 2020, Pages 61-69

Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product

Not relevant, since, on one hand neither additional active substances are contained in the teat disinfection product, and on the other hand, the substance of concern alkyl alcohol C9-C11 ethoxylated, has already been considered in the risk assessment for local effects.

2.2.7 Risk assessment for animal health

In line with similar UA for iodine, eCA ES will refer to previous justification and decision taken.

With reference to the EMEA (European Agency for the Evaluation of Medicinal Products) summary report on iodine-containing products used for veterinary medicine, only small increases in serum iodine concentration have been found after teat dipping indicating that the procedure has a negligible effect on tissue iodine concentrations. These results suggest limited livestock exposure and no-detailed risk assessment was therefore performed for animal health. This is supported by the EFSA 2013 opinion on the safety and efficacy of iodine compounds (E2) as feed additives, in which it was concluded that the iodine level in edible tissues/products is generally found to be highest in milk and not in meat. In addition, iodine-based teat-disinfection products have a long history as safe veterinary hygiene and medicinal products.

The product YODICAMP ORDEÑO is classified by its local effects as H318 (causes serious eye damage), but no adverse effects are expected because it is directly applied on the teats of dairy animals and exposure of the animal´s eyes is not expected.

2.2.8 Risk assessment for the environment

ES CA:
The risk assessment for the environment is reported as submitted by the Applicant. The ES CA assessment is presented in separate boxes on a green background.

Authorisation is requested for the product YODICAMP ORDEÑO® containing as active substance iodine. The biocidal product is a disinfectant for application in product types PT3 (Veterinary hygiene biocidal products). The product is for professional use to disinfect teats of cows, ewes and goats (PT3) applying a 8% v/v dilution of BP by dipping in **pre-milking** and the pure product in dipping cups in **post-milking**.

The intended uses and the dosages of the products are described in table below.

Product name	**Type of application**	**Conc a.s. in PB (% w/w)**	**Dosage a.s. (g Iodine/treatment/cow)[1]**
Disinfection of cow teats before milking (PT3)			
YODICAMP ORDEÑO®	Applied by dipping with diluted product at 8% v/v	2.2% as PVP-Iodine (0.25% max. as Iodine*)	2.5 mL of diluted PB at 8% v/v (equivalent to 0.200 mL of pure product) = 0.00051 Iodine/treatment/cow
Disinfection of cow teats after milking (PT3)			
YODICAMP ORDEÑO®	Applied by dipping	2.2% as PVP-Iodine (0.25% máx. as Iodine*)	10 mL of pure product = 0.025 g Iodine/treatment/cow*

[1]The product dosage used in the environmental risk assessment is according to the ESD-PT3: 10mL of RTU product/treartment/cow when applied via dipping and 2.5mL product/treatment/cow when applied via foaming/towel. *Worst-case dose which is used in the environmental risk assessment.

ES CA:
Some corrections have been made in the previous table:

Product name	Type of application	Conc a.s. in PB (% w/w)	Dosage a.s. (g Iodine/treatment/cow)[1]
Disinfection of cow teats before milking (PT3)			
YODICAMP ORDEÑO®	Applied by dipping with diluted product at 8% v/v	2.2% as PVP-Iodine (0.25% max. as Iodine)	4 mL of diluted PB at 8% v/v (equivalent to 0.320 mL of pure product) = 0.000864 g Iodine/treatment/cow
Disinfection of cow teats after milking (PT3)			
YODICAMP ORDEÑO®	Applied by dipping	2.2% as PVP-Iodine (0.25% máx. as Iodine)	10 mL of pure product = 0.027 g Iodine/treatment/cow*

[1]The product dosage used in the environmental risk assessment is according to the ESD-PT3: 10mL of RTU product/treatment/cow when applied via dipping and 4mL product/treatment/cow when applied via dipping.
*Worst-case dose which is used in the environmental risk assessment.

There is no difference between de YODICAMP ORDEÑO a.s. composition and those BP included in the Iodine (and PVP-iodine) Assessment Report submitted by Sweden on 13th December 2013 (Iodine CAR) for its approval under Regulation No 528/2012 for PT1-3-4-22.

There are not new studies concerning the active ingredient (Iodine and PVP-Iodine) since the product applied for authorisation is identical to the representative products in the CAR and the intended use (the application rate as well summed up) and the exposure to the environment is identical, a very short summary of the environmental risk assessment can be presented here which could be copied from the assessment report or from the CAR.

The risk for the environment was assessed using the AEAT report ED48587/R1 (2007), TGD (2002), the ECHA's Guidance on the Biocidal Products Regulation (Volume IV Environment - Assessment and Evaluation, version 2.0, october 2017), ESD PT3 (2011) and the agreement reach in the WG-I-2018 (Technical Agreements for Biocides, TAB 2018-ENV 64), with their mandatory items:

- 10mL of RTU product/treatment/cow when applied via dipping and 2.5mL product/treatment/cow when applied via foaming/towel.
- 2 events/day for manual milking and 3 events/day for milking systems.
- emission to slurry (milking in the stable) and emission to waste water (in a milking parlour outside the stabel).

A short abstract of Iodine Assessment Report/CAR is showed in the next sections.

ES CA:

YODICAMP ORDEÑO is a biocidal product for external topic use against bacteria aerobic gram-positive and gram-negative and yeasts for use by professional and trained professional users for cleaning, disinfecting and sealing of the udder/teat hole before and after milking in dairy cows, ewes, goats and other lactating females. The application method is manual cleaning before milking and both manual and automatic cleaning after milking.

YODICAMP ORDEÑO is a water formulation containing Polyvinylpyrrolidone Iodine as active substance (a.s.) (2.2% as PVP Iodine, 0.20-0.26% Iodine). This a.s. is classified as Aquatic Acute 1 M=1, Aquatic Chronic 1 M=1 according to their entry in Annex VI of Regulation (EC) No. 1272/2008.

YODICAMP ORDEÑO has several other co-formulants in the formulation. ES CA analysed the information available on the co-formulants (i.e. Safety Data Sheets, C&L Inventory, REACH Registration dossiers, REACH Evaluation Reports and CARs of approved biocidal active substances). Some of the co-formulants are not classified for environmental hazards and therefore do not contribute to the classification or possible risks of the mixture. But one co-formulant carry environmental hazard classification. However it is below the concentration limits specified in Regulation (EC) No. 1272/2008 leading the product to be regarded as hazardous. Therefore it doesn`t contribute to the classification of the biocidal product for environmental hazards.

Therefore the biocidal product YODICAMP ORDEÑO does not contain Substances of Concern for the environment. Consequently, all the information concerning the environmental risk assessment for this product is based on data of the actives substances as included in the Assessment Reports of PT3 uses (final CAR of December 2013).

The application of YODICAMP ORDEÑO on the udder/teat hole is by dipping cup with 4 ml of diluted product at 8% v/v (dose rate of 0.000864 g Iodine/treatment/cow) at pre-milking treatment and by dipping cup with 10 ml of pure product (dose rate of 0.027 g Iodine/treatment/cow) at post-milking treatment (taking into account 12% of iodine in the PVP-Iodine complex and a density of 1.02 kg/L).

2.2.8.1 Effects assessment on the environment

Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required

Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required. Test conducted with Iodine, Iodate and Iodine: EC_{50} are expressed as p.p.m. (mg/L or mg/kg wwt).

Summary table of ecotoxicological studies: Iodine (I_2), Iodide (I^-) and Iodate (IO_3^-)									
Method, Guideline, GLP status, Reliability	**Species/ Inoculum**	**End point**	**Exposure**		**Results**			**Remarks**	**Refe-rence**
			Design	Dura-tion	EC_0 (mg/L)	EC_{50} (mg/L)	EC_{100} (mg/L)		
OECD 203	*Oncorhynchus mykiss*	dead	acute	96h		Iodine: 1.67 Iodate: 220 Iodide: 3780		Fish test	2.2.8 *

OECD 202	*Daphnia magna*	Immobili-sation	acute	48h		Iodine: 0.59 Iodate: 58.5 Iodide: 0.83		Daphnia test	2.2.8 *
OECD 201	*Desmodesmus subspicatus*	Inhibition growth		72h		Iodine: 1.3 Iodate: N.A. Iodide: N.A.		Algae test	2.2.8 *

* From the Assessment Report of Iodine (including PVP-iodine) for Product types 1, 3, 4, 22. Approved on 13th December 2013 submitted by Sweden.
N.A. Not Available data in the CAR

Further Ecotoxicological studies

No data is avalaible.

Summary table - Further ecotoxicological studies

Test conducted with Iodine: EC50 are expressed as mg/L of Iodine (I_2), Iodide (I^-) or Iodate (IO_3^-)

Summary table of further ecotoxicological studies for Iodine (I_2), Iodide (I^-) and Iodate (IO_3^-)									
Method, Guideline, GLP status, Reliability	**Species/ Inoculum**	**End point**	**Exposure**		**Results**			**Remarks**	**Refe-rence[1]**
			Design	Dura-tion	EC_0 (mg/L)	EC_{50} (mg/L)	EC_{100} (mg/L)		
OECD 219	Sewage activated sludge micro-organisms			3h		Iodine: 290 Iodate: N.A. Iodide: N.A.			2.2.8 *

* From the Assessment Report of Iodine (including PVP-iodine) for Product types 1, 3, 4, 22. Approved on 13th December 2013 submitted by Sweden.
N.A. Not Available data in the CAR

Data waiving	
Information requirement	Not necessary
Justification	There are not new studies concerning the active ingredient (Iodine and PVP-Iodine) since the product applied for authorisation is similar to the representative products in the CAR and the intended use (the application rate as well summed up) and the exposure to the environment is identical to the approved under Regulation No 528/2012 for PT1-3-4-22.

Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)

Summary table of effects on specific, non-target organisms believed to be at risk									
Method, Guideline, GLP status, Reliability	**Species/ Inoculum**	**End point**	**Exposure**		**Results**			**Re-marks**	**Refe-rence**
			Design	**Dura-tion**	**EC_0 (mg/L)**	**EC_{50} (mg/L)**	**EC_{100} (mg/L)**		
OECD 207	*Eisenia foetida*	Dead	Acute	14d		Iodine:>1000 Iodate: N.A. Iodide: N.A			2.2.8 *

OECD 208	*Avena sativa*	Seeding emergence and growth	Chronic	21d		Iodine: 11.8 Iodate: 30.4 Iodide: 4.3		mg/kg wwt	2.2.8 *
OECD 217	*Soil microorganisms*	Respiration inhibition		28d		Iodine: 148.7 Iodate: N.A. Iodide: N.A			2.2.8 *
OECD 216	*Soil microorganisms*	Nitration formation		28d		Iodine: 82.6 Iodate: N.A. Iodide: N.A			2.2.8 *

* From the Assessment Report of Iodine (including PVP-iodine) for Product types 1, 3, 4, 22. Approved on 13th December 2013 submitted by Sweden.
N.A. Not Available data in the CAR

Background levels

Iodine and iodine compounds are ubiquitously distributed and there is a natural cycle of iodine species in the environment. Background levels should be taken into account in the environmental risk assessment. There are show in the next table:

Summary table of background levels	
Compartment	**Background level (as iodine)**
Soil	Typically 0.5- 20 mg/kg wt but with extremes up to 98 mg/kg wt Global mean value of 5 mg/kg wt
Groundwater	Mean concentration: 1 µg/L Range: < 1 - 70 µg/L with extremes up to 400 µg/L
Freshwater (river & lake)	0.5 - 20 µg/L
Marine water	45 - 60 µg/L
Rainwater	0.1 - 15 µg/L
Freshwater sediment	Typically: 6 mg/kg
Marine sediment	Typically: 3 - 400 mg/kg
Air	Atmosphere: 10 - 20 ng/m3 Atmospheric concentration: over land 2 - 14 ng/m3; over ocean 17 - 52 ng/m3 Marine air contains: 100 µg/L (may refer to local inhalable air)

PNEC Derivation

The RGB requires that the environmental risk is assessed on basis of Predicted No Effect Concentrations (PNEC), which is determined in line with the Technical Guidance document (version 2003 chapter 3). PNEC values for the different compartments are derived from ecotoxicity data and applying assessment factors. Depending on the type of data (acute or chronic) and number of data a certain assessment factor is selected.

Compartment	**PNEC values**	**Remarks**
Freshwater (µg/L) ($PNEC_{surface\ water}$)	Iodine= 0.59 Iodate=58.5	The lowest EC50 of 0.59 mg/L for iodine was determined in the study on acute toxicity to *Daphnia magna*.

Freshwater sediment (mg/kg) ($PNEC_{sediment}$)	Iodide=0.83 Iodine= 0.029 Iodate= 2.84 Iodide= 0.043	Therefore, $PNEC_{aquatic}$ values for the relevant iodine species using an assessment factor 1000. The $PNEC_{sediment}$ values were calculated on the basis of the $PNEC_{aquatic}$ values, using the equilibrium partitioning method according to the TGD.
Soil (mg/kg wwt) ($PNEC_{soil}$)	Iodine= 0.01182 Iodate= 0.304 Iodide= 0.0043	The lowest EC50 of 13.4 mg/kg dwt (= 11.82 mg/kg wwt) for iodine was determined in the study on non-target plants (*Avena sativa* – shoot fresh weight). Therefore, the PNECterrestrial_EC50 value for Iodine was derived on the basis of the EC50 value using an assessment factor 1000. It should be noted that iodine is not a xenobiotic substance but is present in soil at natural background concentrations of 0.5 to 20 mg/kg soil. Therefore, the application of an assessment factor of 1000 must be considered as unrealistic worst case in the case of iodine.
STP (µg/L) ($PNEC_{STP}$)	Iodine= 2900 Iodate= -* Iodide= -*	The estimated of EC50 value for respiration inhibition based on the water solubility of iodine is 290 mg/L. The assessment factor normally applied to this type of endpoint is 100 (TGD II, 2003). Thus, the $PNEC_{STP}$ microorganisms is derived as.
Air	Not relevant	

* no PNEC derived in the Iodine CAR (2013)

	Values for Iodine		**Values for Iodide**	**Values for Iodate**
Via manure/slurry application (10 years applications)	**Background**	**PNEC**	**PNEC**	**PNEC**
Surface Water-grass (µg/L)	0.5 <-> 20	0,5900	0,8300	58,5000
Surface Water-arable (µg/L)		0,5900	0,8300	58,5000
Soil arable (mg/Kg *wwt*)	0.565 <-> 22.6 extremes up to 110.74	0,0118	0,0043	0,3040
Soil grassland (mg/Kg *wwt*)		0,0118	0,0043	0,3040
Groundwater-grass (µg/L)	1<->70	>0,1	>0,1	>0,1
Groundwater-arable (µg/L)		>0,1	>0,1	>0,1
Via STP				
STP (mg/L)	-	2,9000	not relevant	not relevant
Surface Water (µg/L)	0.5 <-> 20	0,5900	0,8300	58,5000
Soil (mg/Kgwwt)	0.565 <-> 22.6 extremes up to 110.74	0,0118	0,0043	0,3040
Groundwater (µg/L)	1<->70	>0,1	<0,1	>0,1

ES CA:
We agree with the summary of PNEC values. Just a note, PECs for sediments has not been calculated as no predicted no effect concentrations (PNECs) are available. As it is stated on

the iodine AR (December 2013), no further risk assessment has been performed as both the PEC and PNEC values for sediment would have been calculated using the equilibrium partitioning method, and consequently the resulting risk quotient would be the same as described for surface water.

ES CA:

Endocrine disruption activity of non-active substances

The Commission Delegated Regulation (EU) 2017/2100 specifying the scientific criteria for the determination of endocrine-disrupting properties (ED criteria) under Regulation (EU) No 528/2012 (BPR) establishes that the ED criteria become applicable by 7 June 2018 for biocides.

No further ecotoxicological studies are available for YODICAMP ORDEÑO. The product was not tested for potential endocrine disruption properties. YODICAMP ORDEÑO contains the active substance iodine and various co-formulants (see confidential PAR).

For the active substance, as discussed in the Assessment Report for iodine (December 2013), Iodine is an essential element and has a physiological function in thyroid hormone synthesis (i.e. intentionally interacts with the endocrine system). This means that both iodine deficiency as well as iodine excess can impair thyroid homeostasis/thyroid hormone levels. This is to be considered as an endocrine effect.

Biocidal Products Committee (BPC) adopted an Opinion on 27 September 2022 by consensus, concluding that iodine and PVP-iodine have ED properties with respect to humans. Moreover, iodine and PVP-iodine meet the ED criteria for non-target organisms for the T modality. As a result of the identified ED properties, iodine and PVP-iodine fulfil Article 5(1)(d) and 10(1)(e) of the BPR.

For the co-formulants a screening was performed by consulting:
• ECHA data for identification of ED and PBT, under REACH, BPR or CLP
• Identified as ED by United States EPA (https://comptox.epa.gov/dashboard/)
• Identified as ED by the United Nations Environment (July 2017) Programme (http://wedocs.unep.org/bitstream/handle/20.500.11822/25634/edc_report2.pdf?sequence=1&isAllowed=y and https://wedocs.unep.org/bitstream/handle/20.500.11822/25635/edc_report2_factsheet.pdf?sequence=1&isAllowed=y)

During screening performance none of the co-formulant triggered an alert for ED property thus, ES CA considered that there is no concerned regarding the ED properties of this coformulants.

Supervised trials to assess risks to non-target organisms under field conditions

Not relevant for the foreseen use of this BP.

Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk

Not relevant for the foreseen use of this BP.

Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated (ADS)

Not relevant for the foreseen use of this BP.

Foreseeable routes of entry into the environment on the basis of the use envisaged

Exposure to the environment is described in the ESD for PT3. The route of exposure of iodine to the environment is either via application of manure/slurry to agricultural land or by release from the facility drain to an STP and subsequent compartments. Relevant receiving compartments are soil, groundwater and surface water.

Release to seawater may occur in the case of teat dip use and disinfection of milking equipment through runoff after sewage sludge application, but the calculated PEC's are negligible compared to the natural background levels in seawater of 40-65 µg/L and are thus not explicitly summarised here.

Further studies on fate and behaviour in the environment (ADS)

ES CA:

New environmental fate and behaviour on the a.s. or product specific data are not available as they are not considered necessary. All agreed endpoints have been taken from the CAR of the a.s. in PT 3. The co-formulants are not considered Substances of Concern.

Leaching behaviour (ADS)

Not relevant for the foreseen use of this BP.

ES CA:

Additional data on leaching behaviour of the a.s. or the biocidal product are not necessary. New data are not available.

Testing for distribution and dissipation in soil (ADS)

The Iodine K_{oc} 165.8 cm3/g was calculated from the OECD 106 test. The solids-water adsorption coefficients to be used in the environmental exposure calculations are Kp_{soil} = 5.8 cm3/g and Kp_{susp} = 2.2 x 102 cm3/g. (CAR, 2013).

Mineralization (aerobic)	Not applicable due to the fact that iodine is an element
Laboratory studies (range or median, with number of measurements, with regression coefficient)	DT_{50lab} (20°C, aerobic): Not applicable
	DT_{90lab} (20°C, aerobic): Not applicable
	DT_{50lab} (10°C, aerobic): Not applicable
	DT_{50lab} (20°C, anaerobic): Not applicable
	degradation in the saturated zone: Not applicable
Field studies (state location, range or median with number of measurements)	DT_{50f}: No data available and no data required
	DT_{90f}: : No data available and no data required
Anaerobic degradation	Not applicable
Soil photolysis	No data available and no data required
Non-extractable residues	No data available and no data required
Relevant metabolites - name and/or code, % of	Not applicable due to the fact that iodine is an element

ES CA:
Additional data on distribution and dissipation in soil of the a.s. or the biocidal product are not necessary. New data are not available.

Testing for distribution and dissipation in water and sediment (ADS)

STP distribution

Iodide is not highly adsorbed to sludge under typical conditions and iodate can form complexes with calcium which easily adsorb to negatively charged particle surfaces, the majority of the iodine that passes an STP will most probably not be retained in sludge and a sludge retention factor of 20% is chosen for the risk assessment (i.e. 80% of the iodine discharged to the STP remains in the effluent) (CAR, 2013).

Water and Sediment Distribution

According the CAR, in natural water/sediment system, iodide would be the predominant species under aerobic conditions. Iodine can enter sediments through accumulation of plant matter or fixation of iodide in water to humid substances. Weaker and reversible binding of iodide to inorganic components in sediments may also occur (Kd values ranging from 0.22 mL/g for chlorite minerals to 15.14 mL/g for iolite minerals).

Ka Ka_{oc} pH dependence (yes / no) (if yes type of dependence)	Lab-data 1.22 to 124 cm^3/g (five soils); 5.8 cm^3/g (geometrical mean) 51.3 to 3650 cm^3/g (five soils) No pH dependency Data from open literature Kp_{susp}= 220 cm^3/g (geometrical mean) Kp_{soil} = 0.01- 580 cm^3/g; 6.9 cm^3/g (geometrical mean)

ES CA:
Additional data on distribution and dissipation in water and sediment of the a.s. or the biocidal product are not necessary. New data are not available.

Testing for distribution and dissipation in air (ADS)

According the CAR of the Iodine:

Direct photolysis in air	Rapid photolysis of I_2 takes place in the lower atmosphere due to its strong absorption of light in the visible wavelengths ($400 < \lambda < 700$ nm). Lifetime = 5-10 s for an overhead sun
Quantum yield of direct photolysis	No data available
Photo-oxidative degradation in air	Methyl iodide and molecular iodine are the predominant iodine species in air. Both iodine and methyl iodide undergo photochemical reactions to form iodine radicals, which can then go on to form a number of other iodine species through a complex series of reaction pathways.
Volatilization	Iodine is volatilised in several forms with methyl iodide (CH_3I) probably being the most important one.

However, the Iodine in the BP is in the form of complexing-bounded with Polyvinylpyrrolidone, and then is not expected to be volatile.

ES CA:
Additional data on distribution and dissipation in air of the a.s. or the biocidal product are not necessary. New data are not available.

If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms or plants under field conditions (ADS)

Not relevant for the foreseen use of this BP, since the product is used indoor for disinfection and only can reach the environment mixed with manure/slurry or wastewater.

If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given then data on overspray behaviour may be

required to assess risks to bees and non-target arthropods under field conditions (ADS)

Not relevant for the foreseen use of this BP, since the product is used indoor for disinfection and only can reach the environment mixed with manure/slurry or wastewater.

2.2.8.2 Exposure assessment

General information

Assessed PT	PT3. Animal disinfectant
Assessed scenarios	Scenario 1: • Pre-milking with diluted product (at 8% v/v) applied by dipping • Post-milking with pure product applied by dipping
ESD(s) used	PT3a: Manual non-medical teat disinfection and udder washes. PT3b: Automatic teat disinfection (covered by PT3a).
Approach	Average consumption
Distribution in the environment	Calculated based on ECHA- Guidance on the biocidal Products Regulation - Volume IV Environment - Part B Risk Assessment (active substances) Version 1.0; April 2015
Groundwater simulation	Not relevant
Confidential Annexes	Yes (see Excel spreadsheet with ESD PT3 calculations in 3.6 CONFIDENTIAL Annex)
Life cycle steps assessed	Scenario 1: Production: No Formulation: No Use: Yes Service life: No
Remarks	Emission Scenario Document for Product Type 3 (ESD PT3) Veterinary hygiene biocidal products Drafted by Scientific Consulting Company (SCC) GmbH Revised by the Biocides Technical Meeting Endorsed by the Biocides Competent Authorities Meeting Edited by B. Raffael and E. van de Plassche EUR25116EN-2011 European Commission. Joint Research Centre Institute for Health and Consumer Protection Since Euses 2.1.2 does not implement the "PT3-Disinfection for veterinary hygiene: non-medical teat dips" scenario, the calculations were implemented in a Excel® sheet following the equations and intermediate outputs posed in the ESD PT3 document.

ES CA:

Assessed PT1	PT3. Animal disinfectant
Assessed scenarios	Scenario 1: Dairy cows. Pre-milking with diluted product (at 8% v/v) applied by dipping cup and post-milking with pure product applied by dipping cup. - Scenario 1a: Manual teat disinfection. - Scenario 1b: Automatic teat disinfection.
ESD(s) used	* Emission Scenario Document for Product Type 3 (ESD PT3): Veterinary hygiene biocidal products, 2011 * Technical Agreements for Biocides Environment (ENV), July 2021
Approach	Average consumption
Distribution in the environment	Calculated based on ECHA- Guidance on the biocidal Products Regulation - Volume IV Environment - Part B Risk Assessment (active substances) Version 2.0; October, 2017
Groundwater simulation	Not relevant
Confidential Annexes	No
Life cycle steps assessed	Production: No
	Formulation: No
	Use: Yes
	Service life: No
Remarks	Since Euses 2.1.2 does not implement the "PT3-Disinfection for veterinary hygiene: non-medical teat dips" scenario, the calculations were implemented in a Excel® sheet following the equations and intermediate outputs posed in the ESD PT3 document.

Iodine is used in veterinary hygiene biocidal products (PT3) for the purpose of manual and automatic non-medical teat disinfection. Application methods are spraying and dipping of teats, with dipping being most commonly used. In this last case, the teats are immersed before and/or after milking using a cuplike container that holds the disinfectant. At least the lower third of the teats should be immersed. Dip solution remaining in the cuplike container should be discharged. After application through spraying or dipping, the applied teat disinfectant is left to dry on the teat surface and remains there as a protective film, otherwise the worker wipes the treated teats after application.

Two emission pathways are possible: emission to waste water or to the slurry. This depends on whether the cows are milked in the stable (emission to slurry) or in a milking parlour outside the stable (emission to waste water). When the product is discharged in manure, indirect emission will occur to agricultural soil through fertilization with manure. The amount of manure to be used for fertilization is controlled by nitrogen and phosphorus emission standards. When the product is discharged to waste water, indirect emission to surface water and agricultural soil occurs (fertilization with sewage sludge).

Air exposure route
Concerning emissions to air, iodine has a low vapour pressure (40.7 Pa at 25°C) and in view of the high background values of iodine in air, emission to air resulting from application of iodine as disinfectant is not considered to be relevant. This approach is in line with the one

taken in the CAR (2013).

STP exposure route
The PEC and PNEC values were calculated based on the assumption that 100% iodine (I2) is transferred either to two iodide (I^-) or iodate ($IO3^-$) ions. The molecular weight of two iodide ions corresponds to the molecular weight of iodine, consequently the PECs for iodide are the same as for iodine. The molecular weight of two iodate ions is a factor of 1.382 higher than the molecular weight of iodine, therefore the PECs for iodate were calculated by multiplying the PECs of iodine by this factor. No degradation is considered for any of the PEC values. The concept of degradation is not applicable as iodine is an element.

Manure/slurry exposure route
Manure and slurry applications were considered on 10 years applications following the WGIC-2017 discussions. The equations of the Addendum to the OECD SERIES ON EMISSION SCENARIO DOCUMENTS, Number 14: Emission Scenario Document for Insecticides for Stables and Manure Storage Systems were applied following the WG-I-2018 recommendations (and its available spread sheets in the document), it has been taking into account the dissipation via leaching process in soil with a DT_{50} of 643 days for grassland and 2571 days for arable land as agreed at the European level.

Note that dairy cows produce three times more nitrogen than phosphor (0.3389 vs. 0.1047 kg/animal/d), while the nitrogen emission standards are about a factor of two higher. Consequently, the phosphate emission standards combined with the dairy's cows phosphate production allows more manure per hectare and therefore higher PECs. Therefore, only the predicted environmental concentrations (PECs) based on the nitrogen emission standards are presented in the current PAR.

Soil exposure route
The PEC_{soil} values have been calculated according to the legal standards for phosphate abd nitrogen loading in the appendix. In the case of dairy cows, the nitrogen emission standard limits the emission to the environment. Only the results regarding to nitrogen is presented in this ERA.

Emission estimation

ES CA:

YODICAMP ORDEÑO is a biocidal product for cleaning, disinfecting and sealing of the udder/teat hole in dairy cows, ewes, goats and other lactating females. The ESD for PT 3 does not provide default values for relevant parameters for e.g. buffaloes, sheep and goats. Cows are considered worst-case with reference to teat disinfection, as herds are larger than herds of buffaloes, sheep and goats. In addition cows have a higher number of teats compared to other dairy species like sheep and goats, resulting in a lower consumption per treatment. So the current scenario in this PAR cover also ewes, goats and other lactating females, the other target species of this product.

The product YODICAMP ORDEÑO is applied manually two times a day, but three times in milking robots so the scenario 1b: "Automatic teat disinfection" is therefore the worst-case and consequently applied in the environmental risk assessment.

Content of active ingredient (F_{bioc})

The Yodicamp Ordeño® contains 8% of PVP-Iodine at their maximum range. As proposed in the assessment report, the risk assessment is conducted on pure iodine concentration and not PVP-iodine content. Thus the maximum iodine content of the evaluated formulations is 2.5 g Iodine/L (0.25% a.i.).

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 1: PT3a: Manual non-medical teat disinfection and udder washes. PT3b: Automatic teat disinfection (covered by PT3a).			
Application rate of biocidal product (V_{prod})	10.320 (*)	mL/udder (4 teats)	The standard values proposed in ESD PT3 for Dipping application were used (Appendix I, Table 1)
Concentration of active substance (Iodine) in the product ($V_{prod\ i1,i2,i3,i4}$)	2.5	g/L	Worst case, provided by the applicant
Times of application	Pre and Post milking	2	In order to simply the calculus the product volume has been expressed as RTU product in one application. See note below
Concentration of active substance in treatment (F_{bioc})	RTU (ready-to-use) product		The diluted product has been expressed as RTU product
Number of milking events per day (Frequency)	3	day	2 events for manual milking 3 events milking systems (worst case)
Resulting product volume per day	30.960	mL/cow/day	The standard values proposed in ESD PT3 (Appendix I, Table 1) were used
(*) Note: **pre-milking** → diluted product 8% (80 mL product/L) and applied by dipping (4 mL/cow/milking * 8% of dilution = 0.320 mL of RTU product) **post-milking** → dipping with ready to use product (10 mL/cow/milking) 10mL V_{prod} (Pre- + -post) => 10 + 0.320 = 10.320 mL/cow/treatment			

1) F_{bioc}: Content of active ingredient (iodine) in formulation (product)
2) $V_{prod\ i1,i2,i3,i4}$: Amount of product prescribed to be used for one treatment (dipping of the four teats) of one animal
3) F_{dil}: Dilution factor (for preparation of the working solution from the formulation (product)

Calculations for Scenario 2. PEC Calculations

Predicted Environmental Concentrations (PEC) to soil and porewater were calculated using the revised draft ESD (Supplement to the methodology for risk evaluation of biocides, Emission Scenario Document for Product Type 3: Veterinary hygiene biocidal products) for PT3 scenarios in Excel.

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP (Qai_{-STP})	0.0031 kg/d	Daily emission to the sewer system.
$Soil_{grassland}$	0.20511 kg/d	Amount of active ingredient in manure after the relevant number of

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
($Qai\text{-}grass_{i1,i2,i3,i4}$)		biocide applications for the manure application to grassland
$Soil_{arableland}$ ($Qai\text{-}arab_{i1,i2,i3,i4}$)	0.82044 kg/d	Amount of active ingredient in manure after the relevant number of biocide applications for the manure application to arable land

ES CA:

We agree with the exposure assessment proposed by the applicant, but methodological changes from recommendation of the BPC Ad hoc Working Group on Environmental Exposure (agreed at the Environment Working Group V on November 26, 2015) and the proposal for revision of AHEE Recom WG V 2015 (agreed at the WG-I-2018 on January, 2018), included in the Technical Agreements for Biocides Environment (ENV), July 2021, must be taken into account in the risk assessment update.

Furthermore, the available iodine from PVP considered is 2.2%. Additionally, based on the composition of the active substance PVP-I2, the typical (medium) content of iodine is 10 %(w/w), but occasionally the maximum content of iodine in the PVP-Iodine complex can reach up to 12% (w/w), so maximum iodine content or available iodine in the product is 0.264% (w/w). The risk assessment has been carried out based on the maximum available iodine possible: 0.26%.

According to label instructions, the YODICAMP ORDEÑO aplication rate is 1 ml per teat (4 teats/cow; 4 ml/cow, i.e. resulting product volume per day of 12 ml/cow/day). On the other hand, the standard values proposed in Guidance on the Biocidal Products Regulation Volume III Human Health - Assessment & Evaluation (Parts B+C), Version 4.0, December 2017 (Section 6.5.4.1, Guidance on Estimating Livestock Exposure to Active Substances used in Biocidal Products) has been used for dipping 10ml/cow/milking in the post-milking, taking into account what was stated by the applicant in his emission estimation and that this is the worst case. For premilking applied by dipping cup, ES CA has used 4ml/cow/milking of product diluted to 8%, which is equivalent to 0.320ml of pure product.

The tables below present the input parameters for the calculation of emissions to manure or STP in accordance with the characteristic of the product and the ESD for PT03.

Input parameters for emission calculations for the worst case Scenario 1b: "Automatic teat disinfection"				
Parameters	**Nomenclature**	**Value**	**Unit**	**Origin**
Type of housing/manure storage (for application of the notification)	**Cat-Subcat (i1)**	1 - Dairy Cows	[-]	S (ESD Appendix 1: Table 7)
Type of biocide	**bioctype (i2)**	1 - Disinfectant	[-]	S (ESD Appendix 1: Table 7)
Type of application	**appway (i3)**	2 (dipping)	[-]	S (ESD Appendix 1: Table 7)
Relevant emission stream	**stream (i4)**	1 and 3 (STP and slurry/manure	[-]	P (ESD Appendix 1: Table 7)
Content of active ingredient in formulation (product)	F_{bioc}	2,7	[$g.l^{-1}$]	S
Amount of product prescribed to be used for one treatment (dipping of the four teats) of one animal	$Vprod_{i1,i2,i3}$	0,01032	[l]	S
Dilution factor (for preparation of the working solution from the formulation (product))	F_{dil}	1	[-]	S
Fraction of active ingredient released	$F_{stp} = F_{ww}$ $(1-F_{teat})$	0,5	[-]	D
Fraction of active ingredient released	$F_{slurry/manurry}$ $(1-F_{teat})$	0,5	[-]	D
Fraction of active ingredient released	F_{air}	0	[-]	D
Fraction of active ingredient released	F_{teat}	0,5	[-]	D
Number of teat dipping events for one animal and one day (dipping of the four teats of one animal = one disinfectant application)	$N_{app-teat}$	6	[-]	D (TAB ENV 64)
Number of days of lactation period (corresponds to number of emission days)	$N_{day-lact}$ (= $T_{emission}$)	300	[-]	D
Number of disinfectant applications in one year (equals number of disinfectant applications in one lactation period)	$N_{app-bioc}$	1800	[-]	D (TAB ENV 64)
Interval between two disinfectant applications (dipping events)	$T_{bioc-int}$	0,17	[d]	D (TAB ENV 64)
Number of manure applications for grassland	**Nlapp-grass**	4	[-]	D
Number of manure applications for arable land	**Nlapp-arab**	1	[-]	D
Manure application time interval for grassland	T_{gr-int}	53	[d]	D/S (ESD PT3, 2011; Appendix1: Table 12)
Manure application time interval for arable land	T_{ar-int} (Tmanure-int_{arab}	212	[d]	D/S (ESD PT3, 2011; Appendix1: Table 12)
Number of animals in housing for category/subcategory	$Nanimal_{i1}$	100	[-]	D/S (ESD PT3, 2011; Appendix1: Table 8)
Number of milk producing animals per day	**Nmp_animal**	82	[-]	D/S (TAB ENV 63)
Amount of nitrogen per animal for category/subcategory	$Qnitrog_{i1}$	0,3389	[$kg.d^{-1}$]	D(ESD PT3, 2011; Appendix1: Table 11)

If nitrogen immission standards are applied:				
Nitrogen immission standard for one year on grassland	$Q_{N,grassland}$	170	[kg.ha^{-1}]	D(ESD PT3, 2011; Appendix1: Table 13)
Nitrogen immission standard for one year on arable land	$Q_{N,arable\_land}$	170	[kg.ha^{-1}]	D(ESD PT3, 2011; Appendix1: Table 13)
Mixing depth with soil, grassland	$DEPTH_{grassland}$	0,05	[m]	D
Mixing depth with soil, arable land	$DEPTH_{arable\_land}$	0,2	[m]	D
Density of wet bulk soil	$RHOsoil_{wet}$	1700	[kg.m^{-3}]	D

*D: default from ESD, S: set based on product.
[1] For arable land:
If Tbioc-int ≥a) Tmanure-intar2, then Napp-biomanure_ar2 = 1.
If Tbioc-int < Tmanure-intar2, then Napp-biomanure_ar2 = ROUND (z,[n])b) (Tmanure-intar2/Tbioc-int), with n=1.
If Napp-biomanure_ar2 > Napp-bioc. then Napp-biomanure_ar2 = Napp-bioc

[2] For grass land:
If Tbioc-int ≥a) Tgr-intb, then
Napp-manuregr = 1
If Tbioc-int < Tgr-int, then
Napp-manuregr = ROUND (z,[n])c) (Tgr-int/Tbioc-int), with n=1.
If Napp-manuregr > Napp-prescr, then
Napp-manuregr = Napp-prescr

(*) Note:
pre-milking → applied by dipping cup (4 mL/cow/milking * 8% of dilution = 0.320 mL of pure product)
post-milking → dipping with ready to use product (10 mL/cow/milking) 10mL
Vprod (Pre- + -post) => 10 + 0.320 = 10.320 mL/cow/treatment

Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway									
Scenario	**Fresh-water***	**Freshwater sediment**	**Sea-water***	**Seawater sediment**	**STP**	**Air**	**Soil**	**Ground-water**	**Birds/ mammals**
Scenario 1 (via STP)	yes	yes	no	no	yes	no	yes	yes	Not relevant
Scenario 1 (via slurry/ manure) - 10 year application	yes	yes	no	no	yes	no	yes	yes	Not relevant

ES CA:
Two different emission pathways are described in the ESD of PT3 (2011):
-Release to the wastewater treatment plant, or
-Release into the manure.

Both emission pathways are considered in the environmental risk assessment.

The exposed compartments are summarised below.

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water	Other
via STP	yes	yes	n.r.	n.r.	yes	n.r.	yes	yes	no
Via slurry/manure	yes	yes	n.r.	n.r.	n.r.	n.r.	yes	yes	no

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	**Value**	**Unit**	**Remarks**
Molecular weight	253.81	g/mol	AR, 2013
Melting point	113.5-113.7	°C	AR, 2013
Boiling point	184.24-184.5	°C	AR, 2013
Vapour pressure (at 0ºC) Vapour pressure (at 25ºC) Vapour pressure (at 50ºC)	4 40.7 287	Pa	AR, 2013
Water solubility (at 0°C) Water solubility (at 25°C) Water solubility (at 50°C)	0.29 0.3-0.35 0.78	mg/l	AR,2013
Log Octanol/water partition coefficient	Not relevant to a purely inorganic substance like iodine	Log 10	AR,2013
Organic carbon/water partition coefficient (Koc)	51.3 to 3650	l/kg	AR,2013
Henry's Law Constant (at X C)*[if measured data available]*	34.43	Pa/m3/mol	AR,2013
Biodegradability	Iodine is an inorganic substance, which cannot biodegrade. Depending on whether aerobic or anaerobic conditions prevail, iodine is present in the environment either as iodide or iodate.		AR,2013
Rate constant for STP *[if measured data available]*		h^{-1}	
DT_{50} for biodegradation in surface water	Not applicable because Iodine is an element		AR,2013
DT_{50} for hydrolysis in surface water	Hydrolysis reaction of iodine occurs to a very small extent because iodine is sparingly soluble. Hydrolysis of I_2 as the reactant is a pH-dependent dynamic equilibrium reaction	d or hr (at 12ºC)	AR,2013

	with iodide (I^-) and iodate (IO_3^-) as products. At pH values between 4 and 9, iodide is the predominant species. In alkaline and well oxidized waters iodate is the predominant specie.		
DT_{50} for photolysis in surface water	In water, iodide and iodate are the predominant species. In addition a natural background level of methyl iodide might also be found in water. Photolytic dissociation of these compounds can result in the formation of elemental iodine and inorganic iodine species.	d or hr (at 12ºC /pH)	AR,2013
DT_{50} for degradation in soil	Not applicable due to the fact that iodine is an element	d or hr	AR,2013
DT_{50} for degradation in air	Rapid photolysis of I2 takes place in the lower atmosphere due to its strong absorption of light in the visible wavelengths (400 < λ < 700 nm). Lifetime = 5-10 s for an overhead sun	d or hr (at 12ºC)	AR,2013

Calculated fate and distribution in the STP			
Compartment	Percentage [%]		Remarks
	Scenario 1	Scenario n	
Air	N.R	n.a.	Regulation (EU) n°528/2012 concerning the making available on the market and use of biocidal products. Evaluation of active substances. AR, 2013.
Water	80	n.a.	
Sludge	20	n.a.	
Degraded in STP	0	n.a.	

ES CA:
Input parameters

Input parameters for calculating the fate and distribution in the environment for Iodine, Iodide and Iodate			
Parameters for iodine	**Value**	**Unit**	**Remarks**
Molecular weight	235.81	g.mol-1	CAR (2013)
Vapour pressure (at 25°C)	40.7	Pa	CAR (2013)
Water solubility (at 20°C)	290	mg/l	CAR (2013)
Log OctaNol/water partition coefficient	-	-	Inorganic substance
Organic carbon/water partition coefficient (Koc)	Not relevant	L/kg	Inorganic substance
Henry's Law Constant (at 25ºC)	34.43	Pa/m3/mol	
Biodegradability	Not biodegradable	-	Inorganic substance
DT50 for degradation in soil	1.0E+06	D	Inorganic substance
Solids-water partition coefficient in suspended matter ($K_{p, susp}$)	220	L/kg	CAR (2013)
Solids-water partition coefficient in soil ($K_{p, soil}$)	5.8	L/kg	CAR (2013)
Solids-water partition coefficient in soil ($K_{soil-water}$)	8.90	$m^3.m^{-3}$	Calculated
Susp-water partition coefficient ($K_{susp-water}$)	55.9	$m^3.m^{-3}$	Calculated
Parameters for iodide	**Value**	**Unit**	**Remarks**
Transformation rate in surface water iodine to iodide (%)	100	%	
Transformation rate in soil iodine to iodide via the STP (%)	14	%	
Transformation rate in soil iodine to iodide via manure (%)	100	%	
Molecular equivalent iodide/iodine	1		
Parameters for iodate	**Value**	**Unit**	**Remarks**
Transformation rate in surface water iodine to iodide (%)	100	%	
Transformation rate in soil iodine to iodide via the STP (%)	100	%	
Transformation rate in soil iodine to iodide via manure (%)	100	%	
Molecular equivalent iodate/iodine	1.382		

Calculated PEC values

Summary table on calculated PEC values								
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**$PEC_{seawater}$**	**PEC_{seased}**	**PEC_{soil}**	**PEC_{GW}[1]**	**PEC_{air}**
	[mg/l]	[µg/l]	[mg/kg_{wwt}]	[mg/l]	[mg/kg_{wwt}]	[mg/kg]	[µg/l]	[mg/m^3]
Scenario 1 Via STP	I_2:0.0013 I^-:0.0013 IO_3^- :0.0018	I_2:0.0001 I^-:0.0001 IO_3^- :0.0002	N.R.	N.R.	N.R.	I_2:0.0013 I^-:0.0013 IO_3^- :0.0017	I_2:0.2382 I^-:0.0333 IO_3^- :0.3292	N.R.
Scenario 2 Via manure-10 years	N.A.	I_2:1.2834 I^-:1.2834 IO_3^- :1.7737	N.R.	N.R.	N.R.	I_2:0.0372 I^-:0.0372 IO_3^- :0.0514	I_2:12.8345 I^-:12.3845 IO_3^- :17.7373	N.R.

application (grassland)								
Scenario 2 Via manure (arable)-10 years application	N.A.	I_2:0.7105 I^-:0.7105 IO_3^- :0.982	N.R.	N.R.	N.R.	I_2:0.0672 I^-:0.0672 IO_3^- :0.0929	I_2:7.105 I^-:7.105 IO_3^-:9.82	N.R.

[1] If the PEC_{GW} was calculated by using a simulation tool (e.g. one of the FOCUS models), please provide the results for the different simulated scenarios in a separate table.
N.A. Not applicable
N.R. Not relevant

ES CA:

It should be noted that the nitrogen standard is the most relevant in Europe notably in Spain. Therefore, regarding emission via manure application, PEC values were calculated for application to grassland and arable land on the nitrogen standard.

According to the Technical Agreements on Biocides 2021, (version 2.0, entry ENV-63):
- In the emission to STP, the value for the number of milk producing cows is refined to 82.
- In the emission to slurry, the value for the number of milk producing cows is 100.

According to the assessment report for iodine (I2), iodate (IO3-) may be considered to be the dominant chemical form of iodine in the soil solution under aerobic non-flooded soil conditions, while iodide (I-) appears mainly under anaerobic conditions. In surface water, however, both species may appear depending on the acidity (pH) and oxygen concentrations (redox) of the receiving fresh water body. In general iodate is the dominant species in oxygen rich water, while iodide is present in water low in oxygen contents. Predicted environmental concentrations were therefore calculated assuming no transformation (100% iodine) and 100% transformation into iodide or iodate. Only for PECs in soil were recalculated taking into account the following: for spreading of sewage sludge on arable land it is assumed that 100% of iodine is transformed into iodate and 14% into iodide (according to CAR). Limited information on the behaviour of iodate and iodide in environmental compartments is available. Therefore, the physical-chemical properties for iodine were applied to these two transformation products as well. PECs for iodate were derived by multiplying those for iodine with 1.382 (differences in molar weight).

The PEC calculated with ESD PT3 represents the concentration after manure application on arable land and grassland (PIEC). Since fertilizers are applied repeatedly, iodine would accumulate in the soil after consecutive manure applications. This accumulation is counteracted by the effect of degradation and leaching. Concentrations in soil after ten years are therefore calculated according to the Addendums for PT18 (WGV2015 and WGI2018). The emission to soil from the application of slurry/manure has been determined taking degradation and leaching to deeper soil layer into account for a period of 10 years (agreed at BPC WGIV2017).

Based on the biodegradation data of iodine in soil and leaching, the experimentally derived water-solids distribution coefficient for soils is 5.8 L/kg, iodine is practically eliminated from the soil by leaching, maintaining half-lives for topsoil leaching of 2571 days in arable land (20 cm) and 643 days in grassland (5 cm). Due to the value for kleach is derived from the soil depth, this value is different for arable and grassland. These two values have been validated in WG for Union Authorisations containing iodine.

Input parameters for the $PECsoil_{10years}$ calculations considering degradation and leaching of iodine to deeper soil layers are listed in the table below:

Parameters	Symbol	Value	Unit	Remarks
Fraction of rain water that infiltrates into soil	Finf_soil	0.25	-	Guidance on BPR:Vol IV Environment (ECHA, 2017) Equation (55)
Rate of wet precitipation (700 mm/year)	RAINrate	1.92E-03	m/d	Guidance on BPR:Vol IV Environment (ECHA, 2017) Equation (55)
Half-life for biodegradation in bulk soil	DT50biosoil	1.00E+6	d	CAR
First-order rate constant for leaching from soil layer (grassland)	kleach_gr	1.08E-03	d^{-1}	Guidance on BPR:Vol IV Environment (ECHA, 2017) Equation (55)
Half-life for leaching from soils (grassland)	DT50soil_gr	642.71	d	BPC WGIV2017
First-order rate constant for leaching from soil layer (arable land)	kleach_ar	2.70E-04	d^{-1}	Guidance on BPR:Vol IV Environment (ECHA, 2017) Equation (55)
Half-life for leaching from soils (arable land)	DT50soil_ar	2570.82	d	BPC WGIV2017
First-order rate constant for removal from top soil layer (grassland)	ktot_gr	1.08E-03	d^{-1}	Guidance on BPR:Vol IV Environment (ECHA, 2017) Equation (56)
First-order rate constant for removal from top soil layer (arable land)	ktot_ar	2.70E-04	d^{-1}	Guidance on BPR:Vol IV Environment (ECHA, 2017) Equation (56)

Finally, according to the CAR, all considered compartment with PEC/PNEC ratio above 1 will be assessed by a comparison between PEC values for iodine and background level determined for each compartment.

Summary table on calculated PEC and background levels (as iodine)				
	Values for Iodine		Values for Iodide	Values for Iodate
	Background	PEC	PEC	PEC
Via manure application (10 years applications)				
Surface water grassland (µg.L^{-1})	0.5-20	2,14E+00	2,14E+00	2,96E+00
Surface water arable (µg.L^{-1})		1,29E+00	1,29E+00	1,78E+00
Soil grassland (mg.kg$_{wwt}$)	0.565-22.6	1,12E-01	1,12E-01	1,55E-01
Soil arable (mg.kg$_{wwt}$)	extremes up to 110.74	6,75E-02	6,75E-02	9,33E-02
Groundwater grassland (µg.L^{-1})	1-70	2,14E+01	2,14E+01	2,96E+01
Groundwater arable (µg.L^{-1})		1,29E+01	1,29E+01	1,78E+01
Via STP				
Elocal (kg/d)	6,87E-03			
STP (mg/L)	-	2,75E-03	2,75E-03	3,80E-03
Surface water (µg/L)	0.5-20	2,74E-01	2,74E-01	3,79E-01
Soil (mg/kg$_{wwt}$)	0.565-22.6 extremes up to 110.74	8,73E-03	1,22E-03	1,21E-02
Groundwater (µg/L)	1-70	1,67E+00	2,33E-01	2,30E+00

For spreading of sewage sludge on arable land it is assumed that 14% of iodine is transformed into iodide (according to CAR).

Primary and secondary poisoning

Primary poisoning

Not relevant. Iodine is not bioacumulative (Kow<3). A direct exposure of different animals other than treated is considered unlikely.

ES CA:

Primary poisoning

Not relevant. A direct exposure of different animals (birds or mammals) other than treated animal to the biocidal product is considered negligible since there is no direct release of the product in the environment.

Secondary poisoning

As iodine is an essential element, internal concentrations are expected to be regulated within small boundaries. Moreover, because iodine is not hydrophobic (log Kow < 3), passive uptake by partitioning to lipid and other hydrophobic phases is not expected. Therefore, accumulation and biomagnification in higher tropic levels cannot be expected. As iodine is an essential element, internal concentrations are expected to be regulated within small boundaries. Moreover, because iodine is not hydrophobic (log Kow < 3), passive uptake by partitioning to lipid and other hydrophobic phases is not expected. Therefore, accumulation and biomagnification in higher tropic levels cannot be expected.

2.2.8.3 Risk characterisation

Risk assessment via atmosphere emissions

Conclusion: Risk is not relevant. Emissions of Iodine to air resulting from the product application is not considered relevant (CAR, 2013).

ES CA:

Exposure to air is not considered as iodine is assumed to speciate into non-volatile iodide and iodate in the different compartments it is released to. It cannot be expected that airborne iodine will significantly increase the already high background values in air (1.10E-2 to 2.10E-2 µg/m³, according to the CAR on iodine). There are no indications that iodine contributes to depletion of the ozone layer as iodine or organic-bound iodine are not listed as 'controlled substance' in Annex I of Regulation (EC) No 1005/2009 of the European Parliament.

Risk assessment via manure application after 10 years applications and via Sewage treatment plant (STP) to Aquatic compartment and Terrestrial compartment

	Values for Iodine			Values for Iodide		Values for Iodate	
	Background	**PEC**	**PEC/PNEC***	**PEC**	**PEC/PNEC***	**PEC**	**PEC/PNEC***
Via manure: 10 years application							
Surface water grassland (µg.L^{-1})	0.5-20	1.2834	2.1753	1.2834	1.5463	1.7737	0.0303
Surface water arable (µg.L^{-1})		0.7105	1.2043	0.7105	0.8560	0,9819	0.0168
		In the background level for iodine					
Soil grassland (mg.kg$_{wwt}$)	0.565-22.6 extremes up to 110.74	0.0372	3.1534	0.0372	8.6535	0.0514	0.1692
Soil arable (mg.kg$_{wwt}$)		0.0672	5.6962	0.0672	15.6314	0.0929	0.3056
		In the background level for iodine					
Groundwater grassland (µg.L^{-1})	1-70	12.834	>0.1	12.8345	>0.1	17.7373	>0.1
Groundwater arable (µg.L^{-1})		7.105	>0.1	7.1051	>0.1	9.82	>0.1
		In or higher than the background level for iodine					
STP (mg.L^{-1})	Not relevant	0.0013	0.0004	0.0013	not relevant	0.0017	not relevant
Surface water (µg.L^{-1})	0.5-20	0.0001	0.0002	0.0001	0.0002	0.0002	0.000001
		In the background level for iodine					
Soil (mg.kg$_{wwt}$)	0.565-22.6 extremes up to 110.74	0.0012	0.1057	0.0002	0.0406	0.0017	0.0057
		Lower to the background level for iodine					
Groundwater (µg.L^{-1})	1-70	0.2325	>0.1	0.0326	<0.1	0.3253	>0.1
		In or lower to the background level for iodine					

**Values in red indicate a risk quotient (PEC/PNEC) > 1*

Risk assessment via manure application after 10 years (Nitrogen standard)

In surface water
The Risk Quotient (RQ) for Iodine and Iodide is > 1. Neverthess, both Iodine and Iodide $PEC_{surfacewater}$ values are in the range of typically background concentrations (0.5 to 20 µg/L) which indicates acceptable risks.

In soil
The Risk Quotient (RQ) for Iodine and Iodide is > 1. Like in Surface water, the PEC_{soil} (for grass and arable land) values are below or in typically background concentrations ranging from 0.565 to 22.6 mg/kg wwt. Conclusion: The risk is acceptable.

In groundwater
In the risk assessment for groundwater, the PEC values are compared with the limit value of 0.1 µg/L provided for pesticides in the Drinking Water Directive 98/83/EC. However, as iodine and iodine compounds are not xenobiotics, this threshold value can be considered as over conservative. Calculated PEC_{gw} values for iodine are higher than the natural background concentrations of 70 µg/L. The estimation of concentrations in groundwater is based on a worst-case assumption taking into account the partitioning equilibrium. In the absence of possible refinement of this methodology, the assessment of estimated concentrations in groundwater cannot be refined. However, no unacceptable risk is expected for groundwater.

Risk assessment via Sewage treatment plant (STP)

In STP
PEC/PNEC value is below 1 which indicates acceptable risk.

In surface water
PEC/PNEC values in surface water are all below 1 or in the background level for iodine in this compartment which indicates acceptable risks.

In soil
PEC_{soil} values are below or in typically background concentrations ranging from 0.565 to 22.6 mg/kg wwt for iodine.

In groundwater
PEC_{gw} are below the maximum natural background concentration of 70 µg/L for iodine.

Risks are acceptable following a theoretical release to the STP. Therefore, releases to the STP from milking parlour are not considered relevant for Spain since many farms are not connected to a municipal STP having their own STP system.

Conclusion: In all cases the risks are acceptable.

Groundwater

For iodine the PEC_{grw} values of the worst-case application as non-medicinal teat dips or sprays were higher than 0.1 µg/L provided for pesticides in the Drinking Water Directive 98/83/EC.

However, it should be noted that the definition of pesticides in the Drinking Water Directive is limited to organic substances and their relevant metabolites, degradation and reaction products. Based on this definition iodine, iodide and iodate are not within the scope of this

Directive. Moreover, iodine and its species are not xenobiotic substances but essential nutrients which are needed in relatively high concentration, and for this reason the limit concentration of 0.1 µg/L for pesticides is not considered applicable.

Although the calculated iodine concentration in groundwater is above the mean natural background concentration of 1 µg/L it is still below the maximum natural background concentration of 70 µg/L (up to 400 µg/L in exceptional cases).

It should be noted that the PEC in groundwater were calculated following the TGD using the pore water concentration in soil as indication for the groundwater level (in the following noted as "pore water-approach"), not taking into account any removal processes like e.g. lateral transport or plant uptake. This leads to a large overestimation of the real concentrations in groundwater. FOCUS-modelling for the groundwater (and surface water) to achieve more realistic predictions is not applicable to inorganic substances (see for example EFSA conclusion on sulphur under Dir 91/414/EC; available at http://www.efsa.europa.eu/en/scdocs/ scdoc/221r.htm).

For comparison, if the groundwater- and surface water concentrations would be calculated for the average natural background concentration of iodine species in soil of 5 mg/kg, using the "pore water-approach" based on the TGD it results in surface- and groundwater concentrations of 0.16 and 1.6 mg/L, respectively which is 10 - 100 fold higher than the concentrations measured in these compartments in the field. This illustrates that the results of the calculations using the "pore water-approach" must be interpreted with caution.

In conclusion given that the derived conservative Upper Intake Level (UL) for children and adults is 250 and 600 µg iodine/day respectively an increase in the natural groundwater iodine levels of up to 65.9 µg/L for iodine/iodide (using nitrogen standard) appears not to be of any concern.

ES CA:

The table below represents the risk assessment via manure application after 10 years applications and via Sewage treatment plant (STP) to Aquatic compartment and Terrestrial compartment with the background levels (as Iodine).

Summary table on calculated PEC and background levels (as iodine)							
	Values for Iodine			Values for Iodide		Values for Iodate	
	Background	PEC	PEC/PNEC	PEC	PEC/PNEC	PEC	PEC/PNEC
Via manure application (10 years applications)							
Surface water grassland (µg.L^{-1})	0.5-20 µg/L	2,14E+00	**3,62E+00**	2,14E+00	**2,58E+00**	2,96E+00	5,05E-02
Surface water arable (µg.L^{-1})		1,29E+00	**2,18E+00**	1,29E+00	**1,55E+00**	1,78E+00	3,04E-02
		In the background level for iodine					
Soil grassland (mg.kg$_{wwt}$)	0.565-22.6 mg/kgdwt extremes up to 110.74 mg/kgdwt	1,12E-01	**9,50E+00**	1,12E-01	**2,61E+01**	1,55E-01	5,10E-01
Soil arable (mg.kg$_{wwt}$)		6,75E-02	**5,72E+00**	6,75E-02	**1,57E+01**	9,33E-02	3,07E-01
		Lower the background level for iodine					
Groundwater grassland (µg.L^{-1})	1-70 µg/L with extremes up to 400 µg/L	**2,14E+01**	>0,1 µg/L	**2,14E+01**	>0,1 µg/L	**2,96E+01**	>0,1 µg/L
Groundwater arable (µg.L^{-1})		**1,29E+01**	>0,1 µg/L	**1,29E+01**	>0,1 µg/L	**1,78E+01**	>0,1 µg/L
		In the background level for iodine					
Via STP							
Elocal (kg/d)	6,87E-03						
STP (mg/L)	Not relevant	2,75E-03	9,48E-04	2,75E-03	Not relevant	3,80E-03	Not relevant
Surface water (µg/L)	0.5-20 µg/L	2,74E-01	4,64E-01	2,74E-01	3,30E-01	3,79E-01	6,47E-03
		Lower to the background level for iodine					
Soil (mg/kg$_{wwt}$)	0.565-22.6 mg/kgdwt extremes up to 110.74 mg/kgdwt	8,73E-03	7,40E-01	1,22E-03	2,84E-01	1,21E-02	3,97E-02
		Lower the background level for iodine					
Groundwater (µg/L)	1-70 µg/L with extremes up to 400 µg/L	**1,67E+00**	>0,1 µg/L	2,33E-01	>0,1 µg/L	**2,30E+00**	>0,1 µg/L
		In the background level for iodine					

**Values in bold indicate a risk quotient (PEC/PNEC) > 1.*

Conclusion concerning the risk assessment via manure application after 10 years applications:

In surface water

Although the PEC/PNEC ratios for Iodine and Iodide are > 1, the PEC surface water values for iodine are in the range of typically background concentrations (0.5 to 20 µg/L) which indicates acceptable risks.

In soil

The individual PEC / PNEC ratios for the relevant compartment are higher than 1 for iodine and iodide in grassland and arable land. Iodine is a natural substance, and PEC / PNEC values greater than 1 are acceptable since PEC values are within background concentrations. Iodine is not a xenobiotic substance and is naturally present in soil. Its background concentrations are in the range of 0.565 – 22.6 mg/kgdwt (expressed as iodine).

For cases where it is greater than 1, the highest PEC for iodine is 1.12E-01 mg/l, so it is within the lower range of background iodine concentrations in soil.

Therefore, the emission to soil is considered acceptable.

In groundwater

The concentration in the soil's pore water derived by equilibrium partitioning according to the guidance are above the limit values of 0.1 µg/L provided for pesticides in the Drinking Water Directive 98/83/EC.

However, it is stated in the CAR (2013) that the trigger value of 0.1 µg/L is limited to organic substances and their relevant metabolites and degradation products. Since iodine and its species are inorganic substances, which are not xenobiotic but essential nutrients, it is concluded in the CAR that the concentration limit of 0.1 µg/L for pesticides is not applicable to iodine.

The predicted concentrations were compared to natural background concentrations. The PECs are expected to be within the natural background level of iodine in groundwater that ranges between 1 and 70 µg/L with extremes up to 400 µg/L. Therefore, emission to groundwater is considered acceptable and no risk mitigation measures are necessary.

Conclusion concerning the risk assessment via STP:

In STP

The individual PEC/PNEC ratio for the assessed scenario is below 1 for iodine, iodide and iodate in the aquatic compartment, exposed via STP. Therefore, there is no unacceptable risk to this compartment for the proposed use of the teat disinfectant product.

In surface water

PEC/PNEC values in surface water are all below 1 in this compartment, which indicates that emission to surface water is considered acceptable.

In soil

All the PEC/PNEC ratios are below 1, so there are no unacceptable risks for soil.

In groundwater

The same approach used previously can be applied. PECsgw are below the maximum natural background concentration of 70 µg/L for iodine. Therefore, emission to groundwater is considered acceptable.

Primary and secondary poisoning

For the proposed use of the active substances in PT3 applications direct or indirect exposure of birds and mammals to the active substances or contaminated aquatic and terrestrial organisms is considered negligible.

As iodine is not bioaccumulative and the proposed applications (indoor use) will not result in exposure of surface water and the amounts of iodine delivered into the environment through biocidal uses are within the natural occurring background levels, the risk for the primary and secondary poisoning is considered acceptable. The proposed applications meet the standards for birds and mammals.

Because the product is mainly applied indoors and not released to the environment directly, direct uptake by non-target organisms cannot be expected. Moreover, because iodine is an essential nutrient and its hydrophobicity does not exceed the trigger value for bioaccumulation, excessive passive uptake cannot be expected. Therefore, the PEC will not exceed the oral PNEC. No risks from primary and secondary poisoning are expected.

Mixture toxicity

Not relevant. The product only contains one active substance (PVP-Iodine) and no substances of concern. In addition, no active substances from other PTs and no other ingredients that need consideration are contained.

Aggregated exposure (combined for relevant emission sources)

Although iodine is released from multiple sources, aggregated exposure assessment is not deemed necessary as there is no overlap in space and time for the current biocidal product family. Iodine as a teat disinfectant is predominantly released to agricultural soils and therefore not mixed with iodine from other anthropogenic sources. See the figure 1 for decision tree on the need for estimation of aggregated exposure according CAR (2013).

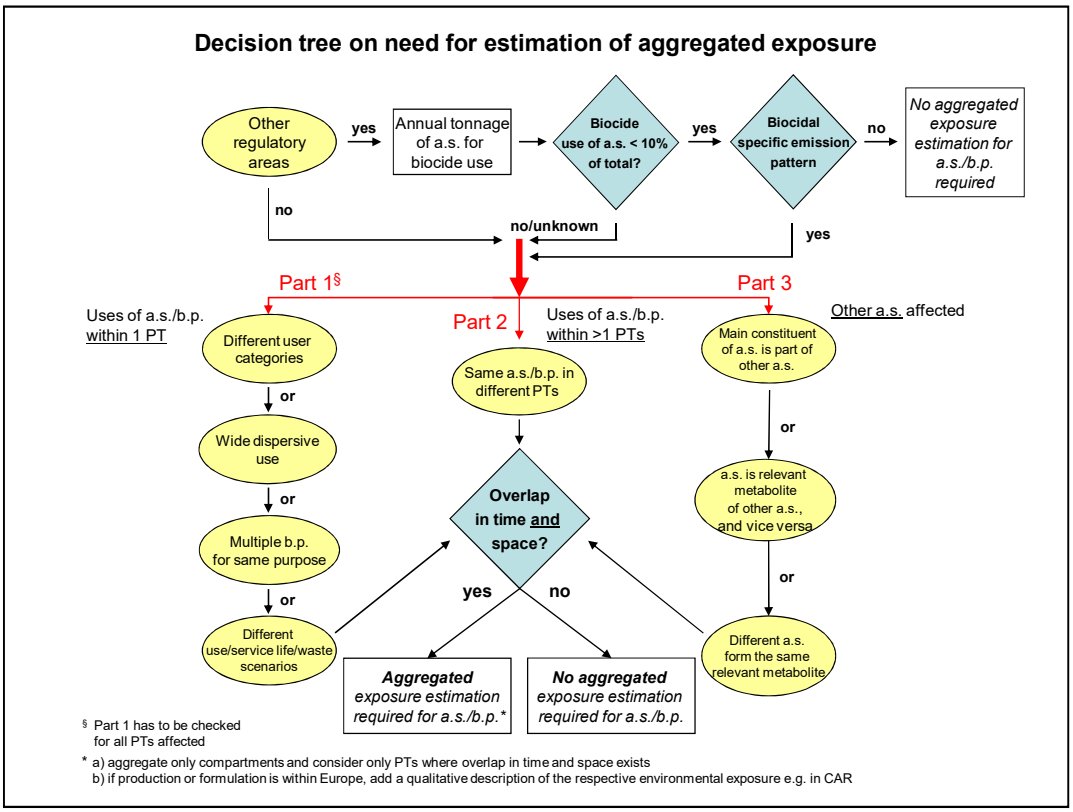


Figure 1: Decision tree on the need for estimation of aggregated exposure

Overall conclusion on the risk assessment for the environment of the product
As iodine is not bioaccumulative and for the proposed applications (indoor use) the amounts of iodine delivered into the environment through biocidal uses are within the natural occurring background levels, the risk for the environment of the product is considered acceptable.

ES CA:
The use of YODICAMP ORDEÑO can be considered acceptable for the environment according to the results of the risk assessment.

Release via manure results in a PEC:PNEC ratio >1 for surface water and also for soil. The expected concentrations are however within the natural background. The accompanied risks are therefore considered acceptable.

When residues are released to the sewer, no unacceptable risks are expected for micro-organisms in the sewage treatment plant, and aquatic organisms in surface water as all predicted environmental concentrations (PECs) are well below the predicted no-effect concentrations (PNECs). Distribution of sewage sludge on agricultural land does not result in unacceptable risks either considering that all iodine is transformed into iodate as soils are aerobic.

It may also be noted that iodine is an essential element to both animals and plants in rather high concentrations (higher than what corresponds to a trace element). It can thus be concluded that the actual risks arising from the use of iodine-containing product should be considered acceptable.

2.2.9 Measures to protect man, animals and the environment

Please, see risks mitigation measures for authorized uses.

2.2.10 Assessment of a combination of biocidal products

For biocidal products that are intended to be authorised for the use with other biocidal products.

2.2.11 Comparative assessment

BACKGROUND

The biocidal product YODICAMP ORDEÑO contains the active substance PVP-iodine. This a.s. does meet the exclusion criteria according to Article 5(1 d) BPR and, therefore, does meet the conditions laid down in Article 10 BPR, and is consequently a candidate for substitution. In accordance with Article 15(2) of Regulation (EU) No 528/2012 of the European Parliament and of the Council 22 May 2012 concerning the making available on the market and use of biocidal products, the Biocidal Products Committee (BPC) has adopted this opinion on the review of approval of the active substance iodine and polyvinylpyrrolidone iodine. These substances are identified as having endocrine-disrupting properties.

Therefore, in accordance with Article 23 of Regulation 528/2012 a comparative assessment will be carried out for the biocidal product. This comparative assessment has been carried out by the ES CA using the agreed guidance, including the Technical Guidance Note on comparative assessment of biocidal products (TNsG-CA i.e. CA-May15-Doc4.3a-final).

APPLICATION ADMINISTRATIVE DETAILS

Procedure: NA-APP

Purpose: Authorisation

Case Number in R4BP: BC-TY019734-97

Evaluating Competent Authority: ES CA

Applicant: PRODUCTOS QP S.A

(Prospective) Authorisation holder: PRODUCTOS QP S.A

ADMINISTRATIVE INFORMATION OF THE BPF

Trade name(s): YODICAMP ORDEÑO

Product type(s): 03 Veterinary hygiene (Disinfectants)

Active substance(s): Polyvinylpyrrolidone Iodine (CAS: 25655-41-8)

SCREENING PHASE

The ES CA began the comparative assessment with the screening phase described in section 6.1 of the TNsG-CA to identify whether the diversity of the active substances - mode of action combination in authorised biocidal products is adequate.

3.1. Intended use and properties of the biocidal product

Use 1 – Teats disinfection

Product Type	PT03 – Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	BP for external topic use for cleaning, disinfecting and sealing of the udder/teat hole **before and after milking**, providing a protective barrier against the entry of germs into the udder through the teat hole, protecting and softening the skin and mucous membranes. Indicated for topical use in dairy cows, ewes, goats and other lactating females.
Target organism (including development stage)	Bacteria Yeast
Field of use	Indoor
Application method(s)	Manual or automatic by **dipping** with a 8% BP dilution for cleaning and disinfecting teats/udder before milking and manual or automatic by dipping with pure BP after milking
Application rate(s) and frequency	For daily cows: 4 ml/cow/event of 8% (v/v) dilution of BP in water **before milking** and 4 ml/cow/event of pure BP **after milking** (1 ml per teat/cow/event x 4 teat/cow), For goats and ewes: 2 ml/animal/event of 8% (v/v) dilution of BP in water **before milking** and 2 ml/animal/event of pure BP **after milking** (1 ml per teat/animal/event x 2 teat/animal), The frequency of application is: 2 events/day for manual milking and 3 events/day for milking systems for dairy cows, and 1 application per day for ewes or goats.
Category(ies) of users	Professional and trained professional
Pack sizes and packaging material	Jerry can; 5, 10, 20 and 25 L. Plastic HDPE Drum; 60 and 200L. Plastic HDPE, with tap.

	IBC / intermediate bulk container; 1000L. Plastic HDPE, with tap.

The mode of action of iodine is non-selective and is based on the following mechanisms:
• Iodine rapidly penetrates into microorganisms showing a high affinity pattern of adsorption. • Iodine combines with protein substances in the bacterial cell; these could be peptidoglycans in the cell walls or enzymes in the cytoplasm. This results in irreversible coagulation of the protein and consequent loss of function.
• Iodine is known to act on thiol groups in the cell, if a thiol enzyme is part of a metabolic chain then metabolic inhibition will result.
• Iodine reacts with key groups of proteins, in particular the free-sulphur amino acids cysteine and methionine, nucleotides and fatty acids. Iodine Product types 1, 3, 4, 22 December 2013 Page 13 of 107
Iodine interferes at the level of the respiratory chain of the aerobic microorganisms by blocking the transport of electrons through electrophilic reactions with the enzymes of the respiratory chain. The rapid penetration of iodine into microorganisms and its mode of action indicate that the time-delay i.e. contact time required for sufficient efficacy depends on the tolerance of the organism to iodine and the concentration of iodine used for treatment. Iodine is more effective at higher temperatures. The germicidal activity of iodine-containing solutions is characterised by their colour. Amber solutions are active whilst pale yellow or colourless solutions are less effective and must be replaced by new solutions. The efficacy of iodine as a biocide has been demonstrated over 170 years of use and due to this long history of use there are numerous papers demonstrating the microbiocidal activity of iodophor products in laboratory and field tests. An overview on literature reviews describing the efficacy of iodophor products has been provided in Document III-A5. Relevant efficacy data for the different target organisms has been summarised in DOCII-A and II-B. In the confidential annex, tables are included summarising the available efficacy data provided by the respective applicants.
Information on resistance: Taking into account the mode of action of iodine which is non-selective, development of resistance against iodine is unlikely. Iodine / iodophors have been used for over 170 years as disinfectants for a variety of applications. Such applications include disinfection of skin in the human hygiene and medical area but also skin of animals using teat dips as well as surfaces such as milk tanks. No reduction in efficacy was reported to the producers of iodine/iodophor based products for such applications indicating that no development of resistant microorganisms or viruses has occurred

3.2. Chemical diversity of the active substances - mode of action combination in authorised biocidal products

According to the information available to the ES CA, there is 1 biocidal product authorised in Spain under Product Type 03 (Veterinary hygiene (Disinfectants) of the Biocidal Products Directive and Biocidal Products Regulations (including Mutual Recognitions and same product authorisations). There is 1 active substance **acid lactic** which has been included in authorised PT03 products.

ACID LACTIC

Use: The active substance is intended to used for cleaning, disinfecting and sealing of the udder/teat hole before and after milking. providing a protective barrier against the entry of germs into the udder through the teat hole, protecting and softening the skin and mucous membranes. Indicated for topical use in dairy cows, ewes, goats and other lactating females.
Target organism: Bacteria and yeast
Category(ies) of users: authorized for Professional and trained professional

Mode of action: In solution, lactic acid exists in a pH-dependent equilibrium between the undissociated and dissociated form. Only in its undissociated state, the acid is able to pass the cells membrane. At a relatively low pH, the uncharged acid enters the cell. Inside the cell, the lactic acid dissociates due to the higher pH. The molecules remain inside the cell, because the resulting ions cannot pass the membrane. The pH inside the cell is lowered and metabolic reactions are inhibited. Further effects are also reported: decrease of the membrane permeability for amino acids, organic acids, phosphates resulting in uncoupling of both substrate transport and oxidative phosphorylation from the electron transport system. Furthermore, an inhibition of the glycolysis is observed. The bactericidal activity of L(+) lactic acid was investigated by studies performed with the representative biocidal product containing 8% of lactic acid. The performed tests provide reliable results for innate efficacy assessment. L (+) lactic acid shows an innate bactericidal activity on samples of the target organisms (amongst others: Staphylococcus aureus, Streptococcus agalactiae, Streptococcus uberis, Streptococcus dysgalactiae, Escherichia coli) after a contact time of 10-30 minutes at concentrations of 6.1-6.8%. The studies performed are sufficient at the approval stage. However, efficacy shall be reviewed in accordance with the relevant guidance documents in the framework of active substance renewal and relevant data shall be provided in the scope of product authorisation. Development of resistance is considered unlikely due to the non-specific mode of action.
Therefore, products based on acid lactic could be eligible as alternative biocidal

Taking into account the weak diversity of active substances in biocidal products authorized for cleaning, disinfecting and sealing of the udder/teat hole, the ES CA concludes that there is no adequate chemical diversity in line with Article 23(3)(b) and the technical guidance note on comparative assessment.
However as PVP-Iodine meets the exclusion criteria in article 5, it is proposed that the comparative assessment for PVP-Iodine must be taken forward to Tier IB (quantitative analysis) in line with section 6.2 of the TNsG-CA.

TIER IB: DETAIL COMPARISON

According to the information available to the ES CA, there is 1 biocidal product authorised in Spain under Product Type 03 (Veterinary hygiene (Disinfectants) of the Biocidal Products Directive and Biocidal Products Regulations (including Mutual Recognitions and same product authorisations). There is 1 active substance **acid lactic** which has been included in authorised PT03 products.
As per documents CA-March14-Doc.4.1-Final and CA-Nov14-Doc.4.4-Final, only data available in the PAR associated to the following exclusion/substitution criteria will have to be compared.

4.1. Concerning Human Health

- **ED PROPERTIES (exclusion criterion)**

PVP-IODINE:
In accordance with Article 15(2) of Regulation (EU) No 528/2012 of the European Parliament and of the Council 22 May 2012 concerning the making available on the market and use of biocidal products, the Biocidal Products Committee (BPC) has adopted this opinion on the review of approval of the active substance iodine and polyvinylpyrrolidone iodine.
Iodine, in excess of physiological needs, meets all the above three criteria – it shows adverse effects (thyroid disorders) in humans; it has an endocrine mode of action (disruption of thyroid hormones metabolism and hypothalamic-pituitary-thyroid axis); and the adverse

effects are a consequence of the endocrine mode of action. Therefore, the biocidal active substances, iodine and PVP-iodine, are identified as having endocrine-disrupting properties with respect to humans.

ACID LACTIC:
In accordance with Assessment report, L(+) lactic acid is not considered to have endocrine disrupting properties and does not fulfil criterion (d) of Article 5(1).
It can therefore be considered that the alternative biocidal product on the market have a lower risk to human health compared to YODICAMP ORDEÑO

4.2 Conclusions of Tier IB assessment

The alternative authorised biocidal product provide a significant lower risk to human health but the alternative biocidal product show more economical and practical disadvantages than the biocidal product relevant.

OVERALL CONCLUSION. COMPARATIVE ASSESSMENT REPORT

ES CA considers that there is not currently an adequate chemical diversity of active substance-mode of action combinations to minimise the occurrence of resistance in the target organisms.
In addition to identifying economic disadvantages linked to the substitution by alternative biocidal product
The conclusions of the comparative assessment are not sufficiently conclusive to support the prohibition or restriction of biocidal product under Article 23(3) of Regulation 528/2012, and the ES CA proposes that the biocidal product YODICAMP ORDEÑO should be authorised for a period not exceeding 5 years in accordance with Article 23(6) of Regulation 528/2012.

3 ANNEXES

3.1 List of studies for the biocidal product

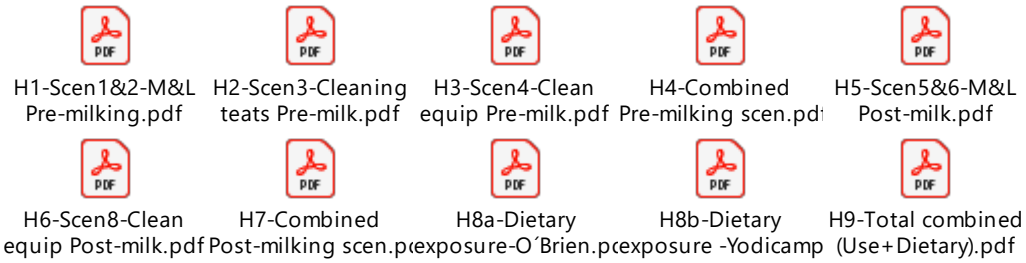
Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
2.2.2./ 15-4885-02	[redacted]	[redacted]	Caracterización fisico-quimica de yodicamo ordeño. Report: 15-4885-02	Y	PRODUCTOS QP, S.A
2.2.2./ 16-4885-01 (24 months report)	[redacted]	[redacted]	Estabilidad a 25±2ºC durante 24 meses de yodicamp ordeño. Report: 16-4885-01	Y	PRODUCTOS QP, S.A
2.2.2 / Cert 03-22	[redacted]	[redacted]	Analytical Certificate Nº 013/22 Viscosity by capillarity viscosimeter of YODICAMP ORDEÑO	Y	PRODUCTOS QP, S.A.
2.2.2 / S3016011253R1/2022	[redacted]	[redacted]	MAMICAMP SELLADOR UN Metal Corrosivity Testing	Y	PRODUCTOS QP, S.A.
2.2.5./ 210026965	[redacted]	[redacted]	Valoración de Actividad Bactericida **para desinfectantes de pezones pre-ordeño** según Norma **UNE-EN 1656:2020 CONFIDENTIAL REPORT**	Y	PRODUCTOS QP, S.A.
2.2.5./ D/21/B0237	[redacted]	[redacted]	Ensayo cuantitativo de superficie para la evaluación de desinfectante de pezones utilizados en el área veterinaria (fase 2, etapa2) con el producto **YODICAMP ORDEÑO (Norma PR NF-EN 17422:2019) –** frente a bacterias en pre-ordeño **CONFIDENTIAL REPORT**	Y	PRODUCTOS QP, S.A.
2.2.5./ 210026963	[redacted]	[redacted]	Valoración de Actividad Levuricida para **desinfectantes de pezones pre-ordeño** en condiciones adicionales según Norma **UNE-EN 1657:2016 CONFIDENTIAL REPORT**	Y	PRODUCTOS QP, S.A.
2.2.5./ D/21/B0238	[redacted]	[redacted]	Ensayo cuantitativo de superficie para la evaluación de desinfectante de pezones utilizados en el área veterinaria (fase 2, etapa2) con el producto **YODICAMP ORDEÑO (Norma PR NF-EN 17422:2019) –** frente a levaduras en pre-ordeño **CONFIDENTIAL REPORT**	Y	PRODUCTOS QP, S.A.
2.2.5./ 150095848	[redacted]	[redacted]	Valoración de Actividad Levuricida según Norma UNE-EN 1657: marzo 2007 **CONFIDENTIAL REPORT**	Y	PRODUCTOS QP, S.A.
2.2.5./ 150095858	[redacted]	[redacted]	Valoración de Actividad Bactericida según Norma UNE-EN 1656: junio 2010 (erratum octubre 2010) **CONFIDENTIAL REPORT**	Y	PRODUCTOS QP, S.A.
2.2.5./ D/21/B0235	[redacted]	[redacted]	Ensayo cuantitativo de superficie para la evaluación de desinfectante de pezones	Y	PRODUCTOS QP, S.A.

			utilizados en el área veterinaria (fase 2, etapa2) con el producto **YODICAMP ORDEÑO (Norma PR NF-EN 17422:2019) –** frente a bacterias en post-ordeño **CONFIDENTIAL REPORT**		
2.2.5./ 210026964	[redacted]	[redacted]	Valoración de Actividad Levuricida para **desinfectantes de pezones post-ordeño** en condiciones adicionales según Norma **UNE-EN 1657:2016 CONFIDENTIAL REPORT**	Y	PRODUCTOS QP, S.A.
2.2.5./ D/21/B0236	[redacted]	[redacted]	Ensayo cuantitativo de superficie para la evaluación de desinfectante de pezones utilizados en el área veterinaria (fase 2, etapa2) con el producto **YODICAMP ORDEÑO (Norma PR NF-EN 17422:2019) –** frente a levaduras en post-ordeño **CONFIDENTIAL REPORT**	Y	PRODUCTOS QP, S.A.

3.2 Output tables from exposure assessment tools

ENVIROMENT EXPOSURE ASSESSMENT

HUMAN HEALTH EXPOSURE ASSESSMENT



Report for assessment *YODICAMP ORDEÑO-(SoC BDG)*

ConsExpo Web - Wed Oct 26 2022

Substance		
Name	Butyldiglycol	
CAS number	112-34-5	
Molecular weight	162	g/mol
Kow	–	
Product		
Name	Yodicamp Ordeño	
Weight fraction substance	3.5	%
Population		
Name	EU framework Biocides adult	
Body weight	60	kg

Scenarios

› Scenario *Scenario 1 -M&L (SoC Butyldiglycol)*

› Scenario *Scenario 3 - Cleaning of teats (SoC Butyldiglycol)*

Scenario *Scenario 1 -M&L (SoC Butyldiglycol)*

Frequency	1	per day
Description		

Inhalation

Exposure model	Exposure to vapour - Evaporation	
Exposure duration	0.75	minute
Product is substance in pure form	No	
Molecular weight matrix	18	g/mol
The product is used in dilution	No	
Amount of solution used	5000	g
Weight fraction substance	3.5	%
Room volume	1	m^3
Ventilation rate	4	per hour
Inhalation rate	1.25	m^3/hr
Application temperature	25	°C

Vapour pressure	2.92	Pa
Molecular weight	162	g/mol
Mass transfer coefficient	0.24	m/min
Release area mode	Constant	
Release area	20	cm^2
Emission duration	0.25	minute
Absorption model	Fixed fraction	
Absorption fraction	1	

Dermal

Exposure model	n.a.
Absorption model	n.a.

Oral

Exposure model	n.a.
Absorption model	n.a.

Results for scenario *Scenario 1 -M&L (SoC Butyldiglycol)*

☐ Show dose descriptions

Inhalation

Mean event concentration	7.5×10^{-5}	mg/m^3
Peak concentration (TWA 15 min)	7.5×10^{-5}	mg/m^3
Mean concentration on day of exposure	3.9×10^{-8}	mg/m^3
Year average concentration	3.9×10^{-8}	mg/m^3
External event dose	1.9×10^{-8}	mg/kg bw
External dose on day of exposure	1.9×10^{-8}	mg/kg bw
Internal event dose	1.9×10^{-8}	mg/kg bw
Internal dose on day of exposure	1.9×10^{-8}	mg/kg bw/day
Internal year average dose	1.9×10^{-8}	mg/kg bw/day

3.3 New information on the active substance

Not applicable.

3.4 Residue behaviour

Not relevant.

3.5 Summaries of the efficacy studies

See summary table of efficacy tests. Section 2.2.5.5.

3.6 Confidential annex

See the document PAR confidential Annex

3.7 Other