REQUEST FOR ADDITIONAL INFORMATION

Submission number:	NR546252-21
Legal name of applicant:	SEBIA
Submitted by:	SEBIA
Substance:	4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated
Uses:	Use-1, Use-2, Use-3

Contents

1. AIM & GOAL

The present document synthesises the Applicant's answers to the Risk Assessment Committee's request for additional information (communication number: AFA-C-2114473062-56-01/F) received on 2019/05/24.

2. REQUEST FOR ADDITIONAL INFORMATION

General question for all uses applied for by SEBIA:

2.1. Question 1

2.1.1. Committees' question

> *The application would be much easier to evaluate if the following information could be provided:*
>
> *a. A table showing the relationship of the uses, the ECS, and the manufacturing sites, including the quantities of 4-tert-OPEO used in each situation and the estimated releases.*
>
> *b. A description of waste collection and storage points at each site/use/ECS and how they are equipped and marked for identification. A plan of the sites would be helpful, as would an example of a standard operating procedures for waste collection.*
>
> *c. A description of the organisational measures in place to minimise emissions of 4-tert-OPEO, including training of operators in the handling of 4-tert-OPEO and procedures for cleaning of spills.*

2.1.2. Applicant's answer

a. The figure 1 is given in order to provide the relationship between the uses, the sites and the exposures scenario presented in the AfA.

The three sites are present in three distinct regions (~ 20 million inhabitants, 200 · 200 km2) and three distinct local environments (freshwater). The sites of Lisses (ES-1, SEBIA) and Paladru (ES-3, REXOR) are both situated in France. The site of Rome (ES-2, INTERLAB) is in Italy.

In the site of Lisses, The production of commercial products related to all uses is performed. In the site of Rome, the production of commercial products related to Use-2 is performed. In the site of Paladru, the GBR support production (Use-1) is performed. GBR support is then employed for gel casting (Use-2) performed on the site of Lisses.

In the site of Lisses (ES-1), a total maximum quantity of 213 kg of OPnEO per year is expected to be used during the review period for all uses. An OPnEO quantity of 220 kg/year was used in the exposure assessment. Two distinct release estimates have been performed. The Worst-case Scenario of release estimate is based on the default Environmental Release Category (ERC) for formulation processes (2% of the substance released in water considered). The

default release estimate is 44kg/year, but not take into account risk management measures (RMM).

The realistic Worst-case of release estimate is based on monitoring measurements performed on-site (0.03% of the substance release in water considered). The release estimate is 0.042kg/year. According to the RMM in place and the strict conditions employed in the manufacturing processes to avoid any release of the substance, the realistic worst-case based on measurements may be considered reasonable. Measurements of release will be continued during the review period and RMM will be improved.

In the site of Rome (ES-2), a maximum quantity of 16 kg of OPnEO per year is expected to be used during the review period. Two distinct release estimates have been performed. The Worst-case Scenario of release estimate is based on the default Environmental Release Category (ERC) for formulation processes (2% of the substance released in water considered). The default release estimate is 0.325 kg/year, but not take into account risk management measures (RMM).

The realistic Worst-case of release estimate is based on monitoring measurements performed on-site (0.012% of the substance released in water considered). The release estimate is 0.0013kg/year. According to the RMM in place and the strict conditions employed in the manufacturing processes to avoid any release of the substance, the realistic worst-case based on measurements may be considered reasonable. Measurements of release will be continued during the review period.

In the site of Paladru (ES-3), a maximum quantity of 0.6 kg of OPnEO per year is expected to be used during the review period. Two distinct release estimates have been performed. The Worst-case Scenario of release estimate is based on the default Environmental Release Category (ERC) for formulation processes into a solid matrix (0.2% of the substance release in water considered). The default release estimate is 0.0012kg/year, but not take into account risk management measures (RMM).

The realistic Worst-case of release estimate is based on a monitoring measurement performed on-site during a GBR production (0.001% of the substance release in water considered). The release estimate is 6E-06 kg/year. According to the RMM in place and the strict conditions employed in the manufacturing processes to avoid any release of the substance, the realistic worst-case based on measurements may be considered reasonable. Measurements of release will be continued during the review period.

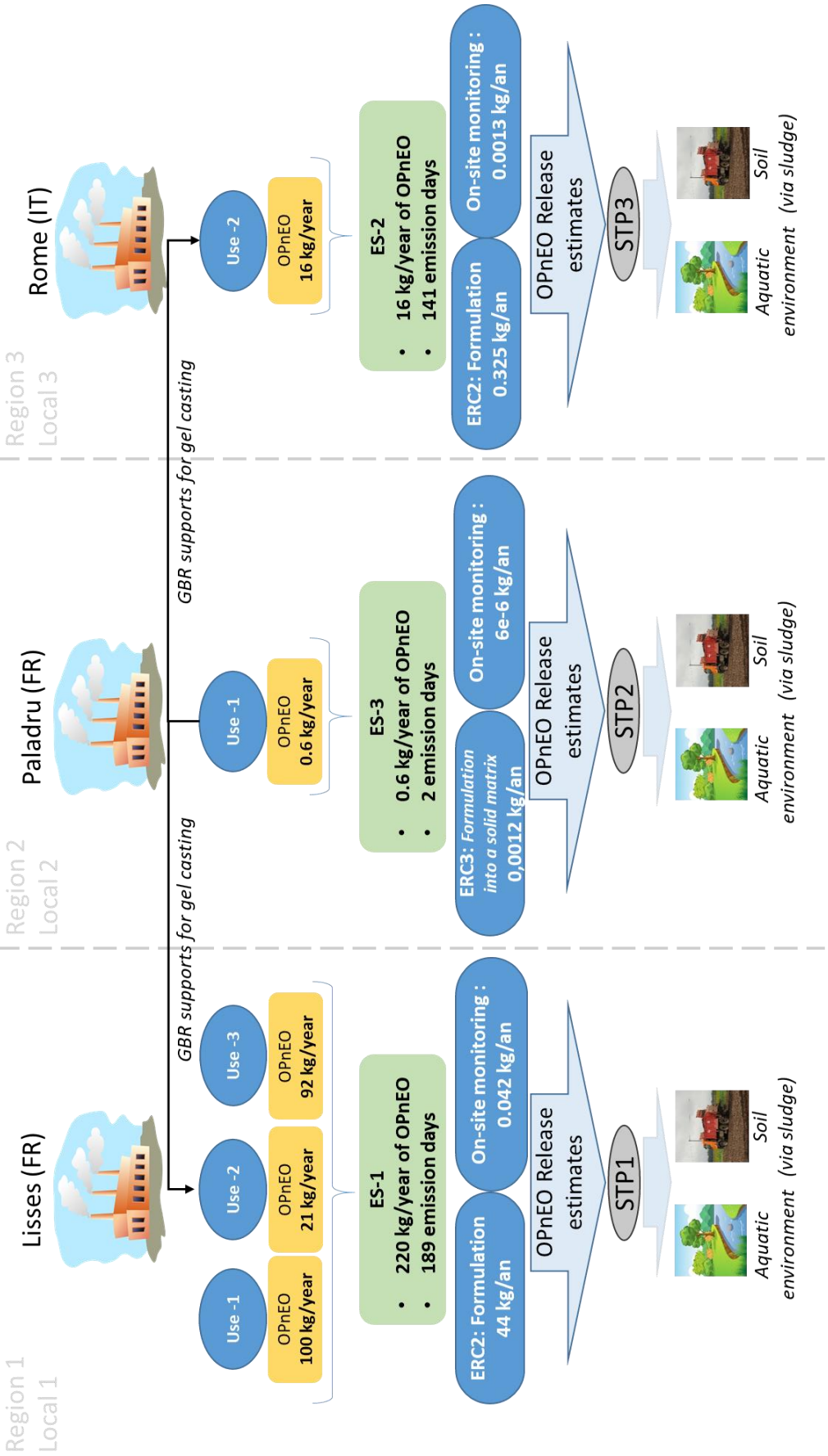

Figure 1: Overview of the relationships between Uses/ES/Sites

b. In each site, OPnEO-containing wastes in both liquid and solid forms are collected in appropriate containers, hermetically closed and stored in specific area dedicated to wastes. Identified workers and services are in charge of the appropriate conditioning of wastes and their traceability among time until their ultimate elimination by incineration. Waste areas are closed in order to avoid external intrusion.

The production site of Lisses (ES-1, All Uses) operates quality management system which complies with the requirements of the ISO 14001:2004 and ISO 13485:2012 international standards for the research, development, production and sales of reagents and equipment for *in vitro* biological analysis. The site is constituted of three facilities linked by tunnels (Picture below). Osmofilms resulting solid wastes (high volumes) are stocked in the Waste Storage area situated outside the other facilities (Fig.2).

Figure 2: Plan of the site of Lisses (outside)

In the "Chemistry" Facilities, productions of buffers, strips and gels containing OPnEO are performed on the ground floor (Fig.3). Solutions of Triton X-100 & X-405 are stored in a specific and closed storage room for hazardous products (Fig.4). All liquid products are stored on retention or in watertight tanks (grey boxes) (Fig.4). Remaining low volumes of OPnEO containing solutions in equipment are collected in dedicated containers, hermetically closed, properly identified as dangerous wastes and stored in a dedicated room before the final elimination by a certified company *via* incineration (Fig.5A, B, and C). Washing waters of equipment (Tanks, filling lines, gel casting machine, …) are collected *via* manholes or reels present in the different production rooms that are connected to underground retention reservoirs present on site (n = 2, 5000 L each). The soiled water collected in retention reservoirs is treated thanks to an evapo-concentrator. The treated water is released in the collective sewage network and the resulting concentrate is collected in a 1000-L tank, then transferred and stocked in Osmofilms (250-L each) in the waste storage area situated outside the site (Fig.5E). Some particular liquid or semi-solid liquid wastes are not suitable for the evapo-concentrator. Those wastes are stored in a specific room (Fig. 5D) and are directly treated in Osmofilms. Osmofilms are collected by a certified company (VEOLIA) to be disposed of *via* incineration. Low volumes solid wastes (single-used equipment, empty containers, soiled vials….) are collected in dedicated containers (Blue containers 200-L, Fig. 5B) and stocked in the waste area present on the ground floor of the "Electronic" facilities. Liquid and solid wastes containing OPnEO are considered as dangerous wastes, collected in appropriate containers, hermetically closed, properly identified as Special industrial wastes (DIS) with the appropriate pictograms (Fig.5 & 6). An example of the waste collection procedures is given in annex 1. Each document, procedure and certificate (Waste transports and treatments) is available for local authorities. Every workers are informed on the precautions to take for the packaging, the identification and the storage of the wastes (liquids and solids) present on site.

Figure 3: Plan of the site of Lisses (Inside)

Figure 4: Storage area for Triton X-100 (left) & X-405 (right)

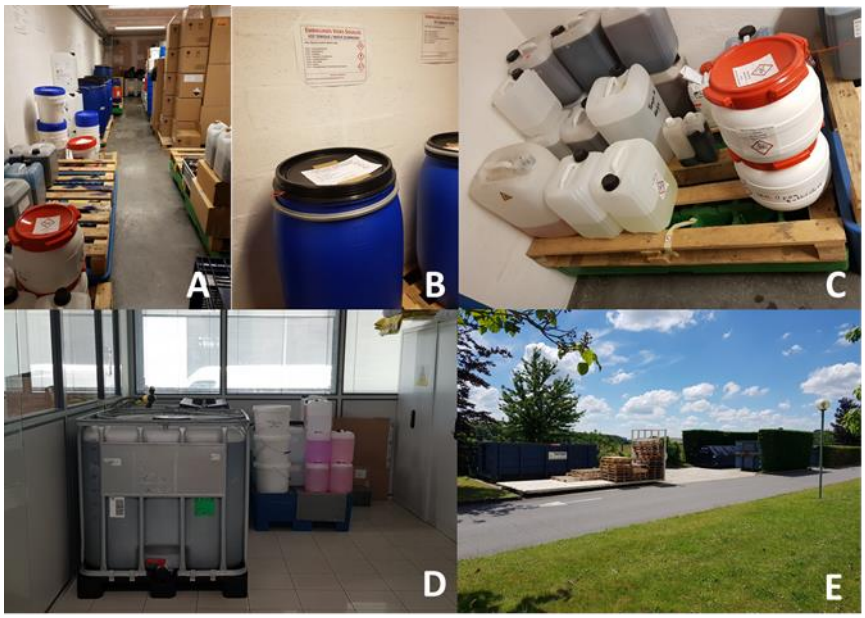

Figure 5: Waste storage area and containers dedicated to waste collection.

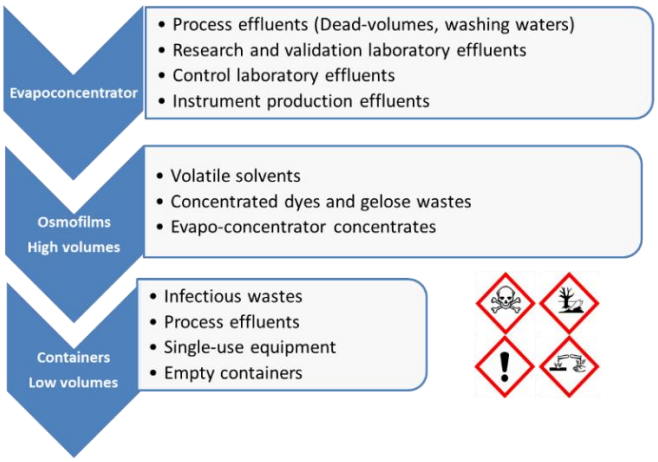

Figure 6: Overview of OPnEO containing wastes and collection routes

The production site of Rome (ES-2, Use-2) operates quality management system which complies with the requirements of the ISO 13485:2012 international standard for the design,

production and sales of automated instruments and dedicated products for the diagnostic electrophoresis of plasma proteins, haemoglobins and CSF, related service of technical and application assistance. The site is constituted of one facility strictly following the GMP (Good Manufacturing Process) standards (Fig.7). Solutions containing Triton X-100 are stored in a specific chemical cabinet (Fig.8). Solid OPnEO-containing wastes are gels, empty containers and single-used equipment including PPE. Liquid OPnEO-containing wastes are process effluents (dead-volumes of solutions and washing waters). Liquid and solid wastes containing OPnEO are considered as dangerous wastes, collected in appropriate containers, hermetically closed (Fig.9), properly identified as Special industrial wastes (DIS) with the appropriate pictograms, stored in a specific area (Fig.10), transferred and then disposed of (twice a month) by a certified company *via* incineration (Controlfilm s.r.l.)(Fig.11). Each document, procedure and certificate (Waste transports and treatments) is available for local authorities. Every workers are informed on the precautions to take for the packaging, the identification and the storage of the wastes (liquids and solids) present on site.

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Figure 7: Plan of the site of Rome

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Figure 8: Chemical cabinet for Triton X-100 storage

Figure 9: Reel and containers used for the collection of Triton X-100 containing wastes

Figure 10: Waste storage area

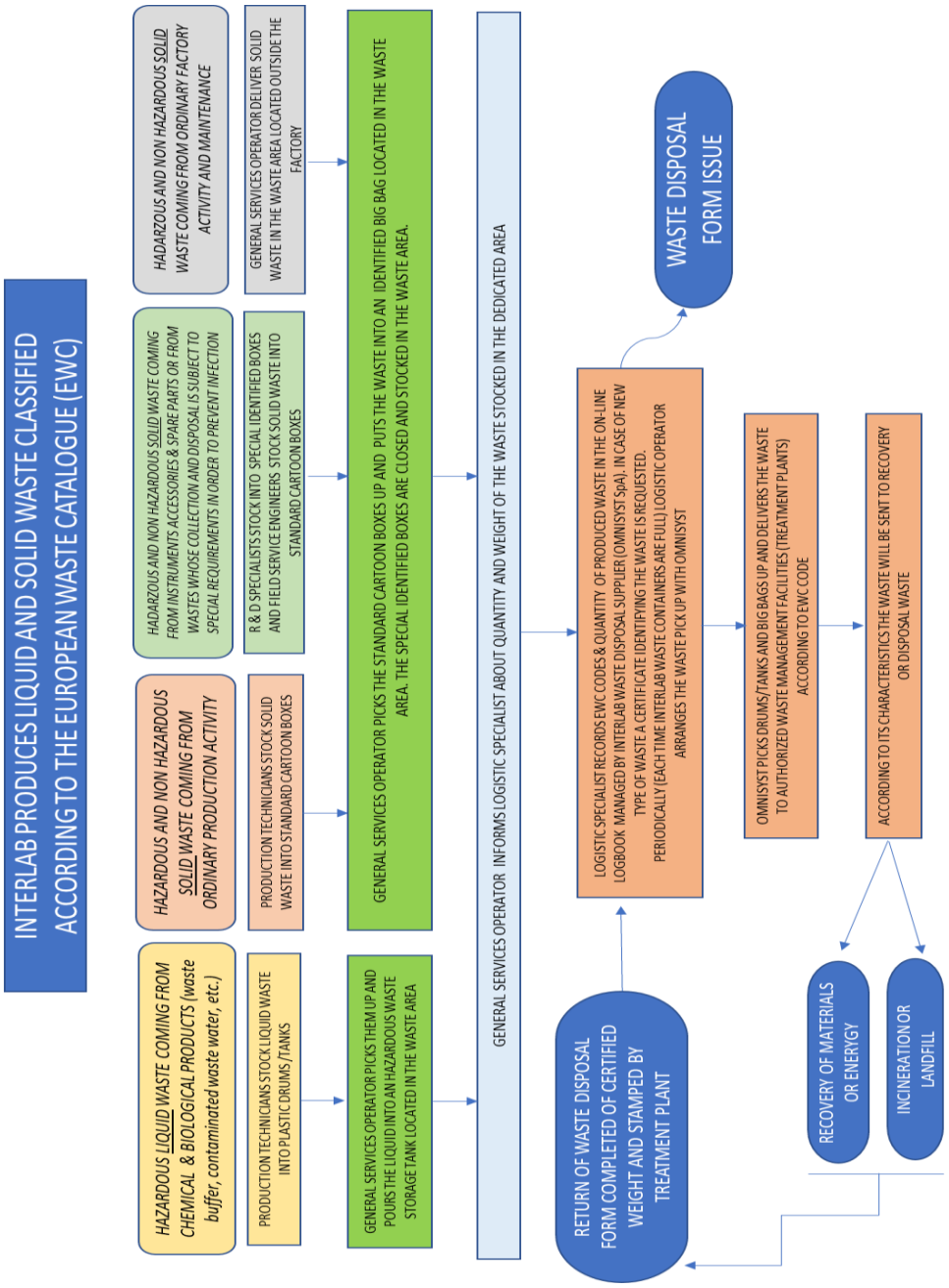

Figure 11: Waste disposal procedure in the site of Rome

The production site of Paladru (ES-3, Use-1) operates quality management system which complies with the requirements of the ISO 14001:2015 & 9001:2015 international standards and OHSAS 18001. The site is constituted of one facility (Fig.12). Solid OPnEO-containing wastes are GBR scraps, empty containers and single-used equipment including PPE. GBR scraps are to date sold to a Dutch company (Earthtrading) and then revaluated. Other solid wastes are disposed of by certified company *via* incineration (CHIMIREC). Liquid OPnEO-containing wastes are process effluents collected in 1000-L plastic tanks “Transicuve” (dead-volumes of solutions and washing waters of equipment) stored on retention outside (Fig 13). Liquid and solid wastes containing OPnEO are considered as dangerous wastes, collected in appropriate containers, hermetically closed, properly identified as Special industrial wastes (DIS) with the appropriate pictograms and then disposed of by certified company *via* incineration

(CHIMIREC). Each document, procedure and certificate (Waste transports and treatments) is available for local authorities. The waste disposal procedure is given in annex 2.

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Figure 12: Plan of the site of Paladru

Figure 13: Stored area for liquid wastes

c. In each site covered by the present AfA, training of workers, operational procedures for both manufacturing and collect/disposal of wastes, safety rules and displays in the work rooms are implemented. Every worker is aware that the use and the production of OPnEO-containing solutions is hazardous for environment. Thus, procedures are implemented in each site to avoid the intentional release of the substance in the collective sewage network (the potential main source of OPnEO contamination of the environment). In case of accidental spills of OPnEO-containing solutions (pure or in mixtures) in the storage area, waste storage area or in the production area, Intervention kits containing absorbent products (Figure 14 & 15) are used and soiled materials placed in a disposable container for incineration. More generally, Safety instructions describe general emergency plans in case of fire, electric & equipment incidents, chemicals or biological solutions incidents. Personal protective equipment and operational procedures are described for each incident sources identified.

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Référence : CS/ORGSEB/05
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TAPIS OBTURATEURS ETANCHES

EVITONS LES POLLUTIONS ACCIDENTELLES

Caractéristiques :

- Permettent l'étanchéisation des regards d'évacuation des eaux, présents au sol.
- Résistent à l'eau, à l'huile et aux produits chimiques.
- La matière extrêmement épaisse et flexible s'adapte de manière idéale à tous les sols.

Précautions à prendre :

- Stocker les tapis dans un conditionnement étanche, à l'abri de la lumière, dans un endroit sec et frais : ils sont sensibles aux UV, à l'humidité, à une température trop élevée (≥ 50°C).
- Après utilisation, nettoyage à grande eau au dessus d'un siphon relié à la cuve de rétention.

IL EST IMPERATIF DE RESPECTER CETTE CONSIGNE DE SECURITE.

Figure 14: Absorbent products present in intervention kits

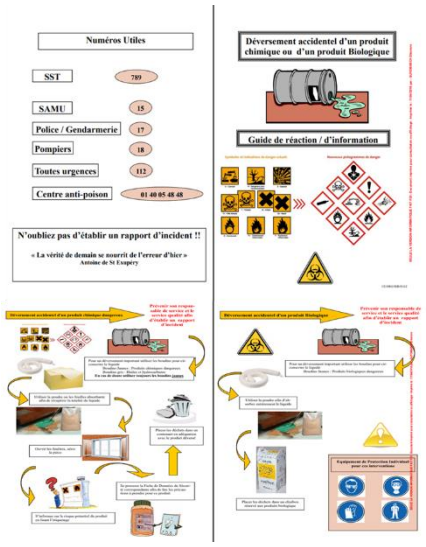

Figure 15: Example of recommendations present in the intervention kits

2.2. Question 2

2.2.1. Committees' question

> *In the declaration that RMM are implemented, the applicant states that "RMM that are necessary to control exposure to 4-tert-OPnEO are being implemented" (CSR pg 14). Could you please confirm that the RMMs described in the application are already implemented? If not, could you provide a timeline for its implementation?*

2.2.2. Applicant's answer

Yes, it is a misunderstanding. To date, each site has already implemented the RMM described the present AfA. The term "are being" was used to emphasize the willingness of the applicant to improve the RMM during the review period. Indeed, after the submission of the present AfA, the applicant has implemented has implemented the improvement of RMM notably concerning the waste management procedure of washing water of glassware. On the site of Lisses, the applicant is currently investigating the technical feasibility to derive the washing machine present in the laundry room in order to connect it to the external tanks buried outside the facility and to treat the resulting water by evapo-concentration.

2.3. Question 3

2.3.1. Committees' question

> *Could you explain in what kind of recipients Triton X-100 and X405 are supplied and what is their volume?*

2.3.2. Applicant's answer

In the site of Lisses (ES-1), 10-L plastic bottles of Triton X-100 & 1-L plastic bottles of Triton X-405 are provided by Carlos-Erba and Sigma-Aldrich respectively. Pure solutions are stored in a dedicated storage room in retention. A maximum of 200-L of Triton X-100 & X-405 are stored in the room at a given time. Triton X-100 is provided approximately one time every two years.

In the site of Rome (ES-2), 1-L plastic bottles of Triton X-100 are provided by SEBIA (Lisses) and stored on retention in a dedicated storage room. A maximum of 10-L of Triton X-100 are stored in the room at a given time. Triton X-100 is provided approximately 1 time every 2 years.

In the site of Paladru (ES-3), 5-L plastic bottles of Triton X-100 (5%) are provided by SEBIA (Lisses) and stored in a dedicated storage area. A maximum of 5-L of Triton X-100 (5%) is stored in the room at a given time. Triton X-100 is provided approximately 2 times a year.

2.4. Question 4

2.4.1. Committees' question

> *In ECS-1 (Lisses site), process step 3 - 'weighing', the glassware is rinsed in water and the rinse water disposed of down the drain - the applicant considers such emissions to be negligible. It is unclear however why this is allowed, when in process step 4 – 'mixture/formulation' - effluent from rinsing of the equipment is collected in a dedicated container. Please explain the technical constraints and the potential costs of the collection of the contaminated rinsing water at ECS-1 step 3.*

2.4.2. Applicant's answer

Under the Step 3 "Weighing" performed on the site of Lisses (ES-1), **potential** release of OPnEO was identified during the preparation of the present AfA. This identified release was linked to the washing of glassware going to laundry room. After the weighing, glassware is rinsed one time and the first washing water is added in the in-process solution (final mixture) to recover the entire weighed quantity of OPnEO needed. Thereafter, glassware is sent in the laundry room for the final washing step. Washing water coming from the laundry room are discarded in the collective sewage network and thus even if the quantity and the concentration of the final mixture in the glassware before the laundry washing are really low (potentially negligible), this could be considered as a potential release source. In order to eliminate the potential release of OPnEO from the glassware washing process, the applicant has begun a process of analysis and reflection in order to collect the second rinse of glassware used under the Weighing Step. The rinsed glassware will be then sent to the laundry washing.

2.5. Question 5

2.5.1. Committees' question

> *In the summary of the Risk management measures, it is stated that for ECS-2 (Rome site) and for ECS-3 (Paladru site) all process effluents and solid wastes are collected in specific tanks and only the washing of durable vessels could generate releases. However, the description of the different steps of the process does not include any description of these releases. Please clarify at which step of the process these releases take place and explain the technical constraints and the potential costs of the collection of the contaminated rinsing water at ECS-2 and ECS -3.*

2.5.2. Applicant's answer

As for ES-1 (Lisses), **potential** releases of OPnEO were identified during the preparation of the present AfA. These identified releases were linked to the washing of glassware going to laundry rooms on both sites. After the weighing, glassware was rinsed one time and the first washing water was discarded in dedicated containers present in the production rooms of the site of Rome (ES-2) and Paladru (ES-3). The glassware was then transferred to the laundry rooms. To date, glassware is rinsed at least two times and washing water are collected in the dedicated containers for incineration. The glassware is finally sent to the final washing process performed in the laundry rooms. Thus, the collection of washing water of glassware coming from the weighing steps can be considered fully achieved in both sites (Rome and Paladru) and no release is expected anymore.

2.6. Question 6

2.6.1. Committees' question

> *Could you please explain what GBR stands for? Is it a kind of plastic*

2.6.2. Applicant's answer

GBR support (Fig.16) is composed of a plastic film recovered with a solution containing Triton X-100 (0.0026% w/w) which is coated and dried to produce a technical support needed to get a good gel casting.

The coating involves applying a varnish or glue on a flexible material (plastic films, aluminum, paper) to provide specific functions related to the end-use of the product: color, printability, sealability, oxygen barrier or with water vapor, food contact, reflection, authentication. The coating of the glue (lamination) or varnish (coating or printing) on the support is carried out by gravure printing with the aid of an engraved cylinder (called a weft), followed by a passage of the film in the drying tunnel to evaporate solvents or water.

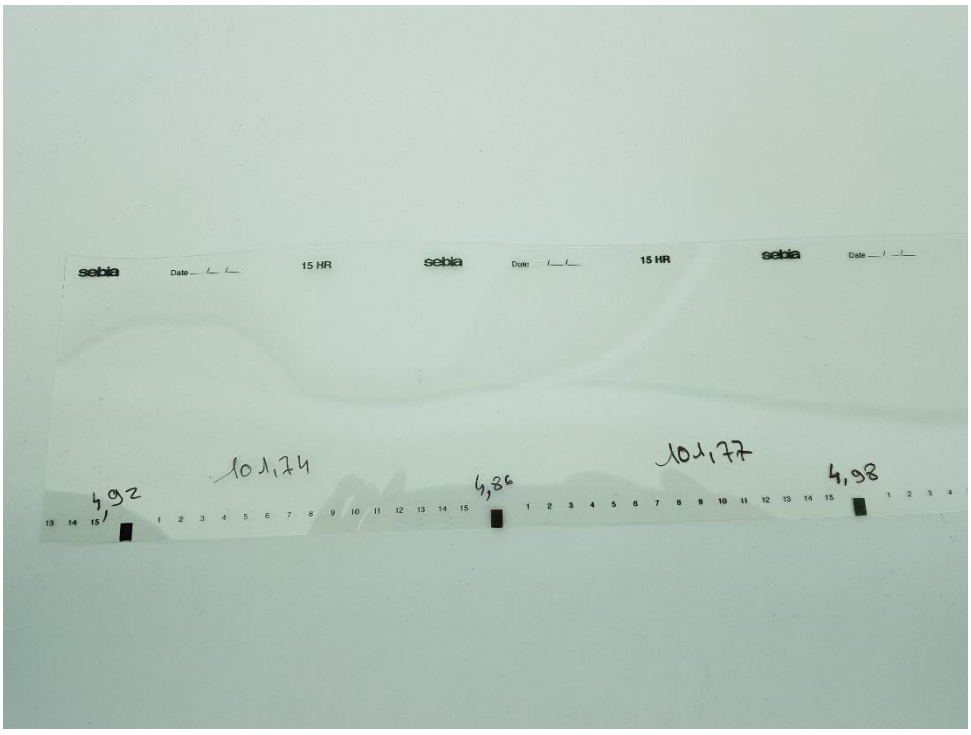

Figure 16: GBR support for gel casting

2.7. Question 7

2.7.1. Committees' question

> *Please specify how the drainage system at the different sites work and how the effluents from the drainage system are treated and monitored.*

2.7.2. Applicant's answer

In the site of Lisses, Activities area involving OPnEO-containing solutions are collected by reels and manholes present in production rooms (Fig.17) and linked to the external containers buried outside. The water is then subsequently treated using an evapo-concentrator (boiling at 40 ° C in low pressure) with a maximum treatment capacity of 1000-L of effluent processed per day. Currently, the average value is 5500-L of effluents processed per month. Distillate is released to the collective sewage network to be treated by the local STP. Concentrates are treated with Osmofilms in the external area (cf. Q1, Fig.2) and then disposed of by a certified provider company *via* incineration. Maintenance operations are registered and tracked *via* the internal informatics tool (Fig.18). It allows the applicant to automatically schedule the annual check of the equipment (with reminder emails). The annual maintenance is performed by the company that supplied the device (Vivlo - sub-contract). Internally, weekly monitoring of the parameters are performed by the applicant .Monitoring measurements are performed on wastewater going to collective sewage network in which the distillate produce by the evapo-concentrator is thrown. In this way, measurements are performed on the wastewater released from the site that will be afterwards treated by the local STP.

Figure 17: Reels and manholes

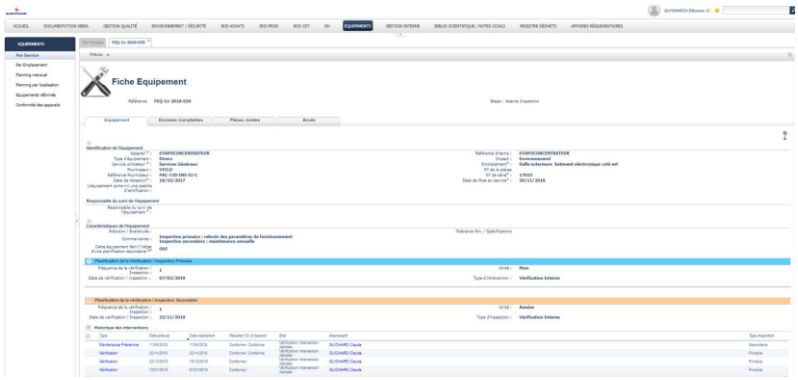

Figure 18: Informatics tool for the maintenance of the evapo-concentrator

In the site of Rome, no drainage systems for industrial wastewater is present. Industrial wastewater potentially containing OPnEO are collected in dedicated containers provided by the certified company in charge of the elimination by incineration. A Similar procedure is implemented in the site of Paladru, industrial wastewater is collected in dedicated containers.

Monitoring measurements are performed on wastewater going to collective sewage network afterwards treated by local STPs.

A yearly monitoring of OPnEO releases will be performed during the review period and in each site covered by the present AfA.

2.8. Question 8

2.8.1. Committees' question

> *Please explain briefly for each site how wastes are treated by external companies (incineration, etc.) and what type of guarantees you require to these companies to ensure that wastes are handled as specified.*

2.8.2. Applicant's answer

In both sites, Wastes are grouped by the hazards potentiality and then disposed of by certified providers (VEOLIA (Lisses), Controlfilm (Rome), and CHIMIREC (Paladru)). Liquid and solid wastes containing OPnEO are collected in appropriate containers stored in specific waste storage areas before the final elimination by certified companies *via* incineration.

The collection of wastes is carried out by specialized companies daily, weekly, monthly or on demand. Solid and liquid wastes packaged and sealed in their appropriate containers are then taken over by the company certified for the appropriate treatment, transported by truck and delivered to treatment centers. Each waste transfer is traceable by regulatory documents (transit advice and waste tracking slips) and recorded in an internal regulatory database during at least 5 years. Each document related to the transfer and treatment of wastes is available for local authorities in charge of compliance checks

2.9. Question 9

2.9.1. Committees' question

> *Please provide a summary table and analysis of all the measured environmental concentrations (the application only contains analytical reports). Additionally a description is needed of how, where and under what conditions the environmental monitoring is conducted:*
>
> *a. Where do the plants discharge waste-water to?*
>
> *b. Where were the samples taken at each site?*
>
> *c. How representative of total 4-tert-OPnEO concentrations are the measured values for OP, OP-1-EO and OP-2-EO?*
>
> *d. What are the background concentrations of OPnEO in the discharge area?*

2.9.2. Applicant's answer

Lisses Site (ES-1):

Monitoring summary of LISSES is given in the table below. Three monitoring measurements were performed during days of production involving OPnEO.

Date	November 2018	December 2018	January 2019	Max measured
	µg/l	µg/l	µg/l	µg/l
4-tert-OP	0.9	0.92	1.4	1.4
OP1EO	0.16	1	1.8	1.8
OP2EO	0.72	0.49	6.1	6.1
Total Alkyphenols	**1.78**	**2.41**	**9.3**	**9.3**

Tonnage_2017/2018 (kg/year)	128.4
Number of emission days (days)	189
Maximum hourly wastewater discharge (L/h)	990
Maximum daily wastewater discharge (L/d)	23760
OP	
Maximum Flux of AlkyTOT (µg/L)	9.3
Maximum daily Flux of AlkyTOT (µg/d)	220968
Maximum daily Flux of AlkyTOT (kg/d)	0.000220968
Maximum yearly Flux of AlkyTOT_189days (kg/year)	0.041762952
Extrapolated Released fraction (%)	0.03

Rome Site (ES-2):

Monitoring summary of Rome is given in the table below. Three monitoring measurements were performed during days of production involving OPnEO.

Date	December 2018	December 2018 (2)	January 2019	Max measured
	µg/l	µg/l	µg/l	µg/l
4-tert-OP	3.7	1.2	3.1	3.7
OP1EO	1.2	1.2	1.2	1.2
OP2EO	0.05	0.05	0.05	0.05
Total Alkyphenols	**4.95**	**2.45**	**4.35**	**4.95**
Tonnage_2017/2018 (kg/year)	11			
Number of emission days (days)	141			
Maximum daily wastewater discharge (L/d)	2000			
OP				
Maximum Flux of AlkyTOT (µg/L)	4.95			
Maximum daily Flux of AlkyTOT (µg/d)	9900			
Maximum daily Flux of AlkyTOT (kg/d)	0.0000099			
Maximum yearly Flux of AlkyTOT_141days (kg/year)	0.0013959			
Extrapolated Released fraction (%)	0.0127			

Paladru Site (ES-3):

Monitoring summary of Paladru is given in the table below. One single monitoring measurement was performed during a days of production involving OPnEO.

Date	October 2018
	µg/l
4-tert-OP	0.2
OP1EO	0.58
OP2EO	0.19
Total Alkyphenols	**0.97**
Tonnage_2017/2018 (kg/year)	0.6
Number of emission days (days)	2
Maximum daily wastewater discharge (L/d)	3200
OP	
Maximum Flux of AlkyTOT (µg/L)	0.97
Maximum daily Flux of AlkyTOT (µg/d)	3104
Maximum daily Flux of AlkyTOT (kg/d)	0.000003104
Maximum yearly Flux of AlkyTOT_2days (kg/year)	0.000006208
Extrapolated Released fraction (%)	0.0010

For the release and PNEC estimates calculated thanks to monitoring data, maximum flux of total alkylphenols measured on sites were considered (Sum of OP, OP1EO, OP2EO and maximal wastewater discharges measured on sites, in red in the tables).

a. In the site of Lisses (ES-1), treated industrial wastewater (distillate of evapo-concentration) is discharged in the collective sewage network and then is treated by the local STP (SIACRE-EXONA). The STP is then releasing the treated water in the Seine River. In the site of Rome (ES-2) and Paladru (ES-3), industrial wastewaters, which are not collected, are discharged in the collective sewage network and then is treated by the local STPs, Rome-Est and Charavines respectively. After the STP treatment, treated waters are released in the Aniene River that is an affluent of the bigger Tiber River in the case of the site of Rome, and in the Fure River that is a sub-tributary of the bigger Isère River in the case of the site of Paladru.

b. In each site, samples for measurements have been performed in the collective sewage network measurement point of each site. On INTERLAB, as they have no access to the point of

reject of their wastewater into the public network, Samples have been performed in the tank of washing water collected during a 24h of production (which are then disposed of *via* incineration). The samples from every site are representative of a daily release, the transport, stabilization and storage of the samples were carried out in an appropriate material (polypropylene or glass bottle of different qualities depending on the analysis parameters). The samples were analysed in a certified laboratory as soon as possible according to the normalized method ISO18857:2.

c. Analysis of alkylphenols ethoxylates (APEO) compounds is still a challenging topic. To date, no normalized method is available in order to measure the concentration of APEO with a number of ethoxylate units above 2. Few analytical standards of APEO are available and thus their quantification is still hard to perform. The only normalized method available and proposed by sub-contracting laboratories is the ISO1887:2 used in the present application. However, the applicant is agree that the actual method may lead to uncertainties about the real concentrations of OPnEO releases on sites. As Triton X-100 and X-405 are complex mixtures with an average of 9 ethoxylate units, measurements have been used as a proxy of OPnEO releases. However, ERC-based release and the subsequent PNEC estimates were kept in the document in order to provide a potential worst-case model that could overcome this analytical uncertainty. Furthermore, the applicant is aware that a new method developed by the EAG Laboratories GmbH (Ulm, Germany) that isolates ethoxylated phenols (OPnEO), such as Triton X-100 or X-405 from wastewater effluents, hydrolyzes the EOs to octylphenol (OP) which is then measured by Gas Chromatography, will be soon available (to date, under reporting). In order to get a better assessment of the release present on both sites, the applicant will switch on this novel and relevant method when public information will be available. This method will allow to reduce the actual uncertainties linked to the normalized ISO method and results will be available for local authorities. To date, no official recommendation or report was made neither by the local nor the European authorities concerning how to measure representatively the APEO in the water compartment. Considering the results of actual measurements, the risk management measures implemented in both sites, and the substitution progress expected by the applicant, releases of OPnEO are expected to be extremely low during the review period.

d. To date, only the concentrations of OP are regularly measured by French and Italian authorities in the water compartment due to its inclusion in the list of priority substances in the Water Framework Directive (WFD). No information about the concentration of ethoxylates compounds are available. However, ethoxylated compounds are assumed to be present ultimately as OP/OP1EO/OP2EO in environment due to the degradation of compounds with high number of ethoxylate units (> 4). Concerning the environment of the site of Lisses, the Seine Normandie Water Agency (Agence de l'Eau Seine Normandie) publishes monitoring data for the control of water quality of the Seine River. In 2018, OP, OP1EO, and OP2EO concentrations measured in water and sediment of the Ablon-sur-Seine station[1] (downstream from SEBIA facilities, around 20 km Lisses) were always below the quantification limit (0.02µg/L for water and 5 µg/kg DW for sediments) suggesting a low contamination of the watercourse by the upstream facilities. Concerning the environment of Paladru, monitoring data obtain on the Tullins Station[2] (downstream from REXOR facilities, around 25-30 km from

[1] *http://qualiteau.eau-seine-normandie.fr/*

[2] *http://www.naiades.eaufrance.fr/*

Paladru) reveal concentration of OP in water and sediment always below the quantification limit (0.03 µg/L for water and 40 µg/kg DW for sediment) suggesting a low contamination of the watercourse by the upstream facilities. Finally concerning the environment of Rome, No measurement data of OP and/or OP1EO and/or OP2EO were found for the Aniene River. However as mentioned in the AOA/SEA document, Alkylphenols (NP & OP and their ethoxylated compounds) have been measured in various location of the Tiber River basin that receive the water of the Aniene River. Relevant concentrations of Alkylphenols have been measured in sediment and fish suggesting that the global management and quality of Tiber Basin ecosystems have to be improved in the next years. However, regarding the special management of OPnEO-containing wastes by Interlab in the facilities of Rome, the impact of the activities performed on-site are expected to be negligible during the review period.

More generally, no or few information of the concentration in sediment, soil or STP discharges are available for France and Italian water bodies. Those information would allow a better characterisation of the whole environmental state at a local scale (near the facilities, upstream and downstream the STPs). Considering the high affinity of OP/OP1EO and OP2EO with the particulate phase and their persistency, it can be assumed that that sediment and soil compartments would be the most sensible environmental compartments regarding the OP & OPnEO contamination. For soil compartment, sludge application is expected to be an important source of OP & OPnEO, as an important part is retain on sludge during the treatment process in STP. Measures on sludge coming from the STP receiving the wastewater of both sites could be highly informative, and performed in order to evaluate the risk of any sludge application by local farmers.

e. The LOQs for the method used by the applicant are 0.05 µg/L for both OP1EO/OP2EO and 0.05µg/L for OP.

2.10. Question 10

2.10.1. Committees' question

> *It is not fully clear how the EUSES modelling has been performed for ECS-1, ECS-2 and ECS-3 particularly regarding the use of two different parameters for several variables. Could you please clarify the meaning of the two columns in the print-outs and how the input parameters relate to the modelling results?*

2.10.2. Applicant's answer

In the print-outs of every EUSES model, the two column correspond to:

- Left column are default values for the different parameters described according to Technical Guidance Documents (TGDs). This is the reference value.

- In the Right column are values inputted by the user, if needed.

Both columns allow to compare the change make by the user compared to the most conservative default value (reference).

On right side of the page, (S), (D) and (O) marks are present. The S, D, O classification of a parameter indicates the status:

- S = Parameter must be present in the input data set for the calculation to be executed (there is no method implemented in the system to estimate this parameter; no default value is set). It is also specified when a default value is changed with the applicant value.

- D = Parameter has a standard default value (most defaults can be changed by the user). Defaults are presented in the sub-module, where they are used in separate tables. Sets of changed default values can be saved.

- O = Parameter is output from another calculation.

In summary, S are parameters changed by the user, O and D are related to the model itself (Fig. 19).

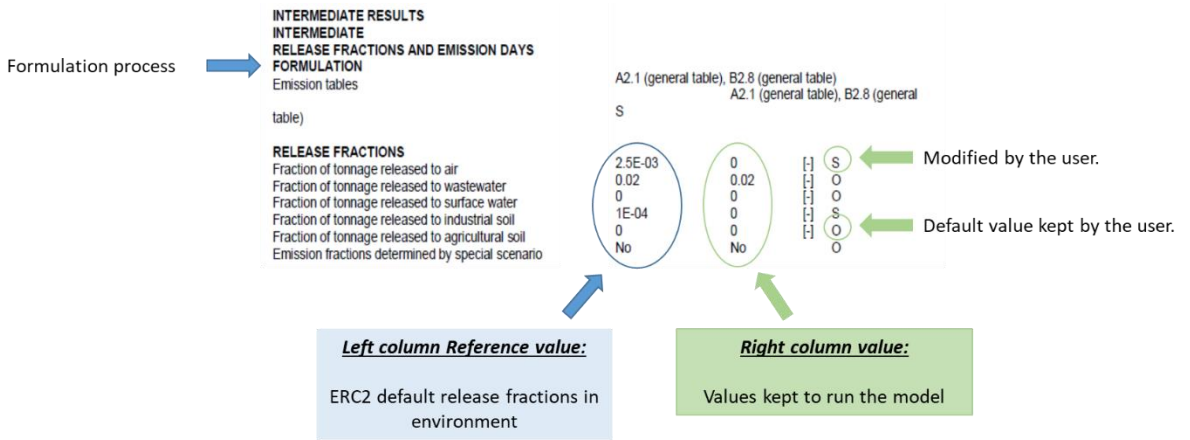

Figure 19: Description of print-outs

2.11. Question 11

2.11.1. Committees' question

> *11. Could you provide an explanation why the PEClocal freshwater is lower than the PEClocal seawater?*

2.11.2. Applicant's answer

PEClocal under EUSES is calculated for a hypothetical aquatic environment after a STP treatment. PEClocal are dependant of dilution factor kept in the model (a higher dilution factor decrease the PEClocal). The dilution factor considers the difference between the water flow rate of STP discharges and the water flow rate of the receiving compartment. Default dilution factor value for PEClocal freshwater is set at 10 (Green, Fig. 20). Default dilution factor value for PEClocal marine is set at 100 (Blue, Fig. 20). In this way, without any modification of default values, the PEClocal seawater is always below the PEClocal Freshwater. Dilution factor may also be modified with available information of STP water discharging rate and the water-flow of the receiving watercourses in order to get a more realistic assessment.

In the context of the present AfA, Each facility is situated in a specific local freshwater environment.

CONFIGURATION	
Type of local STP	With primary settler
	D
Number of inhabitants feeding this STP	1E+04
Effluent discharge rate of this STP	2E+06
Calculate dilution from river flow rate	No
Flow rate of the river	1.8E+04
Dilution factor (rivers)	10
Dilution factor (coastal areas)	100

Figure 20: Default dilution factor values in print-outs

2.12. Question 12

2.12.1. Committees' question

> *Since the exposure assessment is based on the tonnages used in 2017, please explain how the increase in tonnage expected from 2017 to 2022 is taken into account in the risk assessment.*

2.12.2. Applicant's answer

The exposure assessment of each ES (each site) is based on the maximum quantity expected in 2022, which is considered to be the maximum quantity of the substance used during the review period. The value of 2017/2018 have been kept in the tables because they were used to calculate the realistic release fraction thanks to monitoring data.

To calculate the realistic release fraction of the substance in water. Maximum daily flux of Total alkylphenols (OP, OP1EO & OP2EO) monitored on-sites (Kg/day) were converted, thanks to the number of emission days (number of day worked with the substance), in maximal Yearly flux of Total alkylphenols (Kg/year). This quantity compared to the annual tonnage used is considered to be the realistic release fraction. Monitoring have been performed in 2018 mainly and thus quantity used in 2017/2018 was considered for the calculation of the realistic release fraction (see below). To consider the lowest yearly tonnage used is more conservative for the calculation of the realistic release fraction.

$$\frac{Yearly\ release\ measured\ (\frac{kg}{year})}{Yearly\ tonnage\ used\ (\frac{kg}{year})} \times 100$$

For example in the ES-1, 0.042 kg/year of total alkylphenols have been measured during the monitoring campaign performed on the site of Lisses. Compared to the maximal quantity expected in 2022 (220 kg of OPnEO), the resulting realistic release fraction would be of 0.019%. The release fraction used in the model ES-1/monitoring is 0.03%, calculated based on the quantity used the same year of the monitoring (130 kg).

3. Justification for confidentiality

#1 and #2: The plans (inside and outside) of the site of Lisses are considered confidential

#3: The plan of the site of Rome is considered confidential

#4: The picture may contain confidential data concerning the chemicals stored

#5: The plan of the site of Paladru is considered confidential by the applicant