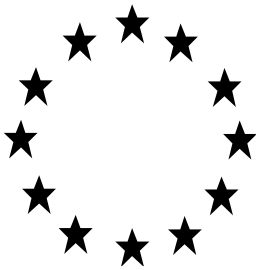
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FAMILY FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)



PVP-Iodine Yodicura

Product type 1

Case Number in R4BP: BC-FU019203-34

Evaluating Competent Authority: Spain

Date: June 2024

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1 CONCLUSION

Explanatory note (only for Spain authorisation):
The conclusions reached in this PAR, which affect the category of "Professional", if appropriate, will be applicable to Professional users at the Spanish level.
Therefore, regarding the category of authorized users, **ES CA will apply article 37 according to the BPR.**

Physical-chemical properties

PVP-Iodine Yodicura is a brownish yellow solution. The density is around 1,02 Kg/m^3.

The products are stable at room temperature.

The products Meta SPC 1 and Meta SPC 2 are not flammable, explosive or oxidizing.
According to result of the test corrosion for metals, Meta SPC1 and Meta SPC 2 are not classified as corrosive for metals.

Regarding analytical methods, all acceptance criteria were satisfied.

Eficacy against target organisms

The efficacy studies submitted demonstrates:
meta-SPC-1: PVP-Iodine 10%, Hygienic Handrub disinfection:
the product PVP-Iodine 10% is efficient against bacteria and yeasts. The product is intended to use as a hygienic handrub disinfection product, with a contact time of 1 minute and application rate of 3 ml

meta-SPC-2: PVP-Iodine 7,5% (soap):
The product PVP-Iodine 7,5% (soap) is efficient against bacteria and yeasts. The product is intended to use as a hygienic handwash disinfection, with a contact time of 1 minute and application rate of 3 ml.

Risk assessment for human health

PVP-Iodine Yodicura does not need to be classified for corrosive/irritant to skin.

A classification of the PVP-Iodine Yodicura as Eye Irrit. 2, H319 is proposed by the applicant. However, ES. CA considers that, according to the CLP Regulation PVP-IODINE YODICURA should be classified as Eye damage 1; H318.

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. Therefore, PVP-Iodine Yodicura is classified as STOT RE 2, H373: May cause damage to organs (thyroid gland) through prolonged or repeated exposure, in Meta SPC 1 according CLP regulation.

The b.p. of the solution (i.e. Yodicura povidona iodada 10%) and the soap (Yodicura solución jabonosa 7.5% povidona iodada) are used by non-professional and professional users (healthcare and institutional professionals, not surgical) for hand skin disinfection. The

assessment of the products presented in this report shows that the intended use for hand skin disinfection has non unacceptable risks for human health

Environmental risk

An acceptable risk is foreseen for all scenarios at assessed compartments, when the claimed application processes on product's label are followed.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

Part I. - First information level

2.1.1 Administrative information

2.1.1.1 Identifier of the product family

Identifier[1]	**Country (if relevant)**
PVP-IODINE YODICURA	Spain

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Laboratorios Montplet, S.L.U.
	Address	Via Trajana 53-59 08020 – Barcelona ESPAÑA
Authorisation number	ES/APPF(NA)-2024-01-00949	
Date of the authorisation	10/07/2024	
Expiry date of the authorisation	10/07/2034	

2.1.1.3 Manufacturer(s) of the products of the family

Name of manufacturer	Laboratorios Montplet, S.L.U.
Address of manufacturer	Via Trajana 53-59 08020 – Barcelona ESPAÑA
Location of manufacturing sites	Via Trajana 53-59 08020 – Barcelona ESPAÑA

2.1.1.4 Manufacturer(s) of the active substance(s)

Active substance	PVP-Iodine
Name of manufacturer	Laboratorios Montplet, SLU
Address of manufacturer	Via Trajana 53-55 08020 - Barcelona España
Location of manufacturing sites	BASF P. O. Box 457 Geismar, Lousiana 70734-0457 Plant: 8404 River Road Geismar, Lousina 70734

Location of manufacturing sites	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

Active substance	Iodine
Name of manufacturer	**Sociedad Quimica y Minera (SQM) S.A**
Address of manufacturer	Los Militares 4290 Piso 4, 8320000 Las Condes (Santiago) Chile
Location of manufacturing sites 1	Plant Nueva Victoria: Route 5 North, Km 1925, Pozo Almonte, I Region, Chile
Location of manufacturing sites 2	Plant Pedro de Valdicia: Route B 180, Antofagasta, II Region, Chile

Active substance	Iodine
Name of manufacturer	**Cosayach S.A. Compañía de Salitre y yodo**
Address of manufacturer	Amunátegui 178, 7th Floor, Santiago Chile
Location of manufacturing sites	Amunátegui 178, 7th Floor, Santiago Chile

Active substance	Iodine
Name of manufacturer	**ACF Minera S.A.**
Address of manufacturer	San Martin 499, Iquique, Chile
Location of manufacturing sites	Faena LagunasKM. 1.722 Ruta A-5,Pozo AlmonteChile

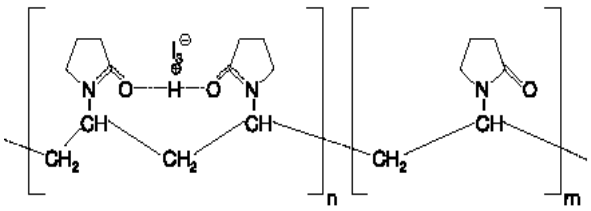
2.1.2 Product FAMILY composition and formulation

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

2.1.2.1 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	

2.1.2.2 Candidate(s) for substitution

The active substance iodine (including PVP-iodine) is not a candidate for substitution in accordance with Article 10 of the BPR (EU) Regulation 528/2012.

2.1.2.3 Qualitative and quantitative information on the composition of the biocidal products

Meta SPC 1 products

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
PVP-Iodine	2-Pyrrolidinone, 1-ethenyl-, homopolymer, compd. With iodine	Active substance	25655-41-8	607-771-8	10	10
Available Iodine	Iodine		7553-56-2	231-442-4	1	1

Meta SPC 2 products

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
PVP-Iodine	2-Pyrrolidinone, 1-ethenyl-, homopolymer, compd. With iodine	Active substance	25655-41-8	607-771-8	7.5	7.5
Available Iodine	Iodine		7553-56-2	231-442-4	0.75	0.75

2.1.2.4 Qualitative and quantitative information on the composition of the biocidal product family

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
PVP-Iodine	2-Pyrrolidinone, 1-ethenyl-, homopolymer, compd. With iodine	Active substance	25655-41-8	607-771-8	7.5	10
Available Iodine	Iodine		7553-56-2	231-442-4	0.75	1

2.1.2.5. Information on technical equivalence

All sources of iodine (including PVP-iodine) from BASF SE are the same as evaluated for inclusion in the Union list of approved substances.
The source of iodine (including PVP-iodine) from ASHLAND Services BV. is the Technical equivalence from ECHA (asset number: EU-0012442-0000)
See Confidential Annex

2.1.2.6. Information on the substance(s) of concern

According to Guidance on the Biocidal Products Regulation Volume III Human Health - Assessment & Evaluation (Parts B+C) (Version 4.0 December 2017), no substances of concern are present in the biocidal product.
Regarding to the environment the biocidal product in the META SPC2 contains a substance of concern, n-(n-dodecyl) pyrrolidone, thus this substance has to be included in the environmental risk assessment.

2.1.2.7 Type of formulation

CL- Contact liquid:

-solution -soap formulation

2.1.3 Hazard and precautionary statements

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

Classification for Meta SPC 1	
Hazard category	Eye Damage. 1 STOT RE 2 Aquatic Chronic 3
Hazard statement	H318: Causes serious eye damage. H373: May cause damage to organs (thyroid gland) through prolonged or repeated exposure. H412 Harmful to aquatic life with long lasting effects
Labelling	
Signal words	Danger
Pictograms	 GHS05 GHS08
Hazard statements	H318: Causes serious eye damage H373: May cause damage to organs through prolonged or repeated exposure (thyroid gland) H412: Harmful to aquatic life with long lasting effects.
Precautionary statements	P260: Do not breathe dust/fume/gas/mist/vapours/spray 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. P314: Get medical advice/attention if you feel unwell. <u>Non-professional users:</u> P101: If medical advice is needed, have product container or label at hand P102: Keep out of reach of children P103: Read label before use P501: Remove the content and / or its container as hazardous waste according to the regulations in force <u>Professional users:</u> P280: Wear protective gloves/protective clothing/eye P501: Dispose of contents/container as hazardous waste to a registered establishment or undertaking, in accordance with current regulations

P273 will not be included in the label since it is part of the intended use of the product. This product is intended for hand disinfection and once it has fulfilled its function, it is eliminated through a sewage system.

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).

Classification for Meta SPC 2	
Hazard category	Eye damage 1 Aquatic Chronic 3
Hazard statement	H318: Causes serious eye damage. H412 Harmful to aquatic life with long lasting effects
Labelling	
Signal words	Danger
Pictograms	 GHS 5
Hazard statements	H318: Causes serious eye damage. H412 Harmful to aquatic life with long lasting effects
Precautionary statements	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. <u>Non-professional users:</u> P101: If medical advice is needed, have product container or label at hand P102: Keep out of reach of children P103: Read label before use P501: Remove the content and / or its container as hazardous waste according to the regulations in force <u>Professional:</u> P280: Wear protective gloves/protective clothing/eye P501: Dispose of contents/container as hazardous waste to a registered establishment or undertaking, in accordance with current regulations
Note	EUH208: Contains n-(n-dodecyl) pyrrolidinone. May produce an allergic reaction.

P273 will not be included in the label since it is part of the intended use of the product. This product is intended for hand disinfection and once it has fulfilled its function, it is eliminated through a sewage system.

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)

META SPC-1

2.1.4.1 Use description 1

Table 1: Use # 1 – hand disinfection (10% PVP-iodine)

Product Type(s)	1
Where relevant, an exact description of the authorised use	The biocidal product is used to disinfect hands.
Target organism (including development stage)	bacteria yeast
Field of use	Hospitals¸ other healthcare facilities, public and private houses
Application method(s)	Apply the solution (3 ml) for both hands, rub on for 1 minute, and let dry. After the product can be washed off.
Application rate(s) and frequency	3 mL of product is applied. One single application. The solution is allowed to dry for 1minute. (drop cap = 3 mL; spray pump = 18 pumps)
Category(ies) of user(s)	non-professional and professionals (healthcare and institutional professionals,). The product is not intended for surgical disinfection.
Pack sizes and packaging material	1. HDPE round bottle with a dropping and screw cap of PP: - 40 mL, 50 mL, 125 mL, 250 mL, 500 mL, 1000 mL - spray pen 10 mL 2. Box containing 5 LDPE vials for single use (of 10 mL). 3. HDPE trigger spray bottle: 25 and 50 mL

2.1.4.1.1 Use-specific instructions for use

Application rate: 3 ml (dropper cap = 3 ml; spray pump = 18 sprays)
Application time; 1 minute
Rinse thoroughly with water.

2.1.4.1.2 Use-specific risk mitigation measures

See section 2.1.5.2

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

See section 2.1.5.3

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

See section 2.1.5.4

2.1.4.1.5 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

META SPC-2

2.1.4.2 Use description 2

Table 2: Use # 2 – hand disinfection (7.5% PVP-iodine)

Product Type(s)	1
Where relevant, an exact description of the authorised use	The biocidal product is used as hand disinfectant.
Target organism (including development stage)	Bacteria Yeast
Field of use	Hospitals, other health care facilities, public, and private houses
Application method(s)	Apply the solution on the hands, rub on for 1 minute, and let dry. After the product can be washed off.
Application rate(s) and frequency	3 mL for both hands. Contact time 1 minute. After the product can be washed off.
Category(ies) of user(s)	non-professional and professionals (healthcare and institutional professionals, not surgical) The product is not intended for surgical disinfection.
Pack sizes and packaging material	HDPE round bottle with a dropper and screw cap of PP: 40 mL, 50 mL, 100 mL, 125 mL, 250 mL, 500 mL, 1000 mL, 5 L.

2.1.4.2.1 Use-specific instructions for use

Soap solution scrub for hand disinfection. - Used for washing and disinfection of hands. - A small amount (approx. 3 mL) of product is used and rubbed for a minimum of 1 minute, until foam appears. - Then it is rinsed thoroughly with water.

2.1.4.2.2 Use-specific risk mitigation measures

See section 2.1.5.2

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

See section 2.1.5.3

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

See section 2.1.5.4

2.1.4.2.5 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

Comply with the instructions for use No apply more than 15 times per day and hospital personal.

2.1.5.2 Risk mitigation measures

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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 clothing and wash it before reuse. Continue to wash the skin with water.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 rinsing for at least 15. 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

IF MEDICAL ADVICE IS NEEDED, HAVE THE PRODUCT CONTAINER OR LABEL AT HAND AND CONTACT THE POISON CONTROL CENTER

Environmental precautions:
Do not allow the product to reach directly the environment (soil, ground- and surface water or any kind of sewer). Inform respective authorities in case of pollution to the environment caused by the product.

2.1.5.4 Instructions for safe disposal of the product and its packaging

Profesional:

Empty containers, unused product and containers are considered hazardous waste. Deposit packaging waste at the established collection points or deliver it to a registered hazardous waste operator as agreed with the extended producer responsibility system. Deliver those the other wastes to a registered establishment or undertaking for hazardous waste, in accordance with current regulations.

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

Do not release to soil, ground or surface water.

Non profesional:

Empty containers and unused product are considered hazardous waste. Dispose of in accordance with current regulations.
Do not release to soil, ground or surface water.

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

Store in accordance with state and local regulations, observe the precautions indicated on the label.
Keep in a cool, dry and well-ventilated place, away from sources of heat and direct sunlight, and incompatible materials.
Do not store at temperatures above 30ºC for long periods of time.
The long-term stability test of the meta-SPC1 10% povidone iodine confirms its stability for 3 years.
The long-term stability test of the meta-SPC2 7,5% povidone iodine confirms its stability for 30 months.

Keep out reach of children and non-target animals/pets

2.1.5.6 Other information

ONLY for SPAIN: In order to adapt the category of authorized users to its national legislation, ES CA will apply Art 37 of the BPR. Definitions (Users in Spain): **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.

2.1.6 Other information

Application codes

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)
Bottle (for solution)	40 mL, 50 mL, 125 mL, 250 mL, 500 mL, 1000 mL, spray pen 10 mL, vials of 10 mL	HDPE (except LDPE vials)	Dropper and screw cap of PP	Professional and non-professional	Yes
Bottle (for soap)	40 mL, 50 mL, 100 mL, 125 mL, 250 mL, 500 mL, 1000 mL, 5 L	HDPE	Dropper and screw cap of PP	Professional and non-professional	Yes
Trigger Spray Bottle (for solution)	25 ml, 50ml	PET	Trigger spray cap	Professional and non-professional	Yes
Box containing 5 LDPE vials for single use	10 ml	LDPE	Vials	Professional and non-professional	Yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

The list of studies performed on the product is presented in the annex 3.1.

2.1.8.2 Access to documentation

SCC Secretary of IRG's members has submitted a Declaration on ownership of data and access rights to Laboratorios Montplet S.L.U. as a member of the BPR Iodine Registration Group "IRG" which submitted a complete dossier for the approval of the biocide active substance Iodine (including polyvinylpyrrolidone (PVP) Iodine), for use in product type 1, therefore it is not needed any letter of access.

2.2 Assessment of the biocidal product FAMILY

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

META SPC-1

Table 1: Use # 1 – hand disinfection (10% PVP-iodine)

Product Type(s)	1
Where relevant, an exact description of the authorised use	The b.p. is used to disinfect hands.
Target organism (including development stage)	bacteria yeast
Field of use	Hospitals¸ other healthcare facilities, public and private houses
Application method(s)	Apply the solution on the hands, rub on for 1 minute, and let dry. After the product can be washed off.
Application rate(s) and frequency	3 mL of product is applied. One single application. The solution is allowed to dry for 1minute.
Category(ies) of user(s)	non-professional and professionals (health carers and institutional professionals,) The product is not intended for surgical disinfection.
Pack sizes and packaging material	1. HDPE round bottle with a dropping and screw cap of PP: - 40 mL, 50 mL, 125 mL, 250 mL, 500 mL, 1000 mL - spray pen 10 mL 2. Box containing 5 LDPE vials for single use (of 10 mL). 3. HDPE trigger spray bottle: 25 and 50 mL (10% formulation)

META SPC-2

Table 2: Use # 2 – hand disinfection (7.5% PVP-iodine)

Product Type(s)	1
Where relevant, an exact description of the authorised use	The b.p. is used as hand disinfectant.

Target organism (including development stage)	Bacteria Yeast
Field of use	Hospitals, other health care facilities, public, and private houses
Application method(s)	lathering with rinse off.
Application rate(s) and frequency	3 mL for both hands. Contact time 1 minute. After the product can be washed off.
Category(ies) of user(s)	non-professional and professionals (health carers and institutional professionals, not surgical) The product is not intended for surgical disinfection.
Pack sizes and packaging material	HDPE round bottle with a dropper and screw cap of PP: 40 mL, 50 mL, 100 mL, 125 mL, 250 mL, 500 mL, 1000 mL, 5 L.

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	EPA OPPTS OPPTS 830.6303 (Physical State); Visual inspection	Povidone-iodine 10% Batch nº: 91237	Before and after storage for 2 years at 20 °C: Brownish yellow solution	[redacted]
Colour at 20 °C and 101.3 kPa	EPA OPPTS OPPTS 830.6302 (Colour); Visual inspection	Povidone-iodine 10% Batch nº: 91237	Brownish yellow solution	[redacted]
Odour at 20 °C and 101.3 kPa	n.a.	-	-	[redacted]
Acidity / alkalinity	CIPAC method 75.3	Povidone-iodine 10% Batch nº: 91237 Povidone-iodine 7.5% Batch nº: 82299	pH=5.2 pH=5.2	[redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Acidity / alkalinity Soap 7.5%	Pharm. Eur. VI	Lote 1	pH at t=0 (initial): 5.2	[redacted]
Relative density / bulk density	OECD 109	Povidone-iodine 10% Batch nº: 89336 Povidone-iodine 7.5% Batch nº: 82299	1.032 g/ml 1.02 g/ml	[redacted]
Storage stability test – **accelerated storage**	CIPAC MT 46.3	META SPC 1 Povidone-iodine 10% Batch nº: 91237	2 weeks at 54 °C (t1) **t=0** Appearance: Physical state, Colour: Solution Brownish yellow Determination packaging and packaging / preparation interactions: Packaging material: 125 ml bottle HDPE yellow opaque; No significant interactions were observed Determination of available Iodine of the active ingredient Povidone-Iodine in 10 % Povidone Iodine formulation: Available iodine: 1.01 % (w/w) pH (1% in water)= 5.0 **t1=2 weeks at 54ºC** Appearance: Physical state,	[redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Colour: Solution Brownish yellow Determination packaging and packaging / preparation interactions: Packaging material: No significant interactions were observed. 0.11 % weight loss of the package Determination of available Iodine of the active ingredient Povidone-Iodine in 10 % Povidone Iodine formulation: Available iodine: 0.97 % (w/w) Δ(a.s.)= -3.96% pH (1% in water)= 4.5	
Storage stability test – **long term storage at ambient temperature**	GIFAP monograph No. 17	META SPC 1 Povidone-iodine 10%.	The formulation is stable for 2 years at 20 °C. No significant changes of physical-chemical properties. No corrosion, no leakage, one phase and no agglomeration were visible. 0.1 % weight loss of the package. Available iodine after storage: 0.99 % (w/w) The appearance and pH value were measured before and after storage. Results for these tests were considered acceptable before and after storage and are discussed under the	[redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			relevant section points.	
Storage stability test– **long term storage at ambient temperature**	Comparable to CIPAC MT 46.3	META SPC 1 Povidone-iodine 10%	The formulation is stable for 36 months at 20 °C. No significant changes of physical-chemical properties. No corrosion, no leakage, one phase and no agglomeration were visible. Appearance: Physical state, colour: T0y: Solution, Brownish yellow opaque and homogeneous T3y: no difference from T0 is observed. Packaging appearance / packaging interactions: T0y: No corrosion, no leakage, one phase and no visible agglomerations. T3y: no difference from T0 is observed. Available Iodine of the active ingredient Povidone-Iodine [% w/w]: T0y:1.02 T3y:0.97 Δ [iodine%]: -5%. pH (as is): T0y:5.3 T3y: 3.3 Density [g/ml]: T0y:1.033 T3y:1.033	[redacted]
Storage stability test– **long term storage at ambient temperature**	Comparable to CIPAC MT 46.3	META SPC 1 Povidone-iodine 10% (DIFFERENT FORMULA)	The formulation is stable for 36 months at 20 °C. No significant changes of physical-chemical properties. No corrosion, no leakage, one phase and no	[redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			agglomeration were visible. Appearance: Physical state, colour: T0y: Solution, Brownish yellow opaque and homogeneous T3y: no difference from T0 is observed. Packaging appearance / packaging interactions: T0y: No corrosion, no leakage, one phase and no visible agglomerations. T3y: no difference from T0 is observed. Available Iodine of the active ingredient Povidone-Iodine [% w/w]: T0y:1.03 T3y:0.95 Δ [iodine%]: -7.8%. pH (as is): T0y:5.36 T3y: 3.76 Density [g/ml]: T0y:1.042 T3y:1.043	
Storage stability test– **long term storage at ambient temperature**	Comparable to CIPAC MT 46.3	META SPC 2 7,5% povidone iodine (batch 02036)	Appearance: Physical state, colour: T0: Soapy solution, Brownish yellow. T30M: no difference from T0 is observed. Packaging appearance / packaging interactions: T0: No corrosion, no leakage, one phase and no visible agglomerations. T30M: no difference from T0 is observed. Available Iodine of the active ingredient	[redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Povidone-Iodine [% w/w]: T0: 0.82 T30M:0.76 Δ [iodine%]: -8%. pH (as is): T0:5.6 T30M:3.4 Density [g/ml]: T0:1.028 T30M:1.028	
Storage stability test – **low temperature stability test for liquids**	CIPAC MT 39.3	META SPC 1 Povidone-Iodine 10 % Batch no.: 91237	After 7 days at 0 °C, the solution in the centrifuge tube was clear and dark brown, no phase separation or sedimentation was observed.	[redacted]
Effects on content of the active substance and technical characteristics of the biocidal product - **light**			Not applicable as the packaging is light-proof. Therefore, the formulation is not exposed to light during storage.	
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**			Not applicable because according to the label instructions the biocidal product has to be stored cool, dry and protected from frost in closed, original containers.	
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	CIPAC MT 46.3	Povidone-Iodine 10 %	The formulation is stable and no significant changes of packaging stability occurred during the accelerated and long-term stability test.	[redacted]
Wettability	-	-	The wettability must be determined for solid biocidal products. Since the biocidal product is liquid, the wettability does not need to be performed.	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Suspensibility, spontaneity and dispersion stability	-	-	The suspensibility, spontaneity and dispersion stability must be determined for solid biocidal products or suspensions, respectively. Since the biocidal product is not solid and no suspension, these tests do not need to be performed.	-
Wet sieve analysis and dry sieve test	-	-	The wet sieve and dry sieve test must be performed for solid biocidal products, dispersible concentrates or suspensions, respectively. Since the biocidal product is not solid, no dispersable concentrate and no suspension, these tests do not need to be performed.	-
Emulsifiability, re-emulsifiability and emulsion stability	-	-	The data on emulsifiability, re-emulsifiability and emulsion stability are required to determine whether a preparation forms and maintains a stable emulsion. Since the biocidal product is a ready-to-use product, these tests do not need to be performed.	-
Disintegration time	-	-	The disintegration time must be determined for biocidal products supplied as tablets. Since the biocidal product is liquid, this test does not need to be performed.	-
Particle size distribution, content	-	-	The data on particle size distribution,	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
of dust/fines, attrition, friability			content of dust/fines, attrition, and friability, are required for solid biocidal products. Since the biocidal product is liquid, these tests do not need to be performed.	
Persistent foaming	-	-	The persistence of foaming must be investigated for biocidal products which have to be diluted with water before application. Since the biocidal product is not intended for dilution with water before use, this test does not need to be performed.	-
Flowability/Pourability /Dustability	-	-	The technical characteristics flowability and dustability have to be determined for solid products like granular preparations or dustable powders and the pourability for suspensions that will be diluted before use. Since the biocidal product is a ready-to-use liquid formulation, these tests do not apply.	-
Burning rate — smoke generators	-	-	The burning rate must be determined for biocidal products intended to be used as smoke generators. Since the biocidal product is not a smoke generator this test does not need to be performed.	-
Burning completeness — smoke generators	-	-	The burning completeness must be determined for biocidal	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			products intended to be used as smoke generators. Since the biocidal product is not a smoke generator this test does not need to be performed.	
Composition of smoke — smoke generators	-	-	The composition of smoke must be determined for biocidal products intended to be used as smoke generators. Since the biocidal product is not a smoke generator this test does not need to be performed.	-
Spraying pattern — aerosols	-	-	The spraying pattern must be determined for aerosols. Since the biocidal product is not an aerosol this test does not need to be performed.	-
Physical compatibility	-	-	The biocidal product is not intended to be used with other products including other biocidal products. Therefore no information is submitted about its physical compatibility with other products.	-
Chemical compatibility	-	-	The biocidal product is not intended to be used with other products including other biocidal products. Therefore no information is submitted about its chemical compatibility with other products.	-
Degree of dissolution and dilution stability	-	-	The degree of dissolution must be determined for water soluble bags and tablets; the dilution stability for water-	-

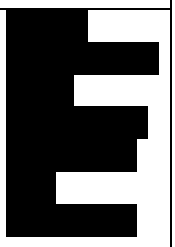
Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			soluble preparations. Since the biocidal product is not a water soluble bag, tablet or a water-soluble preparation, these tests do not need to be performed.	
Surface tension	EU Method A.5, Plate method	Povidone-Iodine 10 %	68 mN/m at 20 °C	[redacted]
Viscosity	OECD Test Guideline 114 (Viscosity of Liquids); Ubbelohde viscometer	Povidone-Iodine 10 %	4.5 mm^2/s at 20 °C	[redacted]

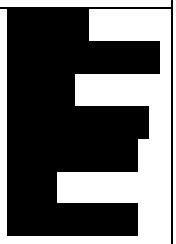
Conclusion on the physical, chemical and technical properties of the product
The long-term stability test of the meta-SPC1 *10% povidone iodine* confirms its stability for 3 years. The long-term stability test of the meta-SPC2 *7,5% povidone iodine* confirms its stability for 30 months.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	-	-	The biocidal product does not contain components in concentrations which are known to confer explosivity or to enhance explosibility properties. Therefore the biocidal product is incapable of exothermic reaction and rapid decomposition with evolution of gases or release of heat and does not have explosive properties. Since the biocidal product does not present any risk for explosion, explosive properties do not need to be tested.	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Flammable gases	-	-	The parameter flammable gases must be determined for biocidal products that are gases. Since the biocidal product is not a gas this test does not need to be performed.	-
Flammable aerosols	-	-	The parameter flammable aerosols must be determined for biocidal products that are supplied as aerosols. Since the biocidal product is not an aerosol this test does not need to be performed.	-
Oxidising gases	-	-	The parameter oxidising gases must be determined for biocidal products that are gases. Since the biocidal product is not a gas this test does not need to be performed.	-
Gases under pressure	-	-	The parameter gases under pressure must be determined for biocidal products that are gases. Since the biocidal product is not a gas this test does not need to be performed.	-
Flammable liquids	-	-	The product is a water based formulation. It is a non-flammable liquid that has no flash point up to the boiling point value of ca. 99 °C, which is approximately equal to the normal boiling point of water.	-
Flammable solids	-	-	The flammability has to be tested for solid biocidal products. Since the biocidal product is liquid, this test does not need to be performed.	-
Self-reactive substances and mixtures	-	-	There are no ingredients with explosive or self-reactive properties present in the biocidal product. Therefore the formulation is not self-reactive.	-
Pyrophoric liquids	-	-	The study does not need to be conducted as based on experience in handling and use and the chemical structure of product contents, pyrophoric properties are not to be expected.	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Pyrophoric solids	-	-	Pyrophoric properties have to be determined for solid biocidal products. Since the biocidal product is liquid this test does not need to be performed.	-
Self-heating substances and mixtures	-	-	The study does not need to be conducted as the biocidal product is liquid. A liquid shows not self-heating behaviour if it is not absorbed on a large surface.	-
Substances and mixtures which in contact with water emit flammable gases	-	-	The biocidal product contains water. Therefore an emission of flammable gases is not expected when the preparation comes in contact with water.	-
Oxidising liquids	-	-	The biocidal product does not contain components which are known to enhance oxidising properties. None of its ingredients is classified as oxidising. Therefore the formulation may not react exothermically with a combustible material and does not have oxidising properties. Since oxidising properties of the biocidal product are unlikely, it is justified not to submit a study for oxidising properties.	-
Oxidising solids	-	-	The oxidising properties have to be determined for solid biocidal products. Since the biocidal product is liquid this test does not need to be performed.	-
Organic peroxides	-	-	Since the biocidal product is not an organic peroxide, tests do not need to be performed.	-
Corrosive to metals	UN Test C.1 as described in Part III point 37.4 of the Manual of Test and Criteria (United Nations	Meta SPC-1 (Povidona yodada 10%)	Uniform corrosion attack after 21 days: (Criterion for mass loss: 39.2%) - Mass loss in aluminium: 4.720% (Worst case: Half way dipped) - Mass loss in steel: 8.546% (Worst case: Totally dipped) Localised corrosion attack after 21 days: (Criterion for intrusion depth: 360µm)	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	Recommendations for the Transportation of Dangerous Goods).		- Intrusion depth (µm) in aluminium: 120µm (Worst case: gas phase) - Intrusion depth (µm) in steel: 190µm (Worst case: Half way dipped). The meta-SPC 1 representative product does not meet the criterion for corrosion according to CLP Regulation. Therefore, the products in meta-SPC 1 shall not be classified as corrosive to metals.	
Corrosive to metals	UN Test C.1 as described in Part III point 37.4 of the Manual of Test and Criteria (United Nations Recommendations for the Transportation of Dangerous Goods).	Meta SPC-2 (Povidona yodada 7,5%)	Uniform corrosion attack after 21 days: (Criterion for mass loss: 39.2%) - Mass loss in aluminium: 4.196% (Worst case: Gas phase) - Mass loss in steel: 7.864% (Worst case: Half way dipped) Localised corrosion attack after 21 days: (Criterion for intrusion depth: 360µm) - Intrusion depth (µm) in aluminium: 110µm (Worst case: half way dipped and gas phase) - Intrusion depth (µm) in steel: 100µm (Worst case: Totally dipped)	
Auto-ignition temperatures of products (liquids and gases)	-	-	The product is a water based formulation. It is a non-flammable liquid that has no flash point up to the boiling point value of ca. 99 °C, which is approximately equal to the normal boiling point of water. The auto-ignition temperature must be determined for gases. Since the biocidal product is liquid, this test does not need to be performed.	-
Relative self-ignition temperature for solids	-	-	The relative self-ignition temperature has to be determined for solid biocidal products. Since the biocidal product is liquid this test does not need to be performed.	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Dust explosion hazard	-	-	The dust explosion hazard must be determined for powders or biocidal products containing, or able to produce, dust. Since the biocidal product is liquid this test does not need to be performed.	-

Conclusion on the physical hazards and respective characteristics of the product
The product meets the requirements regarding the above properties.

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		
Available Iodine in the Povidone-Iodine 10 % Formulation	According to Pharmacopoeia-method for PVP-iodine (titration with sodium thiosulfate with starch as indicator)	Fortification range: 80% - 120%;	Determinations at six concentrations ranging from 80 % to 120 %, relative to a sample weight of 10 g Povidone-Iodine 10 % Formulation, were performed. Component: Availabl	The iodometric titration for the determination of 1 % available Iodine in the Povidone-Iodine 10 % Formulation is a specific method and is not interfered by the ingredients of	Available Iodine in the Povidone-Iodine 10 % Formulation	According to Pharmacopoeia-method for PVP-iodine (titration with sodium thiosulfate with starch as indicator)	Fortification range: 80% - 120%;	-	Study No.: 2009/0114/01

			e Iodine in the Povidone-Iodine 10 % Formulation → Correlation coefficient: 0.9999	the formulation					

Analytical methods for the determination of active substance residues in relevant environmental media (soil, air and water) as well as in animal and human body fluids and tissues were not submitted for the biocidal product since this point is covered by the data set of the active substance.

Conclusion on the methods for detection and identification of the product
Methods for detection and identification have been assessed by titration with sodium thiosulfate.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

Iodine is used in biocidal products for hand disinfection and they are classified as biocidal product type 1. This biocidal product contains an iodine complexed known as Polyvinylpyrrolidone – iodine**.** Iodine (as PVP-I) is an antimicrobial active ingredient for use in hand disinfectant product. The biocidal product PVP-iodine YODICURA contains 7,5 - 10% PVP-I which in turn contains 0,75-1% available iodine.

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

Product Type 1: Human hygiene.
Biocidal products used for human hygiene purposes, applied on or in contact with human skin for the primary purpose of disinfecting the skin.
The biocidal product with PVP-I has demonstrated a bactericide and yeasticidial activity whenever are substantiated by key studies and appropriate results were submitted for product authorisation.

According to the SPC submitted by the applicant, the product PVP-iodine YODICURA 7,5-10 % was intended to be used by general public and professionals to disinfection of intact skin (i.e. hands
Hand disinfectant

1- **meta SPC 1**, 10% pvp-iodine

Use #1#– hand disinfection (10% PVP-idine)

- Hygienic handrub – EN 1500

2- **meta SPC 2**, 7.5% pvp-iodine

Use #2# – hand disinfection (7.5% PVP-iodine)

- Hygienic handwash – EN 1499

According to the use claimed by the applicant:

- The product **PVP-iodine YODICURA** is intended to be used for human hygiene by hand rubbing or hand washing.

- product was tested against bacterias, yeasts and fungi according to the standards:

EN 1276 or EN 13727:
Scientific name:
Pseudomonas aeruginosa
Staphylococcus aureus
Escherichia coli
Enterococcus hirae
The study demostrated the bactericidal activity
EN 1650 or EN 13624:
Scientific name:
Candida albicans
Aspergillus brasiliensis
The study demonstrated the yeasticidal activity but not fungicidal efficacy

EN 1500 and EN1499
Escherichia coli K12

- The organisms to be protected are humans.

2.2.5.3 Effects on target organisms, including unacceptable suffering

The microbicidal activity of povidone iodine covers a broad spectrum of human pathogens such as bacteria, viruses, fungi, mycobacteria. However, the PVP-iodine YODICURA product was tested for bactericidal and yeasticidal activity.

The broad spectrum of activity of PVP iodine may be explained by its mechanism of action; free iodine is known to react with oxidiziable amino acids in microbial enzymes and proteins thereby causing their inactivation. The fact that PVP iodine shows microbicidal action despite the low free availability of iodine can be explained by the high rate of release from the depot of PVP iodine being within the millisecond range.

2.2.5.4 Mode of action, including time delay

The mechanism 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

PT and use number	**Test product**	**Function / Test organism (s)**	**Test method / Test system / concentrations applied / exposure time**	**Test results: effects** *[address here results related to efficacy of the test product and validity of the test]*	**Reference**	**Number in IUCLID section 6.7/Test report title**
PT1 *Use 1.2: Hygienic Handrub disinfection*	*POVIDONA YODADA 10%*	***Bactericidal activity*** *in practical use conditions* *Escherichia coli K12* *normal microorganisms present on the volunteers hands*	***EN 1500*** *(2013)* *Concentrations tested: 100% (v/v).* *Dose of application 3ml* *Contact time: 1min* *Clean conditions.* *The product was not rinsed-off* *Temperature: 20°C ± 1 °C* *Incubation temperature: 36 °C ± 1 °C* *Number of volunteers: 20*	*Passed concentration: 100 % (v/v). Pure.* *Acceptance criteria for test results: immediate effect.*	*Test of efficacy with the product Povidona yodada 10%, for hygienic handrub* [redacted]	*DESIN-2000b-UNE-EN_1500-Hygienic_handrub-22-12-05-Povidona_yodada10-Montplet-D19-56-2-ENGLISH*
PT1 *Use 1.2: Hygienic Handrub disinfection*	*POVIDONA IODADA 10%.*	***Bactericidal activity*** *Quantitative suspension test.* *Pseudomonas aeruginosa CECT-116 (ATCC-*	***EN 1276*** *(2020) phase 2, step 1 test* *Concentrations tested: 80%, 50% and 25% (v/v).* *Contact time: 1min y 3min* *Clean*	*Passed concentration: 80% and 50%* *Acceptance criteria for test results:* *LogR>5 for all microorganisms at test substance in*	*Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants a /* [redacted]	*2021_EN1276_VT_BIO-BCT-IND-CL-01_399_21_001_V01_POVIDONA IODADA 10%*

		15442) *Staphylococcus aureus CECT-239 (ATCC-6538)* *Enterococcus hirae CECT-4081 (ATCC-10541)* *Escherichia coli K12 CECT-405 (ATCC-10536)*	*conditions: 0,3 g/L of bovine albumin.* *Temperature: 20 °C ± 1 °C* *Incubation temperature: 37 °C ± 1 °C*	*1min.*		
PT1 *Use 1.2: Hygienic Handrub disinfection*	*POVIDONA YODADA 10%*	***Yeasticidal activity*** *Quantitative suspension test* *Candida albicans CECT 1394 (ATCC-10231)* *Aspergillus brasiliensis CECT 2574*	***EN 1650*** *(2020) phase 2, step 1 test* *Concentrations tested: Candida albicans: 80, 50%, 25% and 0,1%.(v/v)* *Aspergillus brasiliensis: 80%, 50% and 25%.* *Contact time: 1min y 3min* *Clean conditions: 0,3 g/L of bovine albumin.* *Temperature: 20 °C ± 5 °C* *Incubation temperature: 30 °C ± 1 °C*	*Passed concentration: Candida albicans 80%, 50% and 25%.* *Acceptance criteria for test results:* *LogR>4 for Candida albicans at test substance in 1min.*	*Quantitative suspension test for the evaluation of yeasticidal and/or fungicidal activity of chemica /* [redacted]	*2021_ EN1650_VT_BIO-L.F-IND-CL-01_399_21_001_V01_Povidona Iodada 10%.*
PT1 *Use 2.2:* *Hygienic Handwash disinfection*	*POVIDONA JABONOSA 7.5%*	***Bactericidal activity*** *in practical use conditions* *Escherichia coli K12 NCTC 10538* *on the hands of volunteers*	***EN 1499*** *(2013) phase 2, step 2 test* *Concentrations tested: 100% (v/v).* *Dose of application 3ml* *Contact time: 1min* *Dirty conditions. Rinse-off time:*	*Passed concentration: 100 % (v/v). Pure* *Acceptance criteria for test results: immediate effect.*	*Efficacy test for the product POVIDONA JABONOSA 7.5% in the hygienic handwashing (UNE-EN 1499:2013) /* [redacted]	*DESIN-2051b-Lavado_higiénico_de_manos_UNE-EN_1499-22-11--ENGLISH*

			10 seconds *Room temperature.* *Number of volunteers: 12*			
PT1 *Use 2.2:* *Hygienic Handwash disinfection*	*POVIDONA JABONOSA 7,5%*	***Bactericidal activity*** *Quantitative suspension test.* *Pseudomonas aeruginosa CECT-116* *Staphylococcus aureus CECT-239* *Enterococcus hirae CECT-4081* *Escherichia coli K12 CECT-405*	***EN 1276*** *(2020) phase 2, step 1 test* *Concentrations tested: 50%, 25%, 10% and 0,1%.(v/v)* *Contact time: 1min y 3min* *Dirty conditions: Bovine albumin 3 g/L.* *Temperature: 20 °C ± 1 °C* *Incubation temperature: 30 °C ± 2 °C*	*Passed concentration: 50%, 25% and 10%* *Acceptance criteria for test results:* *LogR>3 for all*	*Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants a /* [redacted]	*2021_EN1276_VT_BIO-BCT-IND-CS-01_399_21_002_POVIDONA JABONOSA 7,5%*
PT1 *Use 2.2:* *Hygienic Handwash disinfection*	*POVIDONA JABONOSA 7,5%*	***Yeasticidal activity*** *Quantitative suspension test*	***EN 1650*** *(2020) phase 2, step 1 test* *Concentrations tested:* *Candida albicans: 50%, 25%, 10% and*	*Passed concentration: Candida albicans 50%, 25% and 10%* *Acceptance criteria for test results:*	*Quantitative suspension test for the evaluation of yeasticidal and/or fungicidal activity of chemica /*	*2021_EN1650_VT_BIO-L.F-IND-CS-01-399_21_001_POVIDONA JABONOSA 7.5%*

		Candida albicans CECT-1394 *Aspergillus brasiliensis CECT-2574*	*0,1%.(v/v)* *Aspergillus brasiliensis: 50%, 25% and 10%.* *Contact time: 1min y 3min* *Dirty conditions: Bovine albumin 3 g/L.* *Temperature: 20 °C ± 1 °C* *Incubation temperature: 30 °C ± 1°C*	*LogR>2 for Candida albicans at test substance in 60s.* *Passed concentration: None of Aspergillus brasiliensis.* *The b.p. did not reach the logarithmic reduction for hygienic handwash disinfection.* *Acceptance criteria for test results:* *LogR>4 for Aspergillus brasiliensis at test substance in 60s.*	[redacted]	

Conclusion on the efficacy of the product
The efficacy studies submitted demonstrates: **meta-SPC-1: PVP-Iodine 10%,** Hygienic Handrub disinfection: the product PVP-Iodine 10% is efficient against bacteria and yeasts. The product is intended to use as a hygienic handrub disinfection product, with a contact time of 1 minute and application rate of 3 ml **meta-SPC-2: PVP-Iodine 7,5%** (soap): The product PVP-Iodine 7,5% (soap) is efficient against bacteria and yeasts. The product is intended to use as a hygienic handwash disinfection, with a contact time of 1 minute and application rate of 3 ml.

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 and no reduction in efficacy was reported to the producers of iodine/iodophor based.
Regarding resistance, so far, no reduction in efficacy has been reported indicating that no development of resistance (microorganisms or viruses) has occurred.

2.2.5.7 Known limitations

Lack of data. No limitations are known.

2.2.5.8 Evaluation of the label claims

The product has shown acceptable efficacy as a hand disinfectant against bacteria and yeasts (PT1).

Product PVP-Iodine 10% has shown efficacy to be use as a hygienic handrub disinfection product, with a contact time of 1 minute and application rate of 3 ml.

Product PVP-iodine 7,5% (soap) has shown efficacy to be use as a hygienic handwash disinfection product, with a contact time of 1 minute and application rate of 3 ml.

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

Not applicable

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

PVP-Iodine Yodicura contains a number of PT 1 (Human hygiene) products with a concentration of active substance, iodine (CAS 7553-56-2), ranging from 0.75– 1 %.

In the products type 1, 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.

The b.p. belonging to the BPF have not been subjected to acute toxicity testing. The toxicological assessment of the b.p. was conducted according to the rules laid down in the Directive 1999/45/EC (DPD) and in the Regulation (EC) No. 1272/2008 (CLP). The b.p. are not classified for acute lethal effects.

The biocidal product need not to be classified for corrosive/irritant to skin. Solid PVP-I (the iodophore within the biocidal product) was irritating to the skin of rabbits (Skin irrit 2; H315), although the reactions were considered to be at least partly a secondary effect related to the adhesion of the test substance and the mechanical force needed for patch removal (Remmele&Leibold, 2005). This adhesive property should be less important for PVP-I in a 10% aqueous solution. Consistently, an *in vitro* study ((Dei Negri, 2009). is submitted showing that PVP-Iodine YODICURA product with 10% PVP-I has no skin irritating potential. In an *in vivo* study (Alvarez i Genoher, 2005), a biocidal product CURADONA GEL containing 10% PVP-I and polyethylene glycol (See Confidential Annex) as the main constituent, is not irritant to the skin. The results obtained with the polyethylene glycol-containing formulation should also be representative for the aqueous solutions of max. 10% PVP-I of the BPF.

A classification of the PVP-Iodine YODICURA as Eye Irrit. 2, H319 is proposed by the applicant. PVP-I was shown to be a strong eye irritant that requires classification with Eye Dam. 1, H318 due to irreversible effects in one rabbit. Nevertheless, according to the CAR of iodine (including PVP-I), H318 has been removed. This is due to a further available study

performed with a product in PT3 with a higher content of iodine and PVP as carrier. The applicant considers that the results of this study are reliable for PVP-Iodine YODICURA as well.
In summary, according to the applicant, most likely no classification for eye irritation of the PVP-Iodine YODICURA is required. However, to address the remaining uncertainty a classification of the biocidal product. as Eye Irrit. 2, H319 is proposed.
ES. CA does not agree with this statement and does not accept the read across proposed in the CAR, because the iodine and PVP-I content in biocidal product PT3 is lower than in PVP-Iodine YODICURA. Therefore, ES. CA considers that, according to the CLP Regulation PVP-Iodine YODICURA should be classified as **Eye damage 1; H318 (Meta SPC 1 y 2)**

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. In line with other biocides dossier evaluations, this classification and the generic concentration limit for mixture (if the concentration is ≥1% →**STOT RE 2; H373**) is taken into account for PVP-Iodine YODICURA, **in Meta SPC-1**

The iodophore, PVP-I, was not sensitising in a guinea pig maximisation test. According to CLP, the b.p. are not classified for skin sensitisation. According to CLP, Meta SPC 2 need to be labelled with EUH208 "Contains n-(n-dodecyl)pyrrolidinone. May produce an allergic reaction."

No studies have been supplied to address the acute oral, dermal and inhalation toxicity. The toxicological assessment of the biocidal product has been conducted according to the rules laid down in CLP Regulation. PVP-Iodine YODICURA is not classified for acute lethal effects.

2.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation

Summary table of in vitro studies on skin corrosion/irritation					
Method,Guideline, GLP status, Reliability	**Test substance, Doses**	**Relevant information about the study**	**Results** *Average score (24, 48, 72h)/ observations and time point of onset, reversibility; other adverse local / systemic effects, histopathologic findings*	**Remarks** *(e.g. major deviations)*	**Reference**
Skin irritation *in vivo*, OECD 404, GLP: yes, RL 1	Rabbit, New Zealand white, 2 males and 1 female	PVP-I 30/06, unchanged (no vehicle) 100% Dose: 0.5g with semiocclusive dressing 4 h	Mean scores per animal (24, 48, 72 h): erythema: 2.0, 3.0, 4.0 oedema: 0.0, 0.0, 1.0, erythema: not fully reversible within 14		[redacted]

			days, oedema: fully reversible. Mechanical skin lesions due to the adhesive test substance		
Skin irritation *in vivo* ISO 10993-10:2010, GLP: no, RL 2	Rabbit, New Zealand, 3 animals	CURADONA GEL, Unchanged (no vehicle) 100%, Dose: 0.5ml 4 h	Mean scores per animal (24, 48, 72 h): erythema: 0.0, 0.17, 0.17 oedema: 0.0, 0.0, 0.0 erythema: fully reversible within 48 h		[redacted]

No human data available on skin corrosion /irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	No classification is required.
Justification for the value/conclusion	Data of the active substance iodine (including PVP-I) were evaluated by the Rapporteur Member State (RMS) Sweden and published as Chemical Assessment Report (RMS SE, 2013). According to the CAR, PVP-I is classified as Skin Irrit. 2, H315. No co-formulant is classified for skin corrosion/irritation. According to CLP Regulation considering the generic concentration limit specified in Annex I, table 3.2.3 (≥10%), the concentration of PVP-I does lead to a classification for skin irritation in Meta SPC-2, but in the submitted study with neat PVP-I (*Remmele & Leibold, 2005a).* , PVP-I showed a skin irritation potential under the test conditions chosen. The reactions were considered to be at least partly a secondary effect related to the adhesion of the test substance and the mechanical force needed for patch removal. This adhesive property should be less important for PVP-I in a 10% aqueous solution. Consistently, an *in vitro* study is submitted showing that PVP-Iodine YODICURA product with 10% PVP-I has no skin irritating potential *(Dei Negri, 2009).*). In an in vivo study, a biocidal product containing 10% PVP-I and polyethylene glycol as the main constituent, is not irritant to the skin (Alvarez i Genoher, 2005). The results obtained with the polyethylene glycol-containing formulation should also be representative for the aqueous solutions of max. 10% PVP-I of the BPF
Classification of the product according to CLP and DSD	Not irritant to skin

Eye irritation

Summary table of animal studies on serious eye damage and eye irritation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance ,Dose levels, Duration of exposure**	**Results** *Average score (24, 48, 72h)/ observations and time point of onset, reversibility*	**Remarks** *(e.g. major deviations)*	**Reference**
Eye irritation *in vivo*, OECD 405, GLP: yes, RL 1	Rabbit, New Zealand white, 1 male and 2 females	PVP-I, unchanged (no vehicle) 100%, Dose: 0.1ml 1 hour after application the eye was rinsed with tap water.	Mean scores per animal (24, 48, 72 h): Corneal opacity: 1.0, 0.7, 1.7 iris: 0.7, 1.0, 1.0 erythema: 3.0, 2.3, 3.0 chemosis: 2.0, 2.3, 2.0, Reversibility: Cornea: not reversible within 28 days (in one rabbit) iris: yes erythema: yes chemosis: yes	-	([redacted]

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Causes serious eye damage.
Justification for the value/conclusion	According to the MSDS, PVP-I needs to be classified as Eye dam. 1, H318. This is supported by a study on neat PVP-I due to irreversible effects in one rabbit. However, according to the CAR of iodine, the proposed classification and labelling of the biocidal product Yodi Cura (PT1), which is similar to PVP-Iodine YODICURA (both contain PVP-I 10%), as H318 has been removed. This is due to a further available study performed with a product in PT3 with a higher content of iodine and PVP as carrier. The applicant considers that the results of this study are reliable for PVP-Iodine YODICURA as well. ES. CA does not agree with this statement and does not accept the read across proposed in the CAR, because the iodine and PVP-I content in biocidal product PT3 is less than in PVP-Iodine YODICURA Therefore, we consider that, according to the CLP Regulation PVP-Iodine YODICURA should be classified as Eye damage 1; H318.
Classification of the product according to CLP and DSD	Eye Damage 1; H318

Data waiving	
Information requirement	Eye irritation study
Justification	The biocidal product contains more than 3% **of PVP-I classified as serious eye damage category 1; H318**. Hence, PVP-Iodine

	YODICURA is classified following criteria of the Regulation (EC) Nº 1272/2008 (CLP Regulation).

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Justification for the conclusion	According to the CAR, the active substance iodine is classified for respiratory tract-irritation. However, the concentration of iodine is far below the generic concentration limit of 20%. In addition, no co-formulants are classified for respiratory tract irritation. Therefore,PVP-Iodine Yodicura is not classified as "specific target organ toxicity single exposure, Category 3 (STOT SE 3); H335
Classification of the product according to CLP and DSD	No classification is required.

Data waiving	
Information requirement	Respiratory tract irritation
Justification	No data available on respiratory tract irritation. According to the CAR, the active substance iodine is classified as STOT SE 3; H335. The concentration of iodine is far below the generic concentration limit of 20%. Regulation (EC) Nº 1272/2008 (CLP Regulation) establishes the following: *"Care shall be exercised when extrapolating toxicity of a mixture that contains Category 3 ingredient(s). A generic concentration limit of 20 % is appropriate; however, it shall be recognised that this concentration limit may be higher or lower depending on the Category 3 ingredient(s) and that some effects such as respiratory tract irritation may not occur below a certain concentration while other effects such as narcotic effects may occur below this 20 % value"* On the other hand, the Guidance on the Application of the CLP Criteria; Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures; Version 4.1; June 2015 stablishes the following: *"Classification in STOT-SE Category 3 for respiratory tract irritation and narcotic effects does not take potency into account and consequently does not have any guidance values. A pragmatic default generic concentration limit of 20% is suggested, although a lower or higher specific concentration limit may be used where it can be justified"*. Therefore, as iodine is present at a concentration below the concentration limit of 20%, it can be concluded that the product PVP-Iodine YODICURA is not classified with regards to respiratory tract irritation properties according to the criteria set out in the Regulation (EC) Nº 1272/2008 (CLP Regulation).

Skin sensitization

Summary table of animal studies on skin sensitisation					
Method, Guideline, GLP status, . Reliability	**Species, Strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, duration of exposure Route of exposure** *(topical/intradermal, if relevant)*	**Results** *(EC3-value or amount of sensitised animals at induction dose); evidence for local or systemic toxicity (time course of onset)*	**Remarks** *(e.g. major deviations)*	**Reference**
Maximisation Test, OECD 406, GLP: yes, RL1	Guinea pig, Dunkin Hartley, Crl:HA, Female, 5 (controls), 10 (in test group)	PVP-Iod 30/06 100%, The intradermal induction was performed with a 5% test substance preparation in 0.9% aqueous NaCl-solution or 5% test substance preparation in Freund's adjuvant / 0.9% aqueous NaCl-solution (1:1) and the epicutaneous induction with a 25% test substance preparation in doubly distilled water. For the challenge, a 10% test substance preparation in doubly distilled water was chosen.	0/10		[redacted]

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not skin sensitizer.
Justification for the value/conclusion	According to the CAR, PVP-I, is not a skin sensitizer. This is supported by an OECD guideline 406 maximisation study. A co-formulant n-(n-dodecyl)pyrrolidinone is classificated as skin sensitizer Category 1 is present at a concentration 0.5% and needs therefore to be with labelled EUH208 "Contains n-(n-dodecyl)pyrrolidinone. May produce an allergic reaction." In Meta SPC-2.
Classification of the product according to CLP and DSD	According to CLP, PVP-Iodine YODICURA are not classified for skin sensitisation. According to CLP, Meta SPC 1 need to be labelled with EUH208 "Contains n-(n-dodecyl)pyrrolidinone. May produce an allergic reaction." **Meta SPC 2: EUH208 "Contains n-(n-dodecyl)pyrrolidinone. May produce an allergic reaction."**

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not respiratory sensitizer.
Justification for the value/conclusion	The active substance iodine, including PVP-I, and the co-formulants are not classified for respiratory sensitisation.
Classification of the product according to CLP and DSD	PVP-Iodine YODICURA is not classified as respiratory sensitizer.

Data waiving	
Information requirement	Respiratory sensitization data
Justification	No animal or human data have been provided to assess the potential for respiratory sensitization. The active substance and the coformulants of the product are not classified as respiratory sensitisers and are not known to be respiratory sensitisers. Therefore, it can be concluded that the product PVP-Iodine YODICURA is not classified with regards to respiratory sensitizer properties according to the criteria set out in the Regulation (EC) Nº 1272/2008 (CLP Regulation).

Acute toxicity

Acute toxicity by oral route

Summary table of animal studies on acute oral toxicity						
Method Guideline GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance Dose levelsType of administration** *(gavage, in diet, other)*	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**Value LD50**	**Remarks** *(e.g. major deviations)*	**Reference**
Acute Oral Toxicity, Similar to OECD 401, GLP: no, RL2	Rat, Sprague-Dawley, Male/female, 10/group, except 5/group at the dose 1000 mg/kg bw (males)	PVP-Iod 30/06 100%, Females: 2150, 3160, 4640 mg/kg bw, Males: 1000, 4640 mg/kg bw, Oral (unspecified)	Males: no dose related deaths, no clinical signs, Females: at 3160 mg/kg bw 2/10 dead within 6 days, at 4640 mg/kg bw 2/10 dead within 48 hours, ruffled fur and ptosis	> 4640 mg/kg bw	some shortcomings, such as lack of details on test substance	[redacted]

Value used in the Risk Assessment – Acute oral toxicity

Value	DL_{50}>2000mg/kg bw
Justification for the selected value	Iodine is not classified for acute oral toxicity. Neat PVP-I has an LD_{50} greater than 4640 mg/kg bw (Kohlmann, 1979). Based on these data, a classification of the b.p. for this endpoint is not necessary since none of the other ingredients are of toxicological relevance.
Classification of the product according to CLP and DSD	PVP-Iodine YODICURA is not classified following criteria of the Regulation (EC) Nº 1272/2008 (CLP Regulation).

No human data on acute oral toxicity are available.

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	CL_{50}:>5mg/l
Justification for the selected value	Acute toxicity by inhalation studies with the biocidal product. have not been conducted. Iodine is subject to harmonised classification and labelling. According to annex VI of CLP Regulation, iodine is classified for acute inhalation toxicity as Acute tox 4*; H332. The co-formulants are not classified for acute toxicity by inhalation. The concentration of iodine in the biocidal product is 0.75% and 1% w/w in the form of 7.5% y 10.0% PVP-I, using the criteria for classifying mixtures under CLP Regulation, the calculation of ATE_{mix} for inhalatory toxicity results is >5mg/l and no classification is triggered.
Classification of the product according to CLP and DSD	PVP-Iodine YODICURA is not classified following criteria of the Regulation (EC) Nº 1272/2008 (CLP Regulation).

No human data on acute inhalation toxicity are available.

Data waiving	
Information requirement	Acute inhalation toxicity study
Justification	There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) Nº 1272/2008 (CLP Regulation), and synergistic effects between any of the components are not expected. So this study does not need to be conducted.

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	DL_{50}: >2000mg/kg bw
Justification for the selected value	Acute dermal toxicity studies with the biocidal product. have not been conducted.

	Iodine is subject to harmonised classification and labelling. According to annex VI of CLP Regulation, iodine is classified for acute dermal toxicity as Acute tox 4*; H312. The co-formulants are not classified for acute dermal toxicity. The concentration of iodine in the biocidal product is 0.75% and 1% w/w in the form of 7.5% and 10.0% PVP-I, using the criteria for classifying mixtures under CLP Regulation, the calculation of ATE_{mix} for dermal toxicity results in >2000mg/kg bw and no classification is triggered.
Classification of the product according to CLP	PVP-Iodine YODICURA is not classified following criteria of the Regulation (EC) Nº 1272/2008 (CLP Regulation).

No human data on acute dermal toxicity are available.

Data waiving	
Information requirement	Acute dermal toxicity study
Justification	There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) Nº 1272/2008 (CLP Regulation), and synergistic effects between any of the components are not expected. So this study does not need to be conducted.

Information on dermal absorption

Summary table of in vitro studies on dermal absorption				
Method, Guideline, GLP status, Reliability	**Species, Number of skin samples tested per dose, Other relevant information about the study**	**Test substance, Doses**	**Absorption data for each compartment and final absorption value**	**Reference**
OECD 428, GLP: yes, Reliability: 1	Human skin membranes (split-thickness), 9 skin membranes from three donors 8h exposure, 16h post-exposure	Biocide 1006 (2.63%w/w available Iodine diluted to 0.66% Iodine), PE 305-1 (0.26% w/w available Iodine as PVP-I)	The mean total absorption was 6.9% (Biocide 1006) and 6.8% (PE 305-1) of the dose applied considering the amounts of iodine found in the receptor fluid, the receptor compartment wash and the skin membranes (excluding tape strips). When additionally including the amounts found in tape strips 3-15, the mean total absorption was 11.3% for Biocide 1006 and 12.0% for PE 305-1 of the dose applied, respectively. The mean maximal flux was 0.128µg/cm^2/h and 0.02µg/cm^2/h for the biocidal formulations containing 0.66% and 0.26% total iodine, respectively. Both products are different from the compositional point of view and contain a different iodine concentration. This shows that the dermal absorption of iodine appears to be largely unaffected by the (co-) formulants contained in each tested formulation and to be independent of iodine concentration. The absorption profiles for iodine from the two biocide formulations were similar (RMS SE, 2013).The results further demonstrated that in the concentration range tested, the dermal penetration of total Iodine was independent of the concentration of Iodine in the biocidal formulations. (See confidential annex).	[redacted]

Value(s) used in the Risk Assessment – Dermal absorption		
Substance	Iodine	Iodine
Value(s)*	12%	7.7 × 10–6 cm/h
Justification for the selected value(s)	In the dermal penetration studies performed with the PVP-iodine and free iodine containing products, a dermal penetration of **11.3 to 12%** was derived for iodine. Both products are different from the compositional point of view and contain a different iodine concentration. This shows that the	A permeability constant, Kp, was calculated from the linear part of the absorption time curve. (RMS Sweden, 2013). $Kp = \frac{F}{C} = \frac{0.02\ \mu g \times cm^3}{2600\ \mu g \times cm^2 \times h}$ With:

	dermal absorption of iodine appears to be largely unaffected by the (co-) formulants contained in each tested formulation and to be independent of iodine concentration. The absorption profiles for iodine from the two biocide formulations were similar. (RMS Sweden 2013).	F: maximum flux, 0.02 µg/cm²/h; C: concentration of iodine, 0.26% = 2.6 mg/cm³ = 2600 µg/cm³ **Kp=7.7×10−6 cm/h**

Data waiving	
Information requirement	Dermal absorption assay
Justification	Alcoholes Montplet S.A. is member of the Iodine Registration Group (IRG). The IRG has submitted studies on dermal absorption of PVP-iodine and free iodine containing products during application of iodine (including PVP-I) approval. (RMS Sweden 2013). The absorption of iodine from PVP-Iodine YODICURA throught skin has not been investigated. The concentration of iodine in the biocidal product is 0.75% and 1% w/w in the form of 7.5% and 10.0% PVP-iodine (PVP-I). Instead, dermal absorption data on exemplary products for PT3, as reported in the CAR of the active substance iodine published by the Rapporteur Member State (RMS) Sweden. In the dermal penetration studies performed with PVP-iodine and free iodine containing products, a dermal penetration of 11.3 to 12% was derived for iodine. Both products are different from the compositional point of view and contain a different iodine concentration. This shows that the dermal absorption of iodine appears to be largely unaffected by the (co-)formulants contained in each tested formulation and to be independent of iodine concentration. The absorption profiles for iodine from the two biocide formulations were similar. According to the EFSA Guidance on Dermal Absorption (2017), "relative absorption (e.g. expressed as a percentage of the applied dose) is generally inversely related to the concentration of the active substance.". Thus, using the 12% dermal absorption value for the concentration of total iodine included in PVP-Iodine Yodicura (1% and 0.75% total iodine) from compared to 0.66 % in MASODINE 1:3 and 0.26% in IoShield, can be considered as worst-case assumption. Therefore it is justified to use the results of the dermal absorption studies in the human exposure and risk assessment for PVP-Iodine YODICURA For rinse-off PVP-Iodine Yodicura used for hand disinfection, the contact time with skin is only for one-five minutes. Therefore, it is reasonable to employ the permeability constant of 7.7×10−6 cm/h rather than percentage absorbed for the risk assessment.

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

Not relevant. No substances of concern are present in the biocidal product.

Available toxicological data relating to a mixture

No relevant

Other

No relevant

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. In line with other biocides dossier evaluations, this classification and the generic concentration limit for mixture (if the concentration is ≥1% →STOT RE 2; H373) is taken into account for PVP-Iodine YODICURA, in Meta SPC-1
Classification of the products according to CLP	PVP-Iodine YODICURA is classified as STOT RE 2, H373: May cause damage to organs (thyroid gland) through prolonged or repeated exposure. In Meta SPC 1

Endocrine Disruption

The biocidal product contains only one active substance. Assessment report (Sweden, December 2013) of Iodine indicates "*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 excess iodine can impair thyroid homeostasis/thyroid hormone levels. This is to be considered as an endocrine effect. However, it would not be justified to conclude from this that iodine should be considered to be an endocrine disruptor. In contrast to typical xenobiotic substances, which are not needed at all for the functioning of the human body, and which normally only have negative effects on man, Iodine is a physiologically essential element.*
Consequently, the concept of endocrine disruption is not meaningful for essential elements such as iodine since it neglects that they are needed for maintaining hormone homeostasis. Furthermore, neither iodine nor iodide are included in the lists of the EU on substances suspected of interfering with the hormone systems of humans and wild-life.".

Currently, the active substance Iodine was identified with 4 more substances as possible endocrine disruptors in the screening study performed "Impact Assessment Report on Criteria to identify EDs, European Commission, 2016". In this document, only the substances included in option 2 and option 3 category I match with the established ED criteria in Commission Delegated Regulation (EU) 2017/2100. Iodine was established within these options.
The process, described in Doc CA-September18.Doc.7.5.a-final, will have a specific duration and the Commission decision will depend on the conclusions on the ED properties of these substances in ECHA's opinion. Then, the conditions for granting the biocidal product authorization will be revised.

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), properties. Based on the available information, ES CA considers that there is no concern regarding the ED properties of these co-formulants. (see annex confidential)

2.2.6.2 Exposure assessment

A biocidal product family (BPF) PVP-Iodine YODICURA was established, comprising of two meta SPC´s and of in total three biocidal products (b.p.):

The meta SPC 1 POVIDONE-IODINE 10% solution comprises of the b.p.

1. Yodicura Povidona iodada 10% (solution); containing 10% PVP-I (1% available iodine)

The meta SPC 2 POVIDONE-IODINE 7.5% soap comprises of the b.p.

2. Yodicura solución jabonosa 7,5% providona iodada (soap formulation); containing 7.5% PVP-I (0.75% available iodine)

All b.p. of the BPF contain iodine (as PVP-I) as an antimicrobial active ingredient for use in skin disinfectants (product type 1).

The b.p. of the solution (i.e. Yodicura povidona iodada 10%) and the soap (Yodicura solución jabonosa 7.5% povidona iodada) are used by non-professional and professional users (healthcare and institutional professionals, not surgical) for hand skin disinfection. The concentration of available iodine is 1% and 0.75%, respectively.

The major path of exposure to iodine from its use in skin disinfectants is via skin contact.
Iodine as a 1% aqueous solution as in the biocidal product is only semi-volatile. A concentration of 1% in water (45 mM) is equivalent to a molar fraction (x) of 8.1×10^{-4} for I_2. According to Raoult's Law, the vapour pressure of iodine from such a solution can be calculated as follows:

$$VP_{sol} = VP_{pure} \times x = 40.7 \text{ Pa} \times 8.1\times10^{-4} = 0.033 \text{ Pa}.$$

The generation of an inhalable mist during hand washing can be excluded. Therefore, iodine vapour is the only relevant source of inhalation exposure.
Exposure via hand-to-mouth contact is unlikely because the product is rinsed off so that the skin surface is free of saliva-dislodgeable iodine. Furthermore, hand-to-mouth contact can be precluded in a professional health care setting.
The b.p. of PVP-Iodine YODICURA BPF are used both by professionals and non-professionals. The non-professional uses iodine-containing products for hand disinfection but at a much lower frequency than health-care professionals. Given the nature of this product (hand disinfection) the product is not expected to be used **by/on** children. Since the SPC exclude children among the potential users, there is no need to consider the hand to mouth exposure for this population either.The professional use serves as a worst case because of its higher frequency and intensity.
Exposure to iodine of the general public will predominantly occur orally via iodine-supplemented table salt and food containing it. This is not within the scope of Regulation 528/2012 and will not be assessed or discussed in this context.

The applicant submitted the evaluation following the CAR for iodine PT1, December 2013 (Sweden).

The assessment does not take into consideration the latest agreements for hand disinfection for professional users, in particular Recommendations 1 (Applicable from 24 March 2014) and 9 of the BPC Ad hoc Working Group on Human Exposure (Applicable from 19 January 2017). Since this product was submitted on 2015 and according to the CA agreement CA-July12-Doc.6.2d for a first authorisation, **the default cut-off date should be the two years before the date of submission of the application (i.e. 2013), none of these agreements should be applicable.**

In addition, regarding the frequency of use, it is to be expected that this b.p. will be used on a sporadic basis. The product has some particularities (such as dyeing the users hands, which exclude them from routine disinfection), the exposure resulting from the use of the agreed frequency (i.e. 10/shift for hand wash products) would most likely be overestimated, i.e., this product is not intended for a routine hand disinfection so the 8 disinfections per day considered in the CAR are considered enough.

The applicant claims that according to the CAR, dermal absorption of iodine was studied in vitro using human skin samples (RMS SE, 2013). The tested formulation consisted of an aqueous ready-to-use product containing of 0.26% iodine as PVP-I. The exposure duration was 8 hours. Since the tested product was less concentrated than any b.p.of the BPF (0.26% vs. 0.75% and 1%), it is assumed that the measured dermal absorption is likely to be higher as the actual absorption of iodine from POVIDONE-IODINE 7,5% or 10%. This is due to the negative correlation between dermal absorption and concentration of a substance in a mixture/product. The 12% absorption is too conservative and the flux value should be used instead. This rationale is supported (See rational on previous section 2.2.6.1 for further information).

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	Yes	n.a.	n.a.	n.a.	n.a.
Dermal	n.a.	Yes	Yes	n.a.	n.a.	n.a.	n.a.
Oral	n.a.	No	No	n.a.	n.a.	n.a.	n.a.

* The presence of iodine in food and drinking water, both of which are not related to biocidal uses, appears to be most relevant for human exposure. The recommended daily intake of 150-200 µg/person/day has been taken into account in the risk characterisation

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario**	**Primary or secondary exposure Description of scenario**	**Exposed group**
1.	Hand disinfection	Primary exposure, Disinfection of the skin area of both hands with a soap formulation with a concentration of available iodine of 0.75%	Professionals, non-professionals
2.	Hand disinfection	Primary exposure, Disinfection of the skin area of both hands with a solution formulation with a concentration of available iodine of 1%	Professionals, non-professionals

Industrial exposure

Not relevant.

Professional exposure

Scenario [1]

Hand disinfection (handrub) with POVIDONE-IODINE 7,5% soap formulations

Description of Scenario [1]		
The b.p. POVIDONE-IODINE 7,5% soap formulations (Yodicura solución jabonosa 7,5% providona iodada) are used as hand disinfectant. Iodine-containing hand disinfectant will be used by health care professionals. Therefore, multiple uses per workday are anticipated. It is recognised that the individual use frequency and duration may vary substantially from user to user. 5 min treatment before rinse-off is a worst-case assumption applying to the hand disinfection. The dermal germ load is drastically reduced by the treatment; the brown product is then rinsed off. The skin is then dried with sterile towels and dressed with surgical gloves. In the case of the soap formulation 3 mL (i.e. 3.1g for a density of 1.032 g/mL) are consideredThe hand disinfectant will be applied to both hands. According to HEAdhoc Recommendation no.6, for liquid product PT1 with scenario ”Hygienic and surgical hand disinfection in health care facilities for professional users by hand washing with hand soap”, the ConsExpo model *“Cosmetics\Bath-shower products\Soap liquid\Exposure, instant application\uptake diffusion”* is used for dermal exposure assessment. The default scenario is extended to include exposure to iodine vapour that may be released from the biocidal product during its application. To this end, according to the HEAdhoc Recommendation no.6, for the liquid product PT1 with scenario ”Hygienic and surgical hand disinfection in health care facilities for professional users by hand washing with hand soap”, the ConsExpo model *“Cleaning and washing\Application hand dishwashing liquids\Exposure to vapour\Evaporation”* is used for the inhalation exposure assessment. Thibodeaux's method was chosen for setting the mass transfer rate of iodine (0.207 m/min). For details on the exposure assessment please refer to Appendix 3.2.		
	Parameters	Value

Tier 1	Exposure frequency[1]		8 per day
	Exposed skin area[2]		820 cm^2
	Product amount	Soap[3]	3.1 g
	Exposure duration[5]		5 minutes
	Body weight		60 kg
	Mass transfer rate[6]		0.207 m/min
	Ventilation rate[7]		0.6 /h
	Permeability constant (Kp)[8]		7.7×10^{-6} cm/h
	Absorption of inhaled iodine vapour		100 %
	Molecular weight matrix[9]		18 g/mol
	Inhalation rate[10]		16 m^3/day

[1] According to the CAR, the annual use frequency is 1825 which is equivalent to 8 uses per day for a user with 228 workdays per year
[2] equivalent to both hands according to the Recommendation 14.
[3] Calculated as 3 mL x 1.032 g/mL density = 3.1 g used for one application
[5] exposure duration is adapted to intensive disinfection
[6] Thibodeaux's method for water based products as in Iodine Assessment Report
[7] default value for low ventilation rate
[8] see above (Information on dermal absorption)
[9]The substance is part of a product. Molecular weight of the matrix is the average molecular weight of the rest of the total product (the product minus the substance in question) following ConsExpo 4.1 formula. If the product consists largely of a single component (e.g. water) the mol weight matrix is roughly equal to the molecular weight of that component (e.g. 18 g/mol for water).
[10]The inhalation rate following Recommendation nº14 of the HEEG Working group is considered to be conservative enough, instead of the rate considered in the CAR of the active substance.

Calculations for Scenario [1]

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [1] / Hand disinfection (handrub)	1 / none	2.3×10^{-4} mg/kg bw/day	5.3×10^{-4} mg/kg bw/day	-	7.6×10^{-4} mg/kg bw/day

The inhalation mean event concentration is 3.1×10^{-2} mg/m^3.

Scenario [2]

Hand disinfection (handrub) with YODICURA POVIDONA IODADA 10% (solution)

Description of Scenario [2]
As the soap formulations, the b.p. Yodicura Povidona iodada 10% (solution) is used to disinfect the hands. Therefore, to address this scenario, the parameters of Scenario [1] were adopted for the assessment of the dermal exposure.

For details on the exposure assessment please refer to Appendix 3.2.		
	Parameters	Value
Tier 1	Exposure frequency[1]	8 per day
	Product amount[2]	3.1 g
	Exposed skin area[3]	820 cm²
	Exposure duration[4]	5 minutes
	Body weight	60 kg
	Mass transfer rate[5]	0.207 m/min
	Ventilation rate[6]	0.6 /h
	Permeability constant (Kp)[7]	7.7×10^{-6} cm/h
	Absorption of inhaled iodine vapour	100 %
	Molecular weight matrix[8]	18 g/mol
	Inhalation rate[9]	16 m^3/day

[1] According to the CAR, the annual use frequency is 1825 which is equivalent to 8 uses per day for a user with 228 workdays per year

[2] Calculated as 3 mL x 1.032 g/mL density = 3.1 g used for one application

[3] equivalent to both hands according to the Recommendation 14.

[4] exposure duration is adapted to intensive disinfection

[5] Thibodeaux's method for water based products as in Iodine Assessment Report

[6] default value for low ventilation rate

[7] see above (Information on dermal absorption).

[8]The substance is part of a product. Molecular weight of the matrix is the average molecular weight of the rest of the total product (the product minus the substance in question) following ConsExpo 4.1 formula. If the product consists largely of a single component (e.g. water) the mol weight matrix is roughly equal to the molecular weight of that component (e.g. 18 g/mol for water).

[9]The inhalation rate following Recommendation nº14 of the HEEG Working group is considered to be conservative enough, instead of the rate considered in the CAR of the active substance.

Calculations for Scenario [2]

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [2] . Hand disinfection solution	1 / none	3.1×10^{-4} mg/kg bw	7.0×10^{-4} mg/kg bw	-	1.0×10^{-3} mg/kg bw

The inhalation mean event concentration is 4.2×10^{-2} mg/m³.

Non-professional exposure

The biocidal use of POVIDONE-IODINE 7,5% Soap formulations (Yodicura solución jabonosa 7,5% providona iodada) and of YODICURA POVIDONA IODADA 10% (solution) by non-professionals is qualitatively identical to the professional use. However, the daily use rate is going to be lower than 8 per day and also the contact time is less than 5 minutes. Hence, the exposure of professionals (Scenarios [1] and [2]) constitutes a worst-case scenario that

also covers non-professionals. No designated calculations for non-professionals are conducted.

Combined scenarios

No combine exposure is foreseen

Exposure of the general public

Not applicable. After hand disinfection the user can expose another person to iodine in biocidal product during any intervention. However, this secondary exposure is expected to be negligible compared to the operator of the hand disinfection. Hence, no designated calculations for treated persons are conducted.
There is no realistic indirect exposure scenario that can unambiguously be attributed to the use of iodine in biocidal products.

Combined scenarios

No combine exposure is foreseen

Monitoring data

No further information on surveys or studies with the actual product or with a surrogate were submitted.

Dietary exposure

Not applicable, the BPF. under evaluation is not expected to lead to any dietary exposure. However, the following information has been provided by the applicant and is included below for informational purposes:
The presence of iodine in food and drinking water, both of which are not related to biocidal uses, appears to be most relevant for human exposure.
Exposure to iodine of the general public will predominantly occur orally via iodine-supplemented table salt and food containing it. This is not within the scope of Regulation 528/2012 and will not be assessed or discussed in this context.

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.	Feed additive	Dairy cows and minor dairy ruminants	2 mg / kg complete feed[2]
		Laying hens	3 mg / kg complete feed[2]
		Horses	3 mg / kg complete feed[2]
		Dogs	4 mg / kg complete feed[2]
		Cats	5 mg / kg complete feed[2]

[2] Scientific Opinion on the safety and efficacy of iodine compounds as feed additives for all species. 2013. European Food Safety Authority (http://www.efsa.europa.eu/en/efsajournal/doc/3101.pdf)

		Fish	20 mg / kg complete feed[2]
		All other animal species	10 mg / kg complete feed[2]
2.	Food additive	Table salt (Germany)	15-20 ppm iodate[3]
		Table salt (Spain)	51-69 ppm iodate/iodide[3]

Estimating Livestock Exposure to Active Substances used in Biocidal Products
Food, drinking water or livestock exposure by iodine can be excluded when applied according to the recommended uses.

Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s)
Food, drinking water or livestock exposure by iodine can be excluded when applied according to the recommended uses.

Estimating transfer of biocidal active substances into foods as a result of non-professional use
Food, drinking water or livestock exposure by iodine can be excluded when applied according to the recommended uses.

Exposure associated with production, formulation and disposal of the biocidal product
Exposure during the production of the b.p. should be addressed under other EU legislation (e.g. REACh) and not repeated under Regulation (EU) 528/2012. The Biocides Technical Meeting (TMI06) agreed that a risk assessment for production and formulation of the active substance was not required, unless the active substance was totally new to the EU market and manufactured in the EU. This is not the case for iodine which is an existing biocidal active substance within the EU.

Aggregated exposure
Not applicable.

Summary of exposure assessment

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group**	**Tier/PPE**	**Estimated total uptake** (mg/kg bw /day)
1.Hand disinfection (handrub)	Professionals Hands disinfection (8 disinfections per day)	1 / none	7.6×10^{-4}
2. Hand disinfection solution	Professionals Hands disinfection (8 disinfections per day)	1 / none	1.0×10^{-3}

[3] Germany and Spain are two examples of countries with regulations on salt iodization in Europe. Iodine defiency in Europe. 2007. World Health Organization (http://www.who.int/nutrition/publications/VMNIS_Iodine_deficiency_in_Europe.pdf)

The non-professional users use iodine-containing products for hand disinfection but at a much lower frequency than health-care professionals. Therefore, the professional use serves as a worst case for hand disinfection because of its higher frequency and intensity.

Risk characterisation for human health

In order to characterize the risk the applicant has submitted the following information on the active substance:

Healthy adults can tolerate iodine intakes of more than 1000µg per day[4] without any adverse side effects. However, the upper levels recommended by the EU Scientific Committee on Food are far lower in groups who have been exposed to an iodine deficiency in the past. Due to this and the uncertainty about whether relevant clinical sequelae may occur in individuals with normal thyroid function due to long-term or chronic exposure to higher doses, the EU Scientific Committee on Food (SCF) established an Upper Intake Level for adults of **600µg/day**[5]. These Upper Intake Level was regarded as the appropriate reference value for the purpose of the performance of human health exposure and risk assessment in the context of the European Dossier on biocidal products. It also should be pointed out that a higher Upper Intake Level of e.g. 1000 µg/day can be considered as "safe" (in particular for healthy professionals) because such an intake level normally would not cause adverse effects to human health.

The relevant effect was an inhibitory effect on the thyroid secretion in healthy men. At iodide intake levels of 30 µg/kg bw/day (equivalent to approximately 1800 µg iodide/day) no clinical thyroid pathology occurred. In the opinion of SCF, one major reason for the applied uncertainty factor of 3 is the uncertainty about whether relevant clinical sequelae may occur in individuals with normal thyroid function due to longer-term or chronic exposure to higher doses.

Besides the exposure due to the treatment, the user is also exposed to iodine by the dietary exposure. User is exposed to iodine through background in milk (due to natural sources and feed supplementation) and by other dietary sources. This exposure represents between 25% and 46% of the UL considering respectively the recommended dietary intake of iodine.

In addition, to address local effects (i.e. irritation of the respiratory tract), the inhalation exposure was also evaluated using the occupational exposure limit (OEL) value of 1 mg/m^3.

Reference values to be used in Risk Characterisation

Reference	Study	NOAEL (LOAEL)	AF	Correction for oral absorption	Value
AELshort-term AELmedium-term AELlong-term	Upper intake Level deduced by Scientific	600 µg/day	-	-	0.01 mg/kg bw/d

4 Iodine defiency in Europe. 2007. World Health Organization (http://www.who.int/nutrition/publications/VMNIS_Iodine_deficiency_in_Europe.pdf)

5 Tolerable Upper Intake Levels For Vitamins And Minerals. Scientific Committee on Food. February 2006. European Food Safety Authority (http://www.efsa.europa.eu/de/ndatopics/docs/ndatolerableuil.pdf)

	Committee on food*				
$AEC_{inhalation}$					1 mg/m^3 (0.1ppm)
ARfD	Not applicable. Substance is not acute toxic or harmful.				
ADI	Not available	-	-	-	-

*The SCF adopted the value of 600 µg/day as a UL for adults including pregnant and lactating women (2002). The UL for toddlers was set at 200 µg/day.

Maximum residue limits or equivalent

Residue definitions:

MRLs or other relevant reference values	Reference	Relevant commodities	Value
AEL = UL (Upper Intake Level)	Iodine CAR	Food	Europe: 600 µg/day (0.01 mg/kg bw/d.) USA: 1200 µg/day, 0.02 mg/kg bw/d.
ARfD	Iodine CAR	-	Not applicable. Substance is not acute toxic or harmful.
Drinking water limit	Iodine CAR	water	No drinking water limit is established. 30 µg/L is a threshold proposed and calculated is based on 10% Upper Intake Level and a daily intake of 2 L drinking water

Specific reference value for groundwater
Iodine and iodine compounds are ubiquitously distributed and there is a natural cycle of iodine species in the environment. The mean concentration of iodine in groundwater is 1 µg/L. The maximum natural background concentration is 70 µg iodine/L (RMS SE, 2013).
No specific reference value for groundwater was established. Thus, the European standard value of 0.1 µg/L for the maximum admissible concentration of pesticides in drinking water (Council Directive 98/83/EC) might apply. It should also be noted that the definition of pesticides in the Drinking Water Directive 98/83/EC is limited to organic substances and their relevant metabolites, degradation and reaction products, and thus iodine would not fall 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 value of 0.1 µg/L is not considered applicable.
Furthermore, given that the derived conservative Upper Intake Levels for adults is 600 µg iodine/day, an increase in the natural groundwater iodine levels of up to 30 µg/L appears not to be of any concern (Calculation is based on 10% Upper Intake Level and a daily intake of 2 L drinking water).

Risk for industrial users

Not relevant.

Risk for professional users

Systemic effects

Task/ Scenario	**Tier**	**Systemic NOAEL**	**AEL**	**Estimated uptake**	**Estimated uptake/ AEL** (%)	**Acceptable** (yes/no)
[1] Hand disinfection (handrub)	1	600 µg/ day	0.01 mg/kg bw/day	7.6×10^{-4}	7.6	Yes
[2] .Hand disinfection solution	1	600 µg/ day	0.01 mg/kg bw/day	1.0×10^{-3}	10.1	Yes

User is exposed to iodine through background in milk (due to natural sources and feed supplementation) and by other dietary sources. This exposure represents between 25% and 46% of the UL considering respectively the recommended dietary intake of iodine (approach proposed in the CAR) or the dietary intake values discussed recently for iodine union authorisations at the European level. Please find below the risk assessment considering this values:

Task/ Scenario	**Tier**	**Systemic NOAEL**	**AEL**	**Estimated uptake (mg/kg bw/d)**	**Estimated uptake/ AEL due to biocidal use plus dietary intake 46%UL**	**Acceptable** (yes/no)	**Estimated uptake/ AEL due to biocidal use plus dietary intake 25%UL**	**Acceptable** (yes/no)
[1] Hand disinfection (handrub)	1	600 µg/ day	0.01	7.6×10^{-4}	53.60	Yes	32.60	Yes
[2]Hand disinfection solution	1	600 µg/ day	0.01 mg/kg bw/day	1.0×10^{-3}	56.10	Yes	35.10	Yes

Local effects
The inhalation mean concentration is 0.031 mg/m³ for soap and 0.042 mg/m^3 for hand disinfection solution (See annex 3.2). The $AEC_{inhalation}$ of 1 mg/m³ is not exceeded. Hence, regarding local effects by inhalation, the proposed use is considered to be safe.

The b.p. is not intended for routine hand disinfection given its particularities (need to rinse off and dyeing of the hands) and exposure is therefore limited to 8 times per day. The probability for exposure of eyes by splashes is negligible due to the application method (no spraying). In addition, in the soap formulations due to the intrinsic characteristic of the products the splashes cannot happen. Direct contact with eye is not foreseen. The only reasonable path for eye exposure would be hand to eye contact. It should be noticed that after each task is completed, the product dries after 5 minutes, and the hands are washed, so the hand to eye contact is restricted to the time from application to finishing the task. Relevant instructions for use that minimise exposure or possible health effects (washing of eye after accidental exposure) are labelled, and this product will be used by professionals (See next section for non-professionals local effects).
On the basis of the above considerations, it can be concluded that the risk is controlled by the qualitative RMMs.

Hazard		**Exposure**						**Risk**
Hazard Category	**Effects in terms of C&L**	**PT**	**Who is exposed?**	**Task**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Relevant RMM**	
High	H318: Causes serious eye damage.	1	Professionals	Hand disinfection	Eye (hand to eye contact)	8 times per day	The probability for exposure of eyes by splashes is negligible due to the application method The only possible contact route is the hand to eye contact: There are several mitigation factors to be taken into account: • The product dries after 5 minutes and is rinsed off after the intervention • The product dyies the user hands, so it is unlikely that a user	Acceptable: -Low likelihood of exposure of critical site of contact -Used for short duration -Low amount used per event -Packaging design to eliminate exposure -Packaging to be fitted with a tactile warning -Proper

							could forget to wash its hands after the medical action • The professional user should use disposable gloves during the application of the biocidal product. In addition, the professional user would prevent any misuse. Finally the SPC reads "Wash hands once the task is completed" and "Avoid contact with eyes".	instructions of use

Conclusion
The use of of the biocidal product can be considered safe for professional users.

Risk for non-professional users

The non-professional users use iodine-containing products for hand disinfection but at a much lower frequency than health-care professionals. Therefore, the professional use (Scenarios [1] and [2]) serves as a worst case for hand disinfection because of its higher frequency and intensity.

Systemic effects

Task/Scenario	**Tier**	**Systemic NOAEL**	**AEL**	**Estimated uptake**	**Estimated uptake/ AEL** (%)	**Acceptable** (yes/no)
[1] Hand disinfection (handrub)	1	600 µg/ day	0.01 mg/kg bw/day	7.6×10^{-4}	7.6	Yes
[2] .Hand disinfection solution	1	600 µg/ day	0.01 mg/kg bw/day	1.0×10^{-3}	10.1	Yes

User is exposed to iodine through background in milk (due to natural sources and feed supplementation) and by other dietary sources. This exposure represents between 25% and 46% of the UL considering respectively the recommended dietary intake of iodine. Please find below the risk assessment considering this values:

Task/ Scenario	**Tier**	**Systemic NOAEL**	**AEL**	**Estimated uptake (mg/kg bw/d)**	**Estimated uptake/ AEL due to biocidal use plus dietary intake 46%UL**	**Acceptable** (yes/no)	**Estimated uptake/ AEL due to biocidal use plus dietary intake 25%UL**	**Acceptable** (yes/no)
[1] Hand disinfection (handrub)	1	600 µg/ day	0.01	7.6×10^{-4}	53.60	Yes	32.60	Yes
[2]Hand disinfection solution	1	600 µg/ day	0.01 mg/kg bw/day	1.0×10^{-3}	56.10	Yes	35.10	Yes

The risk is acceptable

Combined scenarios
Not applicable

Local effects
The inhalation mean concentration is 0.031 mg/m³ for soap and 0.042 mg/m³ for hand disinfection solution (See annex 3.2). The $AEC_{inhalation}$ of 1 mg/m³ is not exceeded. Hence, regarding local effects by inhalation, the proposed use is considered to be safe.

Non-professionals are rarely expected to disinfect their hands. This b.p. is intended to be part of first care aids home packages. It should be noticed that this product in no case could be applied on wounded skin, so the frequence of use is extremely low. The b.p. is not intended for routine hand disinfection and exposure is therefore limited. The probability for exposure of eyes by splashes is negligible due to the application method (no spraying). In addition, in the soap formulations due to the intrinsic characteristic of the products the splashes cannot happen. Direct contact with eye is not foreseen. The only reasonable path for eye exposure would be hand to eye contact. It should be noticed that after each task is completed, the product dries after 5 minutes, and the hands are washed, so the hand to eye contact is restricted to the time from application to finishing the task. Relevant instructions for use that minimise exposure or possible health effects (washing of eye after accidental exposure) are labelled.
On the basis of the above considerations, it can be concluded that the risk is controlled by the qualitative RMMs.

Hazard		Exposure						Risk
Hazard Category	**Effects in terms of C&L**	**PT**	**Who is exposed?**	**Task**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Relevant RMM**	
High	H318: Causes serious eye damage.	1	Professionals	Hand disinfection	Eye (hand to eye contact)	8 times per day	The probability for exposure of eyes by splashes is negligible due to the application method The only possible contact route is the hand to eye contact: There are several mitigation factors to be taken into account: • The product dries after 5 minutes and is rinsed off after the intervention • The product dyies the user hands, so it is unlikely that a user could forget to wash its hands after the medical action Finally the SPC reads "Wash hands once the task is completed" and "Avoid contact with eyes".	Acceptable: -Low likelihood of exposure of critical site of contact -Used for short duration -Low amount used per event -Packaging design to eliminate exposure -Packaging to be fitted with a tactile warning -Proper instructions of use -low frequency per year.

Conclusion
The use of of the biocidal product can be considered safe for non-professional users.

Risk for the general public

Systemic effects

Not applicable

Combined scenarios
Not applicable

Risk for consumers via residues in food

Not applicable. The BPF. under evaluation is not expected to leave residues in food that could lead to consumer exposure.
The presence of iodine in food and drinking water, both of which are not related to biocidal uses, appears to be most relevant for human exposure.
Exposure to iodine of the general public will predominantly occur orally via iodine-supplemented table salt and food containing it. This is not within the scope of Regulation 528/2012 and will not be assessed or discussed in this context.

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

Not applicable

2.2.7 Risk assessment for animal health

Food, drinking water or livestock exposure by iodine can be excluded when applied according to the recommended uses. Therefore no unacceptable risk to consumer health via residues in food needs to be expected.

2.2.8 Risk assessment for the environment

ESCA: Please notice that the risk assessment for the environment is reported as provided by the applicant. The ES CA position is presented in **grey boxes**.

Products of the biocidal product family (BPF) PVP-Iodine YODICURA are used as human hygiene biocidal products (PT 1). They contain an iodophor, i.e. iodine complexed with Polyvinylpyrrolidone (PVP).
The products contain either 7.5% (Yodicura solución jabonosa 7.5% povidona iodada) or 10% (Yodicura povidona iodada 10%) PVP-iodine, corresponding to 0.75% and 1.0% w/w free iodine, respectively. They are applied directly to the skin or with the aid of a tissue. Whereas the soap products will be rinsed off with water after a short exposure period, the solution can remain on the skin for a longer time period before also being washed of. For the latter product, a transfer to the clothing during the service life can occur however these remains will also be removed when the clothing is washed.
Solution and soap are intended to be used for personal hygiene purposes as well as in the professional health care sector. The products are applied at an amount of 3 mL (soap products and solution) per application.. The complexing agent Polyvinylpyrrolidone is a widely-used constituent in food, medicinal, and cosmetic products. Emissions to the environment arising from the use of PVP-Iodine YODICURA

products compared to the emissions resulting from the consumption of PVP-containing food and cosmetic products are negligible. PVP is not classified with respect to the environment. Therefore, the complexing agent will not be considered in the risk assessment.
According to the production description of the applicant, unacceptable emissions to the environment can be excluded and therefore, no risk assessment was conducted for this life cycle stage. The primary receiving compartment for emissions during use/service life is the municipal sewage treatment plant due to the washing of treated skin or clothes. This is true for products used by professional health care personal of a hospital and the private user as well as for the products used as 'leave-on' or 'rinse-off' products. Secondarily, surface water bodies or the terrestrial compartment might be affected by the STP effluent or sewage sludge applications. Empty containers/bottles are discharged to solid waste, which is governed under national legislation and therefore no matter for consideration in this context.
In line with the CAR for Iodine, neither an environmental risk assessment for the atmosphere nor for biota has been conducted. With respect to the high background values in air, emissions to air resulting from the application of iodine as disinfectant are not relevant. Referring biota, amounts of iodine potentially released to the environment due to the use as disinfectants are within the natural background levels and there is no concern with respect to secondary poisoning.

A two-tiered risk assessment has been conducted. Firstly, environmental concentrations (PEC values) calculated according to the ESD for PT 1 and the TGD have been compared to the Predicted No Effect Concentrations (PNEC values) derived from standardised OECD tests with terrestrial and aquatic organisms. Since the established PNEC values represent no realistic indicators for the toxicity of iodine in the form it is present in the environment as a tier 2 the calculated PEC values have been compared to the natural background concentrations. At TMII/2012 it was concluded, that the risk arising from tier 1 can be disregarded if the PEC values are within the range of natural background levels. For the current risk assessment both approaches have been included for reasons of consistency with the CAR, however, only the tier 2 approach is relevant with respect to a conclusion from the environmental risk assessment.

ES CA:

As it is stated by the applicant, PVP-iodine-YODICURA is a biocidal product family intended for human hygiene (PT1) based in iodophor, i.e. iodine complexed with Polyvinylpyrrolidone (PVP). This family contains two types of products a solution and a soap formulation containing either 7.5% (Yodicura solución jabonosa 7.5% povidona iodada) or 10% (Yodicura povidona iodada 10%) PVP-iodine, corresponding to 0.75% and 1.0% w/w free iodine, respectively.

For both products, the recommended dose is 3 ml, this value has been supported by the efficacy studies.

ES CA agrees with the tiered approach conducted by the applicant.

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

The toxicity of all components within the formulations is known without any component of unknown toxicity. Regarding the ecotoxicological properties, the products of the PVP-Iodine YODICURA biocidal product family are harmful to aquatic organisms. The biocidal products are classified as Aquatic Chronic 3 (H412: Harmful to aquatic life with long-lasting effects) according to Regulation (EC) No 1272/2008.
The biocidal product family (BPF) contains the substance n-(n-dodecyl)pyrrolidone classified for the environmental as H400: Very toxic to aquatic life and H410: Very toxic to aquatic life with long lasting effects, therefore this substance is considered as substance of concern because it leads the classification of the BPF.
PNEC values for have been derived according to the correspondent guidance on the Biocidal Products Regulation-Volume IV Environment- Assessment and Evaluation (Parts B + C), using the correspondent ecotoxicological information provided in the MSDS of the supplier.

ESCA agrees with the classification of the biocidal product family proposed by the applicant:

Harmonised environmental classification of the active substances
The environmental classification of the active substances are the following:

Classification for the active substance				
Active substance	**Env. Classification**	**M-Factor**	**Concentration of a.s. in the product (%)**	
			Min.	**Max.**
Polyvinylpyrrolidone iodine *	H400, H411	M = 1	7.5	10
** Available iodine*			0.75	1

According to Reg. (EC) No 1272/2008 (0.ATP) the harmonised classification of Iodine for its environmental effects is Aquatic Acute 1, H400 Very toxic to aquatic life (M=1). At the WG ENVII-2018 it was decided to classify Iodine as Aquatic Chronic 1, H410 Very toxic to aquatic life with long lasting effects.

Environmental classification of the substance(s) of concern

The biocidal product contains a substance that influence the environmental classification.

Classification for the substance of concern N-Dodecyl-2-pyrrolidone				
substance	**Env. Classification**	**M-Factor**	**Concentration of a.s. in the product (%)**	
			Min.	**Max.**
N-Dodecyl-2-pyrrolidone	H400, H411	M = 1	0	0.5

Environmental classification of the biocidal product family

Classification and precautionary statements for the biocidal product family

Meta SPC 1 y Meta SPC 2

H412 - Harmful to aquatic life with long lasting effects.
Professionals:
P501 - Dispose of contents/container as hazardous waste to a registered establishment or undertaking, in accordance with current regulations.
General public:
P501 - Dispose of content and / or its container as hazardous waste according to the regulations in force

*P273 will not be included in the label since it is the intended use of the product. This product is intended for hand disinfection and once it has fulfilled its function, it is eliminated through a sewage system.

PBT-assessment:

According to the AR of Iodine (2013), the term persistence is not appropriate, since iodine is an element and not degradable. Estimation of bioaccumulation potential for iodine is not considered relevant. In the concerned environmental compartments iodine speciates into the ionic forms iodide and iodate. In line with what has been discussed for inorganic metals (e.g. Ni and Zn), bioaccumulation is not relevant because these substances (and iodine) are regulated in animals of several taxonomic groups. The acute toxicity to mammals is low, but iodine is very toxic to aquatic organisms. However, the screening T criterion (L(E)C50 to aquatic organisms less than 0.1 mg/L) is not fulfilled, and there is no chronic data available, which is needed to assess the T criterion. It is concluded that iodine is not a PBT or vPvB substance.

The active substance N-Dodecyl-2-pyrrolidone is neither PBT - nor vP/vB substance.

ED-assesssment:

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 excess iodine, can impair thyroid homeostasis/thyroid hormone levels. This is to be considered 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.

There is an indication for endocrine disrupting properties of the N-Dodecyl-2-pyrrolidone.

For more detail, please, see the confidential PAR.

Ecotoxicological endpoints, as reported into the MSDS of n-(n-dodecyl)pyrrolidone and REACH Registration dossier			
Specie	**Endpoint**	**Value**	**Unit**
Oncorhynchus mykiss	LC50 (96 h) flow through	0.59	mg/L
*Danio rerio**	EC10 (35 days)	0.018	mg/L
Lepomis macrochirus	LC50 (96 h) static system	0.93	mg/L
Daphnia magna	EC50 (48h) flow through	0.139	mg/L
Daphnia magna	EC50 (48h) static system	0.27	mg/L
*Daphnia magna**	NOEC (21 days)	0.046	mg/L
Pseudokirchneriella subcapitata	ErC50(72h)	0.086	mg/L
Pseudokirchneriella subcapitata	NOErC50(72h)	0.046	mg/L
Activated sludge	NOEC	22.2	mg/L
Dog	NOAEL oral (90 days)	38 1520	mg/kg bw/day mg/food/day

*REACH Registration dossier: https://www.echa.europa.eu/web/guest/registration-dossier/-/registered-dossier/15673/6/1

Derived PNEC values for the SoC		
Compartment	**n-(n-dodecyl)pyrrolidone**	**Unit**
	Value	
Fresh water	0.0018(AF 10)	mg/L
Sediment (EPM)	0.052	mg/kg ww 0.241 mg/kg dw
STP	2.22	mg/L
Soil (EPM)	0.042	mg/kg ww 0.047 mg/kg dw
PNECoral mammals	16.9 (AF 90)	mg/kg food/day

ES CA:
ES CA agrees with the information on PNEC values of the SoC (https://www.echa.europa.eu/web/guest/registration-dossier/-/registered-dossier/15673/6/1)

Regarding to the active substance (Assessment report, 2013):
STP:
Iodine: $PNEC(I_2)_{STP}$ = 2.9 mg iodine/L
Iodide and iodate: no PNEC derived in the CAR (2013) on iodine.
Aquatic compartment:
Iodine: $PNEC(I_2)_{aquatic}$ = 0.59 µg iodine/L
Iodate: $PNEC(IO_3^-)_{aquatic}$ = 58.5 µg iodine/L
Iodide: $PNEC(I^-)_{aquatic}$ = 0.83 µg iodine/L

Iodine: PNEC(I_2)$_{marine}$ = 0.059 µg iodine/L
Iodate: PNEC(IO_3^-)$_{marine}$ = 5.85 µg iodine/L
Iodide: PNEC(I^-)$_{marine}$ = 0.083 µg iodine/L

Terrestrial compartment:
Iodine: PNEC(I_2)$_{soil\_EC50}$ = 0.0118 mg iodine/kg_{wwt} (= 0.0134 mg/kg_{dwt})
Iodate: PNEC(IO_3^-)$_{soil\_EPM}$ = 0.304 mg iodine/kg
Iodide: PNEC(I^-)$_{soil\_EPM}$ = 0.0043 mg iodine/kg

Information on background levels of the a.s.:
The fate and behaviour of iodine in the environment is described in detail in Doc. IIA, Chapter 4 (CAR Iodide). Iodine I ubiquitous in the environmental compartments soil, water and air

Background concentration of iodine in the environment (CAR, 2011 on iodine)	
Compartment	**natural background concentration**
Air	-
STP	-
Surface water	0.5 – 20 µg iodine/L
Fresh water sediment	typically 6 mg iodine/kg
Sea water	45 - 60 µg iodine/L
Maine sediment	3 - 400 mg iodine/kg
Soil	0.5 – 20 mg/kg_{dwt} with extremes up to 90 mg/kg_{dwt} (corresponding to 0.4 - 18 mg iodine/kg_{wwt} with extremes up to 86 mg/kg_{wwt}) depending on soil types and locations. Highest concentrations are found in peaty soils (18.7-98.2 mg/kg dwt). Concentrations in sandy and clayey soils are respectively 1.7-5.4 mg/kg dwt and 2.1-8.9 mg/kg dwt (source DOCIIIA, 7.2.1/01-03 and references therein).
Groundwater	mean concentration: 1 µg/L. Ranges of < 1-70 µg iodine/L (with extremes up to 400 µg/L) depending on geographical location and local geology. Higher concentrations can be found in saline waters such as coastal and arid areas (source DOCIIIA, 7.2.3.2 and references therein).

Further Ecotoxicological studies

Data waiving	
Information requirement	No further ecotoxicological studies are required.

Justification	The products within the PVP-Iodine YODICURA biocidal product family are formulated as soap and solution . They include an iodophor, i.e. iodine complexed with Polyvinylpyrrolidone (PVP). The products contain either 7.5% (Yodicura solución jabonosa 7.5% povidona iodada) or 10% (Yodicura povidona iodada 10%) PVP-iodine, corresponding to 0.75% and 1.0% w/w free iodine, respectively. The members of the product family are used as antiseptics for hand and forearm disinfection and healthy skin disinfection (e.g. before any surgical intervention). Iodine-containing products are used by the general public (non-professionals) and more often by professional users in the health-care sector. For professional use several uses per workday are anticipated. The application amount is ca. 3 mL (soap products and solution . After a period of time (maximum 5 min for the soap formulation) the product is rinsed off with fresh water and released to wastewater. Consequently, sewage treatment plants (STP) are an important emission pathway. Molecular iodine is chemically unstable with oxidising properties. It is assumed that it will speciate into iodate and iodide when reaching the wastewater stream. Considering that 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. Therefore, surface water bodies or the terrestrial compartment might be affected by the STP effluent or sewage sludge applications. Exposure to air is not considered as iodide and iodate are assumed not to be volatile. In view of the high background concentrations of iodine in air, emissions to air resulting from the use of biocidal products are not relevant. Iodine and iodine compounds are ubiquitously distributed and there is a natural cycle of iodine species in the environment. Consequently, a lot of research has been made on the fate and distribution of iodine

	in the environment as indicated in the EU Assessment Report of iodine (including PVP-iodine). The environmental effects of iodine including its speciates iodite and iodate as well as PVP-iodine are well investigated by reliable OECD guideline studies. The formulation type is not expected to change the mode of action of the active substance or its bioavailability. Tests with the formulation would not yield to other results than available tests with the active substance iodine/PVP-iodine. The products are classified as H412 "Harmful to aquatic life with long-lasting effects" according to Regulation (EC) No 1272/2008. The environmental risk assessment focusses on the exposure due to professional health care personal since the daily use is much higher compared to the use by non-professionals. A two-tiered risk assessment was conducted. Firstly, environmental concentrations (PEC values) calculated according to the ESD for PT 1 and the TGD have been compared to the Predicted No Effect Concentrations (PNEC values) derived from standardised OECD tests with terrestrial and aquatic organisms. Since the established PNEC values represent no realistic indicators for the toxicity of iodine in the form it is present in the environment, the calculated PEC values have been compared to the natural background concentrations. For the current risk assessment both approaches have been included for reasons of consistency with the CAR, however, only the tier 2 approach is relevant with respect to a conclusion from the environmental risk assessment. Synergistic effects of the substances are not reported and are therefore no matter of concern.

ES CA: no further ecological studies has been submitted.

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

No data available. Based on the data requirements for PT1, no study needs to be presented.

ES CA: not relevant.

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

Not relevant due to the use pattern.

ES CA: not relevant.

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

Not relevant due to the use pattern.

ES CA: not relevant.

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

Not relevant.

ES CA: not relevant

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

Products of the biocidal product family (BPF) PVP-Iodine YODICURA are fomulated as soap and solution. They include an iodophor, i.e. iodine complexed with Polyvinylpyrrolidone (PVP). The products contain either 7.5% (Yodicura solución jabonosa 7.5% povidona iodada) or 10% (Yodicura povidona iodada 10%) PVP-iodine, corresponding to 0.75% and 1.0% w/w free iodine, respectively. They are intended to be used for personal hygiene purposes as well as in the professional health care sector. The products are applied at an amount of 3 mL (soap products and solution) per application.
Unacceptable emissions to the environment during the formulation of the products can be excluded and therefore, no risk assessment was conducted for this life cycle stage.
During use and service life of the biocidal products, the primary receiving compartment for emissions of iodine is the municipal sewage treatment plant due to the washing of treated skin or clothes. This is true for products used by professional health care personal of a hospital and the private user as well as for the products used as 'leave-on' or 'rinse-off' products. Secondarily, surface water bodies or the terrestrial compartment might be affected by the STP effluent or sewage sludge applications. In view of the high background concentrations of iodine in air, emissions to air resulting from the use of biocidal products are not relevant.

Empty containers/bottles are discharged to solid waste, which is governed under national legislation and therefore no matter for consideration in this context.

The environmental risk assessment focusses on the exposure due to professional health care personal since the daily use is much higher compared to the use by non- professionals. A two-tiered risk assessment was conducted. Firstly, environmental concentrations (PEC values) calculated according to the ESD for PT 1 and the TGD have been compared to the Predicted No Effect Concentrations (PNEC values) derived from standardised OECD tests with terrestrial and aquatic organisms. Since the established PNEC values represent no realistic indicators for the toxicity of iodine in the form it is present in the environment, the calculated PEC values have been compared to the natural background concentrations. For the current risk assessment both approaches have been included for reasons of consistency with the CAR, however, only the tier 2 approach is relevant with respect to a conclusion from the environmental risk assessment.

The formulation type (soap and solution) is not expected to change the mode of action of the active substance or its bioavailability. Also synergistic effects of other substances within the products are not reported and are therefore no matter of concern. Tests with the formulations are not considered to yield other results than tests with the active substance.

ES CA:

The relevant receiving compartments based on the exposure pathway:

Scenario	**Relevant exposure compartment**				
	Air	**Soil**	**STP**	**Surface Water**	**Groundwater**
via STP	n.r.	+	+	+	+
Via slurry/manure	n.r.	+	-	+	+

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

Data waiving	
Information requirement	Further studies on fate and behaviour in the environment are not required.
Justification for the conclusion	The primary receiving compartment for emissions arising from the use of the products is the municipal sewage treatment plant due to the washing of treated skin or clothes. When entering STPs, iodine is separated from PVP and the other non-active ingredients of the products, so the fate and behaviour of iodine can be regarded as non-influenced by these substances. Hence, extrapolation from the data available for the active substance to the behaviour of the active substance in the biocidal products is possible. Also the formulation type (solution and soap) is not expected to change the mode of action of the active substance or its bioavailability. Furthermore, synergistic effects of the active and non-active ingredients are not reported and are therefore no matter of concern. Tests with the formulations are not considered to yield other results than tests with the active substance.

ESCA: not relevant

Leaching behaviour (ADS)

Data waiving	
Information requirement	Leaching behaviour
Justification for the conclusion	Due to the products' use as disinfectant on human skin, a leaching study is not indicated.

ESCA: not relevant

Testing for distribution and dissipation in soil (ADS)

Data waiving	
Information requirement	Testing for distribution and dissipation in soil

Justification for the conclusion	Due to the indoor use of the products, direct emissions to soil do not occur. The primary receiving compartment for emissions arising from the use of the products is the municipal sewage treatment plant due to the washing of treated skin or clothes. When entering STPs, iodine is separated from PVP and the other non-active ingredients of the products, so the fate and behaviour of iodine can be regarded as non-influenced by these substances. Hence, extrapolation from the data available for the active substance to the behaviour of the active substance in the biocidal products is possible. Also the formulation type (solution and soap) is not expected to change the mode of action of the active substance or its bioavailability. Furthermore, synergistic effects of the active and non-active ingredients are not reported and are therefore no matter of concern. Tests with the formulations are not considered to yield other results than tests with the active substance.

ESCA: not relevant

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

Data waiving	
Information requirement	Testing for distribution and dissipation in water and sediment
Justification for the conclusion	Due to the indoor use of the products, direct emissions to surface water bodies do not occur. The primary receiving compartment for emissions arising from the use of the products is the municipal sewage treatment plant due to the washing of treated skin or clothes. When entering STPs, iodine is separated from PVP and the other non-active ingredients of the products, so the fate and behaviour of iodine can be regarded as non-influenced by these substances. Hence, extrapolation from the data available for the active substance to the behaviour of the active substance in the biocidal products is possible. Also the formulation type (solution and soap) is not expected to change the mode of action of the active substance or its bioavailability. Furthermore, synergistic effects of the active and non-active ingredients are not reported and are therefore no matter of concern. Tests with the formulations are not considered to yield other results than tests with the active substance.

ESCA: not relevant

Testing for distribution and dissipation in air (ADS)

Data waiving	
Information requirement	Testing for distribution and dissipation in air
Justification for the conclusion	In line with the CAR air is no relevant compartment for iodine with respect to the high background values in the athmosphere.

ESCA: not relevant

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)

Data waiving	
Information requirement	Overspray study
Justification for the conclusion	Since a spray application is not intended an overspray study is unnecessary.

ESCA: not relevant

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)

Data waiving	
Information requirement	Overspray behaviour
Justification for the conclusion	The biocidal products are only applied indoors as liquid formulations. So data on the overspray behaviour are not required.

ESCA: not relevant

2.2.8.2 Exposure assessment

The b.p. of the solution subfamily (i.e. Yodicura povidona iodada 10%) and the soap subfamily (Yodicura solución jabonosa 7.5% povidona iodada) are used by non-professional and professional users (health carers and institutional professionals, not surgical) for hand skin disinfection. The concentration of available iodine is 1% and 0.75%, respectively.

Skin antiseptics are applied and used in very short time on the skin. After the used, soap products are rinsed off with fresh water and released to wastewater. Consequently, sewage treatment plants (STP) are an important emission pathway. Release of STP effluents containing potential iodine residues leads to emissions to surface water and sediment. Emissions to soil could arise indirectly, via the application of STP sludge and via aerial deposition. Furthermore, soil porewater concentrations as an indicator for potential groundwater levels will be assessed.

The emission scenario document for PT 1 products, when employed by professionals, presents a use scenario in hospitals. A typical hospital, being responsible for the health care of 10000 inhabitants, has 400 beds, 75% of them (i.e., 300 beds) are occupied. The exposure assessment is based on the average consumption of disinfectants per bed. In the absence of empirical data, the average consumption of products of the BPF per occupied bed was set to 0.13 g a.i. per day by default (ESD PT 1. Table 3.8). This scenario can be considered to represent an absolute worst case.

General information

Assessed PT	PT 1
Assessed scenarios	Scenario 1: Disinfection by professionals in hospitals

ESD(s) used	Emission Scenario Document for Product Type 1: Van der Aa, Eefje & Balk, Froukje (2004): Supplement to the methodology for risk evaluation of biocides: Environmental emission scenarios for biocides used as human hygiene biocidal products (product type 1). Report 4L1784.A0/R016.
Approach	Scenario 1: Average consumption
Distribution in the Environment	Calculated based on TGD 2003
Groundwater simulation	Calculated based on TGD 2003, no higher tier assessment Conducted
Confidential Annexes	No
Life cycle steps assessed	Scenarios: Production: No Formulation No Use: Yes Service life: Yes
Remarks	No

For the b.p. of the solution subfamily (i.e. Yodicura povidona iodada 10%) (META SPC 1), the concentration of PVP-I is 10%. Thus, the maximum concentration of available iodine is 1%.
-The b.p. of the soap subfamily contain both 7.5% PVP-I (META SPC 2), being the maximum concentration of available iodine 0.75%.

Since the products in META SPC 1 results in the higher emissions rate per day, they are assessed as worst cases. These products can either be applied by professionals an non-professionals. The current risk assessment focusses on the exposure due to professionals health care personal since the daily use is much higher compared to the use by non-professionals consumption.

Substance of Concern

The BPF contains the substance n-(n-dodecyl)pyrrolidone, in a concentration of 0.5%, considered as Substance of Concern. Therefore the environmental risk assessment has been performed at the same exposure conditions as for the a.s.. This substance is only present in products in META SPC 2.

ESCA agrees with the assessment proposed by the applicant.

Emission estimation

Scenario

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: Disinfectants used for skin and hand application in hospitals based on average consumptions			
Average use of disinfectant for professional use	0.13	g a.i./day/ occupied bed	Default value. ESD Table 3.8

Number of occupied beds	300		Default value. ESD Table 3.8

Calculations for Scenario

Resulting local emission to relevant environmental compartments for the a.s.		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	0.039	

Substance of concern, n-(n-dodecyl)pyrrolidone,

For n-(n-dodecyl)pyrrolidone there is no default values in the ESD for calculation of Qsubst therefore the calculation has been performed according to the TAB ENV 41, Oct 2022. The intended use of the product is for health carers and institutional professionals, not surgical.

Input parameters for calculating the local emission for n-(n-dodecyl)pyrrolidone			
Input	**Value**	**Unit**	**Remarks**
Scenario: Disinfectants used for skin and hand application in hospitals based on an average consumption			
Number of beds in model hospital ($Nbeds_{pres}$)	400	-	
Fraction released to wastewater (F_{water})	1	-	
Hospital staff (nursing staff, surgical staff or surgical staff)	Nursing staff	-	TAB
Type of application ("Hand wash with soaps and liquid soaps" or "Hand rubs")	Hand wash with soaps and liquid soaps		TAB
Number of hospitals personal per present bed ($N_{TE/press\_bed*}$)	1.5	$FTE.bed^{-1}$	TAB
Efficient dose rate of the hand desinfectant (Q_{form})	0.003	L/event	S
Fraction of the active substance in the hand desinfectant (F_{form})	0.005	-	S
Density of the product (RHO_{form})	0.9041	g/mL	According to MSDS
Number of disinfection events/FTE/day (N_{appl})	10	$FTE^{-1}.d^{-1}$	TAB
Nursing staff ($Qsubst_{pres\_bed}$)	0.00020	$Kg.bed^{-1}/d$	O, Nursing staff: $Qsubs_{pres\_bed}=N_{FTE/pres\_bed}*Q_{for\ m}*F_{form}*RHO_{form}*N_{appl}$
Based on average consumption per bed			
Emission rate to wastewater (standard STP) (Elocalwater)	0.081	kg.d-1	O, Elocalwater = $Nbeds_{pres}$ * $Qsubst_{pres\_bed}$ * F_{water}

*FTE/bed: Number of hospital personal per bed, default value: 1.5 FTE/bed

Resulting local emission to relevant environmental compartments for n-(n-dodecyl)pyrrolidone		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	0.081	

ESCA agrees with the local emission calculated for the active substance however, ES CA does not agree with the $E_{local\ STP}$ calculate for the SoC, n-(n- dodecyl)pyrrolidone. The value obtained by ES

CA for the $E_{local\ STP}$ is 0.09 kg/d (The applicant has chosen the density of the SoC, 0.9041 mg/ L, instead of the density of the biocidal product, 1.032 mg/L).

Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway							
	Fresh-water	Freshwater sediment	STP	Air	Soil	Ground-water	Other
Scenario	yes	Yes	Yes	no	yes	yes	-

ES CA agrees with the identification of the relevant compartments based on the exposure pathway.

Input parameters (only set values) for calculating the fate and distribution in the environment for the a.s			
Input	Value	Unit	Remarks
Molecular weight	253.81	g/mol	Source: CAR
Melting point	114	°C	Source: CAR
Boiling point	184	°C	Source: CAR
Vapour pressure (at 25°C)	40.7	Pa	Source: CAR
Vapour pressure (at 25°C)	1 x E-06	Pa	Used for calculation*
Water solubility (at 25°C)	0.30 – 0.33	g/L	Source: CAR
Water solubility (at 25°C)	100	g/L	Used for calculation*
Log Octanol/water partition coefficient	-	Log 10	Not relevant for an inorganic substance; Source: CAR
Log Octanol/water partition coefficient	2.49	Log 10	Used for calculation*
Organic carbon/water partition coefficient (Koc)	165.8	l/kg	Source: CAR; geomean
Solid water adsorption coefficients			
Kp_{susp}	220	cm^3/g	Used for calculation*
Kp_{soil}	5.8	cm^3/g	Used for calculation*
Henry's Law Constant (at 25°C)[if measured data available]	34.43	Pa/m3/mol	Source: CAR
Biodegradability	-		Not relevant for an inorganic substance; Source: CAR
Rate constant for STP [if measured data available]	-	h^{-1}	Not relevant for an inorganic substance; Source: CAR
DT_{50} for biodegradation in surface water	-	d or hr (at 12ºC)	Not relevant for an inorganic substance; Source: CAR

DT_{50} for hydrolysis in surface water	CAR: Hydrolysis of iodine only to a small extent since the substance is sparingly soluble. Hydrolysis of I2 as the reactant is a pH-dependent dynamic equilibrium reaction with iodide (I-) and iodate (IO3) as products. At pH values between 4 and 9, iodide is the dominant species. In alkaline and well oxidized waters iodate is the predominant species.		
DT_{50} for hydrolysis in surface water	-	d or hr	Used for calculation*
DT_{50} for photolysis in surface water	CAR: 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.		
DT_{50} for photolysis in surface water	-	D or h	Used for calculation*
DT_{50} for degradation in soil	-	d or hr (at 12ºC)	Not relevant for an inorganic substance; Source: CAR
DT_{50} for degradation in air	CAR: Very rapid photolysis of I_2; lifetime = 5- 10 s for an overhead sun; Methyl iodide and molecular iodine are the predominant iodine species in air.		
DT_{50} for degradation in air	-	d or hr	Used for calculation

* The parameter Kair-water is automatically calculated by EUSES from the molecular weight, the water solubility and the vapour pressure. Kair-water is of no relevance for the EUSES exposure estimations but technically necessary to enable further calculations. So the following input parameters have been used, which are applicable for the species iodide and iodate (except the molecular weight):
Molecular weight: 253.81 g/mol (taken from iodine)
Water solubility: 100 g/L
Vapour pressure: 1×10^{-6} Pa
Furthermore, the EUSES program requires the insertion of a log Pow value, also for technical reasons. A log Pow of 2.49 has been taken although this value has no influence on the outcome of the emission calculation.
Referring to the adsorption of iodine in soil, measured adsorption coefficients have been used, i.e. Kp_{soil} = 5.8 cm^3/g and Kp_{susp} = 220 cm^3/g.

Calculated fate and distribution in the STP for the a.s		
Compartment	Percentage [%] Scenario 1	Remarks
Air	0	Used for calculation*
Water	80	
Sludge	20	
Degraded in STP	0	

*The review of the active substance iodine came to the result, that volatilisation of the parent compound is not relevant since iodine is highly reactive and will be transformed into other species. Based on literature data as well as laboratory and field experiments, a distribution of 20% to sludge and 80% to STP effluent has been used.

ESCA agrees with the input parameter used for the a.s.

Input parameters (only set values) for calculating the fate and distribution in the environment for n-(n-dodecyl)pyrrolidone			
Input	**Unit**	**Value**	**Remarks**
Molecular weight	g/mol	253.43	MSDS data
Vapour pressure	Pa	0.00204 (25 ºC)	MSDS data
Water solubility	mg/L	51.7 (20 ºC)	MSDS data
Log Octanol/water partition coefficient	Log 10	4.03	MSDS data
Organic carbon/water partition coefficient (Koc)	L/kg	1588	QSAR calculation EPIweb 4.1
Henry's Law Constant	Pa m^3/mol	0.072	QSAR calculation EPIweb 4.1
Biodegradability		Readily biodegradable	MSDS data
BCF fish	L/kg	531	QSAR calculation EUSES
BCF earthworms	L/kg	129	QSAR calculation EUSES

Calculated fate and distribution in the STP for n-(n-dodecyl)pyrrolidone		
Compartment	Percentage [%] Scenario 1	Remarks
Air	0.01	Used for calculation SimpleTreat 4.1
Water	7.14	
Sludge	12.2	
Degraded in STP	80.6	

ES CA has changed some parameters of the SoC:

Input parameters (only set values) for calculating the fate and distribution in the environment for n-(n-dodecyl)pyrrolidone			
Input	**Unit**	**Value**	**Remarks**

Organic carbon/water partition coefficient (Koc)	L/kg	1300	EUSES 2.2
Henry's Law Constant	Pa m^3/mol	0.0447	EUSES 2.2

Calculated fate and distribution in the STP for n-(n-dodecyl)pyrrolidone		
Compartment	Percentage [%] Scenario 1	Remarks
Air	0.002	EUSES 2.2 Simple treat 4
Water	7.28	
Sludge	10.40	
Degraded in STP	82.30	

There are small differences between the values proposed by the applicant and those chosen by the ESCA but, since the $E_{local\ stp}$ has been also change, ESCA has decided to recalculate PEC values for the SoC.

Calculated PEC values

Calculated PEC values for the a.s.		
Compartment	Abbreviation [unit]	PEC value
Sewage treatment plant	PEC_{STP} [µg/L]	15.6
Surface water	PEC_{water} [µg/L]	1.55
	PEC_{sed} [mg/kg wwt]	0.076
Terrestrial compartment	PEC_{soil} [mg/kg dwt]	0.109 (iodate 0.151*, iodide 0.015**)
	$PEC_{groundwater}$ [µg/L]	18.1 (25 iodate*, 2.53 iodide**)
Air	PEC_{air} [ng/m^3]	Not relevant
Biota	PEC_{biota} [mg/kg]	Not relevant

* mg/kg iodate = mg/kg iodine * 1.382 (100% of the iodine is transformed into iodide, mol weight correction with factor 1.382)
** mg/kg iodide = mg/kg iodine * 0.14 (only 14 %of the iodine is transformed into iodide)

ES CA agrees with the values obtained for the a.s.

Calculated PEC values for (n-(n-dodecyl)pyrrolidone)		
Compartment	Abbreviation [unit]	PEC value
Sewage treatment plant	PEC_{STP} [mg/L]	905.58E-03
Surface water	PEC_{water} [mg/L]	905.57E-04
	PEC_{sed} [mg/kg wwt]	0.01.97E-02
Terrestrial compartment	PEC_{soil} [mg/kg wwt]	9.18E-02
	$PEC_{groundwater}$ [µg/L]	**0.15**

Air	PEC_{air} [ng/m^3]	Not relevant
Biota	$PEC_{biota, terrestrial}$[mg/kg]	8.96E-03
	$PEC_{biota, aquatic}$[mg/kg]	0.08

ES CA: PEC values recalculated with EUSES 2.2 by ES CA :

Calculated PEC values for (n-(n-dodecyl)pyrrolidone)		
Compartment	Abbreviation [unit]	PEC value
Sewage treatment plant	PEC_{STP} [mg/L]	3.28E-03
Surface water	PEC_{water} [mg/L]	3.27E-04
	PEC_{sed} [mg/kg wwt]	9.54E-03
Terrestrial compartment	PEC_{soil} [mg/kg wwt]	0.012
	$PEC_{groundwater}$ [µg/L]	1.72E-01

Primary and secondary poisoning

Primary poisoning Not applicable

Secondary poisoning

Amounts of iodine potentially released to the environment due to the use as disinfectants are within the natural background levels and there is no concern with respect to secondary poisoning.

According to the ECHA Guidance IV B+C (2017), the calculation of a possible risk to man via the food chain (PECoralpredator) should be conducted if the substance shows a potential for bioaccumulation, indicated by a log Kow value >3.
N-(n-dodecyl)pyrrolidone reveals a log Kow of 4.03 indicating that there might be a risk for bioaccumulation. Therefore, the secondary poisoning has been assessed.

ES CA agrees with the applicant, the log Kow of permethrin (4.03) is above the trigger value of 3 suggesting that the substance may have significant potential for bioconcentration in both aquatic and terrestrial biota.

PEC values obtained by EUSES 2.2:

Summary table on secondary poisoning		
		n-(n-dodecyl)pyrrolidone
Aquatic food chain		**PEC $_{oral,predator,aquatic}$ (mg/kg)**
		7.1E-02

	Terrestrial food chain		PEC oral.predator.terrestrial (mg/kg)	
			1E-02	

2.2.8.3 Risk characterisation

Atmosphere

With respect to the high background values in air, emissions to air resulting from the application of iodine as disinfectant are not relevant.

Sewage treatment plant (STP), aquatic compartment, terrestrial compartment and groundwater

PEC and PNEC values for iodine, iodide and iodate as well as environmental background concentrations for iodine

Compart-ment [unit]	PEC values			PNEC value			Environmental background concentrations
	Iodine (I_2)	Iodide (I^-)	Iodate (IO_3^-)	Iodine (I_2)	Iodide (I^-)	Iodate (IO_3^-)	Iodine (I_2)
STP [mg/L]	0.0156	-	-	2.9	-	-	-
Surface water [µg/L]	1.55			0.32	-	-	0.5 – 20
Sediment [mg/kg]	0.076	-	-	-	-	-	6
Soil [mg/kg dwt]	0.109	0.015	0.151	0.0134	0.0043	0.304	0.5 – 20
Groundwater [µg/L]	18.1	2.53	25.0	0.1*	-	-	1 – 70

*Limit value for pesticides in the Drinking Water Directive 98/83/EC
- not relevant

PEC/PNEC values for iodine, iodide and iodate as well as a comparison to environmental background concentrations for iodine

Compartment	PEC/PNEC value			Within Environmental background concentrations for Iodine (I_2)?
	Iodine (I_2)	Iodide (I^-)	Iodate (IO_3^-)	
STP	0.0054	-	-	-
Surface water	4.84	-	-	yes
Sediment	-	-	-	yes
Soil	8.13	3.49	0.50	yes
Groundwater	181	-	-	yes

*Limit value for pesticides in the Drinking Water Directive 98/83/EC
- not relevant

The PEC/PNEC values for iodine for surface water, soil and groundwater indicate a risk for these compartments. However, the calculated PEC values are all at the lower limit of the natural background levels. With respect to the conclusions drawn in the Competent Authority Report for iodine, a risk for organisms in the environment due to the use of iodine as disinfectant within the PVP-Iodine YODICURA product family is therefore not indicated.
The comparison of environmental concentrations (PEC values) to the Predicted No Effect Concentrations (PNEC values) derived from standardised OECD tests with terrestrial and aquatic organisms is no appropriate tool for assessing a potential risk for environmental compartments. The reasons are:

- Iodine is an essential element for both, animals and plants at high concentrations
- There are already considerable iodine (and iodine species) background concentrations in environmental compartments
- Standard assessment factors applied to terrestrial and aquatic tests are overly conservative
- Iodine occurs in different forms at different pH and redox conditions in the environment, being characteristic for the different compartments. In the aquatic environment for example dissolved organic iodine can be found. A risk characterisation based on standard test with limited inorganic iodine species is therefore of low relevance.

Therefore, at TMII/2012 it was concluded, that the risk arising from PEC/PNEC comparison can be disregarded if the PEC values are within the range of natural background levels. The calculated PEC values are all at the lower limit of the natural background levels. Congruent with the conclusions drawn in the Competent Authority Report for iodine, a risk for organisms in the environment due to the use of iodine as disinfectant within the PVP-Iodine YODICURA product family is therefore not indicated.

ES CA agrees with the conclusions given by the applicant.

Risk characterization for the substance of concern: n-(n-dodecyl)pyrrolidone

PEC/PNEC values for n-(n-dodecyl)pyrrolidone	
Compartment	**PEC/PNEC value**
STP	<0.01
Surface water	0.16
Sediment	0.20
Soil	0.31
Groundwater*	**0.15** µg/L
Secondary poisoning terrestrial	<0.01
Secondary poisoning aquatic	<0.01

*Limit value for pesticides in the Drinking Water Directive 98/83/EC is 0.1 µg/L

The scenario yield PEC/PNEC ratios below one for n-(n-dodecyl)pyrrolidone indicating acceptable risk for all the environmental compartments, except for groundwater because exceeds the maximum permissible concentration in groundwater of 0.1 µg/L for biocides (Council Directives 98/83 /EC), therefore a refined emission to groundwater has been assessed using the FOCUS PEARL version 4.4.4 by applying the physical-chemical parameters of n-(n-dodecyl)pyrrolidone presented in the input table.
The required organic matter-water partitioning coefficient (K_{om}) was derived by K_{oc}/1.724. The Freundlich constant (1/n) was set equal to 1, i.e. no concentration-dependent sorption to soils.

Emission via distribution of sewage sludge:

The dose (kg/ha) was derived from PEC_{soil} by applying the agreed mixing depth for grassland and arable land, and a soil density of 1700 kg/m³. Sewage sludge is mixed with the soil's top layer (incorporation) for which the mixing depth is set to the agreed values for grassland and arable land. The application scheme (timelines and crops) is the one agreed for grassland and arable land. Irrigation, tillage, and crop uptake were not considered.

N-(n-dodecyl)pyrrolidone may enter indirectly the soil and porewater via the STP. The exposure assessment is based on a representative application to grassland (alfalfa) and agricultural land (maize). The application scenarios are adopted according to the standard crop type, number of applications and application timing for the use in PEARL 4.4.4:

Agricultural land:

- Maize
  - One sewage sludge application, 20 days before emergence (relative application)
  - Incorporation: 0.2 m

- Grassland:
  - alfalfa
    - One sewage sludge application per year on 1st of March (absolute application)
    - Incorporation: 0.1 m

The specific application rates to be used in the FOCUS modelling are derived based on the input parameter $Application\_rate_{agr/grass}$ [kg/ha] at one application date. The

$Application\_rate_{agr/grass}$ is calculated by the following equation (according to the TAB ENV 36, 2021):

$Application\_rate_{ars/grass}$ [kg/ha] = $App\_sewage\_sludge\_{agr/grass}$ [kg/ha] x Csludge [mg/kg] x 10^{-06}.

With,

$App\_sewage\_sludge\_{agr}$ = annual sewage sludge application rate on agricultural land = 5,000 kg/ha
$App\_sewage\_sludge\_{grass}$ = annual sewage sludge application rate on grassland = 1,000 kg/ha
Csludge = concentration of icaridin-acid in dry sewage sludge [mg/kg] (according to eq. 39 in guidance BPR IV B+C, 2017).

Considering a worst-case concentration in dry sewage sludge of 12.2 mg n-(n-dodecyl)pyrrolidone/kg, the application rates for agricultural land and grassland are 1.22E- 02 kg/ha and 6.12E-02 kg/ha respectively.

Dosage applied to calculate emission to groundwater

Dosage applied to calculate emission to groundwater		
	Grassland	**Arable land**
	kg/ha/y	kg/ha/y
n-(n-dodecyl)pyrrolidone	1.22E-02	6.12E-02

Summary of PECgw simulations with FOCUS PEARL 4.4.4

Summary of PEC_{gw} simulations with FOCUS PEARL 4.4.4	
Input parameters related to n-(n-dodecyl)pyrrolidone	
Molecular weight (g/mol)	253.43
Vapour pressure at 25°C (Pa)	2.03E-03
Water solubility at 20°C (mg/L)	51.7
Sorption to soil organic carbon (Kom = Koc / 1.724))	921
DT_{50} in soil at 12°C (d)	30
Coefficient for uptake by plant (-)	0
1/n	1

PECgroundwater - Output (FOCUS PEARL 4.4.4) in µg/L

$PEC_{groundwater}$ - Output (FOCUS PEARL 4.4.4) in µg/L		
Location	**Grassland (crop)**	**Arable land (crop)**
Chateaudun	<0.0001	<0.0001
Hamburg	<0.0001	<0.0001
Jokioinen	<0.0001	-
Kremsmunster	<0.0001	<0.0001
Okehampton	<0.0001	<0.0001
Piacenza	<0.0001	<0.0001
Porto	<0.0001	<0.0001
Sevilla	<0.0001	<0.0001
Thiva	<0.0001	<0.0001

Conclusion: For n-(n-dodecyl)pyrrolidone the calculated pore water concentration in the scenario exceeds the trigger value of 0.1 µg/L. However, groundwater concentrations of n-

(n-dodecyl)pyrrolidone are below 0.1 µg/L when considering higher tier FOCUS PEARL modelling.

ES CA:

Risk characterization for the substance of concern: n-(n-dodecyl)pyrrolidone

PEC/PNEC values for n-(n-dodecyl)pyrrolidone	
Compartment	PEC/PNEC value
STP	1.48E-03
Surface water	1.64E-01
Sediment	3.96E-02

Soil	2.55E-01
Groundwater*	1.72 µg/L

*Limit value for pesticides in the Drinking Water Directive 98/83/EC is 0.1 µg/L

The scenario yield PEC/PNEC ratios below one for n-(n-dodecyl)pyrrolidone indicating acceptable risk for all the environmental compartments, except for groundwater because exceeds the maximum permissible concentration in groundwater of 0.1 µg/L for biocides (Council Directives 98/83 /EC).
Values for ground water refined using the FOCUS PEARL version 4.4.4 has been recalculated using the following input parameters:

Summary of PEC_{gw} simulations with FOCUS PEARL 4.4.4	
Input parameters related to n-(n-dodecyl)pyrrolidone	
Molecular weight (g/mol)	253.43
Vapour pressure at 25°C (Pa)	2.03E-03
Water solubility at 20°C (mg/L)	51.7
Sorption to soil organic carbon (Kom = Koc / 1.724))	754
DT_{50} in soil at 12°C (d)	30
Coefficient for uptake by plant (-)	0
1/n	1
Csludge (mg/kg)	12.75

The groundwater concentrations of n-(n-dodecyl) pyrrolidone refined using FOCUS PEARL are below 0.1 µg/L for all scenarios.

Primary and secondary poisoning

Primary poisoning Not applicable

Secondary poisoning

Amounts of iodine potentially released to the environment due to the use as disinfectants are within the natural background levels and there is no concern with respect to secondary poisoning. With regards to the identified substance of concern, n-(n-dodecyl) pyrrolidone, secondary poisoning has been assessed with PEC/PNEC ratios below one indicating acceptable risk.

ES CA agrees with the conclusion of the applicant, there is no risk of secondary poisoning.

Mixture toxicity

The complexing agent Polyvinylpyrrolidone is a widely-used constituent in food, medicinal, and cosmetic products. Emissions to the environment arising from the use of PVP-Iodine YODICURA products compared to the emissions resulting from the consumption of PVP- containing food and cosmetic products are negligible. PVP is not classified with respect to the environment. Besides, at TMII/2012 it was concluded that, the risk arising from PEC/PNEC comparison can be disregarded if the PEC values are within the range of natural background levels. The calculated PEC values are all at the lower limit of the natural background levels. Congruent with the conclusions drawn in

the Competent Authority Report for iodine, a risk for organisms in the environment due to the use of iodine as disinfectant within the PVP-Iodine YODICURA product family is therefore not indicated.
The risk assessment of the SoC (n-(n-dodecyl) pyrrolidone) indicates that there is not risk for environmental compartments.
Therefore the environmental risk assessment on mixture toxicity has not been carried out.

ES CA agrees with the conclusion of the applicant.

Aggregated exposure (combined for relevant emission sources)

The applicant has no data about the use of the active substances in other human disinfectants or other PTs. Therefore it is not possible to conduct a risk assessment for aggregated exposure.

Overall conclusion

Overall conclusion on the risk assessment for the environment of the product
An acceptable risk is foreseen for all scenarios at assessed compartments, when the claimed application processes on product's label are followed.

2.2.9 Measures to protect man, animals and the environment

Recommended methods and precautions

Environmental precautions:

Avoid any spillage in the environment. Pay special attention to the cleaning water. Avoid contamination of drains, surface or subterranean water and soil.

2.2.10 Assessment of a combination of biocidal products

No relevant

2.2.11 Comparative assessment

No relevant

3 ANNEXES

3.1 List of studies for the biocidal product FAMILY

See confidential annex

3.2 Output tables from exposure assessment tools

SUBSTANCE			
NAME	IODINE		
CASNUMBER	7553-56-2		
MOLECULAR WEIGHT		253	G/MOL
KOW	2.49	10LOG	
PRODUCT			
NAME	PVP-IODINE YODICURA (BPF)		
WEIGHT FRACTION SUBSTANCE		1	%
POPULATION			
NAME	PROFESSIONAL		
BODY WEIGHT	60	KG	
SCENARIO HAND DISINFECTION (HANDRUB) WITH POVIDONE-IODINE 7,5% SOAP			
FORMULATIONS			
FREQUENCY	8	PER DAY	
DESCRIPTION			
INHALATION			
EXPOSURE MODEL		EXPOSURE TO VAPOUR - EVAPORATION	
EXPOSURE DURATION		5	MINUTE
PRODUCT IN PURE FORM		NO	
MOLECULAR WEIGHT MATRIX		18	G/MOL
THE PRODUCT IS USED IN DILUTION			NO
PRODUCT AMOUNT		8.77	G
WEIGHT FRACTION SUBSTANCE		0.75	%
ROOM VOLUME	1	M³	
VENTILATION RATE		0.6	PER HOUR
INHALATION RATE		16	M³/DAY
APPLICATION TEMPERATURE		20	°C
VAPOUR PRESSURE		40.7	PA
MOLECULAR WEIGHT		253	G/MOL
MASS TRANSFER COEFFICIENT		0.207	M/MIN
RELEASE AREA MODE		INCREASING	
RELEASE AREA	820	CM²	
APPLICATION DURATION		5	MINUTE
ABSORPTION MODEL		FIXED FRACTION	
ABSORPTION FRACTION		100	%
DERMAL			
EXPOSURE MODEL		DIRECT CONTACT - INSTANT APPLICATION	
EXPOSED AREA	820	CM²	
WEIGHT FRACTION SUBSTANCE		0.75	%
PRODUCT AMOUNT		8.77	G
ABSORPTION MODEL		DIFFUSION THROUGH SKIN	
CONCENTRATION		7.5	MG/CM³
SKIN PERMEABILITY		7.7E-06	CM/HR
EXPOSURE TIME	5	MINUTE	
ORAL			

EXPOSURE MODEL	N.A.		
ABSORPTION MODEL	N.A.		
RESULTS FOR SCENARIO HAND DISINFECTION (HANDRUB) WITH POVIDONE-IODINE 7,5% SOAP FORMULATIONS			
INHALATION			
MEAN EVENT CONCENTRATION	0.0314	MG/M³	
PEAK CONCENTRATION (TWA 15 MIN)		0.0314	MG/M³
MEAN CONCENTRATION ON DAY OF EXPOSURE		0.000873	MG/M³
YEAR AVERAGE CONCENTRATION	0.000873	MG/M³	
EXTERNAL EVENT DOSE	2.91E-05	MG/KG BW	
EXTERNAL DOSE ON DAY OF EXPOSURE		0.000233	MG/KG BW
INTERNAL EVENT DOSE	2.91E-05	MG/KG BW	
INTERNAL DOSE ON DAY OF EXPOSURE		0.000233	MG/KG BW/DAY
INTERNAL YEAR AVERAGE DOSE	0.000233	MG/KG BW/DAY	
DERMAL			
DERMAL LOAD 0.0802	MG/CM²		
EXTERNAL EVENT DOSE	1.1	MG/KG BW	
EXTERNAL DOSE ON DAY OF EXPOSURE		8.77	MG/KG BW
INTERNAL EVENT DOSE	6.58E-05	MG/KG BW	
INTERNAL DOSE ON DAY OF EXPOSURE		0.000526	MG/KG BW/DAY
INTERNAL YEAR AVERAGE DOSE	0.000526	MG/KG BW/DAY	
INTEGRATED			
INTERNAL EVENT DOSE	9.49E-05	MG/KG BW	
INTERNAL DOSE ON DAY OF EXPOSURE		0.000759	MG/KG BW/DAY
INTERNAL YEAR AVERAGE DOSE	0.000759	MG/KG BW/DAY	

SCENARIO HAND DISINFECTION (HANDRUB) WITH YODICURA POVIDONA IODADA 10% (SOLUTION)			
FREQUENCY 8	PER DAY		
DESCRIPTION			
INHALATION			
EXPOSURE MODEL	EXPOSURE TO VAPOUR - EVAPORATION		
EXPOSURE DURATION	5	MINUTE	
PRODUCT IN PURE FORM	NO		
MOLECULAR WEIGHT MATRIX	18	G/MOL	
THE PRODUCT IS USED IN DILUTION		NO	
PRODUCT AMOUNT	3.1	G	
WEIGHT FRACTION SUBSTANCE	1	%	
ROOM VOLUME 1	M³		
VENTILATION RATE	0.6	PER HOUR	
INHALATION RATE	16	M³/DAY	
APPLICATION TEMPERATURE	20	°C	
VAPOUR PRESSURE	40.7	PA	
MOLECULAR WEIGHT	253	G/MOL	
MASS TRANSFER COEFFICIENT	0.207	M/MIN	
RELEASE AREA MODE	INCREASING		
RELEASE AREA 820	CM²		
APPLICATION DURATION	5	MINUTE	
ABSORPTION MODEL	FIXED FRACTION		
ABSORPTION FRACTION	100	%	
DERMAL			
EXPOSURE MODEL	DIRECT CONTACT - INSTANT APPLICATION		
EXPOSED AREA 820	CM²		
WEIGHT FRACTION SUBSTANCE	1	%	

PRODUCT AMOUNT	3.1	G	
ABSORPTION MODEL	DIFFUSION THROUGH SKIN		
CONCENTRATION	10	MG/CM³	
SKIN PERMEABILITY	7.7E-06	CM/HR	
EXPOSURE TIME 5	MINUTE		
ORAL			
EXPOSURE MODEL	N.A.		
ABSORPTION MODEL	N.A.		
RESULTS FOR SCENARIO HAND DISINFECTION (HANDRUB) WITH YODICURA POVIDONA IODADA 10% (SOLUTION)			
INHALATION			
MEAN EVENT CONCENTRATION	0.042	MG/M³	
PEAK CONCENTRATION (TWA 15 MIN)		0.042	MG/M³
MEAN CONCENTRATION ON DAY OF EXPOSURE		0.00117	MG/M³
YEAR AVERAGE CONCENTRATION	0.00117	MG/M³	
EXTERNAL EVENT DOSE	3.89E-05	MG/KG BW	
EXTERNAL DOSE ON DAY OF EXPOSURE		0.000311	MG/KG BW
INTERNAL EVENT DOSE	3.89E-05	MG/KG BW	
INTERNAL DOSE ON DAY OF EXPOSURE		0.000311	MG/KG BW/DAY
INTERNAL YEAR AVERAGE DOSE	0.000311	MG/KG BW/DAY	
DERMAL			
DERMAL LOAD 0.0378	MG/CM²		
EXTERNAL EVENT DOSE	0.517	MG/KG BW	
EXTERNAL DOSE ON DAY OF EXPOSURE		4.13	MG/KG BW
INTERNAL EVENT DOSE	8.77E-05	MG/KG BW	
INTERNAL DOSE ON DAY OF EXPOSURE		0.000701	MG/KG BW/DAY
INTERNAL YEAR AVERAGE DOSE	0.000701	MG/KG BW/DAY	
INTEGRATED			
INTERNAL EVENT DOSE	0.000127	MG/KG BW	
INTERNAL DOSE ON DAY OF EXPOSURE		0.00101	MG/KG BW/DAY
INTERNAL YEAR AVERAGE DOSE	0.00101	MG/KG BW/DAY	

3.3 New information on the active substance

3.4 Residue behaviour

3.5 Summaries of the efficacy studies (B.5.10.1-xx)

All efficacy tests information is summarised in the efficacy table, section 2.2.5.5.

3.6 Other

See confidential annex