

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

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1. AIM & GOAL

The present document synthesises the Applicant's answers to the Socio-Economic Assessment Committee's request for additional information (communication number: AFA-C-2114479068-38-01/F) received on 2019/07/22.

2. REQUEST FOR ADDITIONAL INFORMATION

SEAC related questions

2.1. Question 1

2.1.1. Committees' question

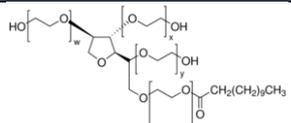
In the analysis of alternatives, the applicant states that a primary selection of several non-ionic surfactants has been made through a bibliographic research and considering their non-ionic nature, cloud point, CMC and the Hydrophilic-Lipophilic Balance. Based on this initial selection, you have shortlisted six candidates that will be subject to further R&D phases. In order to be able to understand which surfactants have been already considered by you as potential alternatives, we would like to ask for the four uses a comprehensive list of those surfactants which have been identified but rejected and the criteria on which the rejection was based.

2.1.2. Applicant's answer

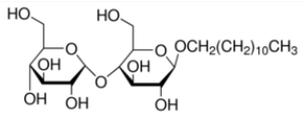
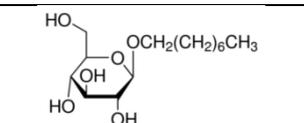
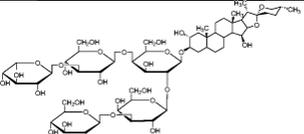
Triton X-100 was Initially selected due to its good results: good proteins positioning, qualitative and quantitative performances reached with good repeatability / reproducibility of results. The only criteria for its selection was its non-ionic property, which is indispensable to avoid side reactions that may misleading results.

Hence, the candidates SDS, CHAPS and CHAPSO were disqualified because of their anionic and zwitterionic nature. Thus, the pre-selected alternatives are listed in the following table.

a. Pre-selected potential alternatives

Substance	Formula	CAS	Reason for rejection
Tween Ex: Tween 20		9005-64-5	None
Brij Ex: Brij 35	$\text{CH}_3(\text{CH}_2)_{10}\text{CH}_2(\text{OCH}_2\text{CH}_2)_n\text{OH}$ n ~ 23	9002-92-0	None

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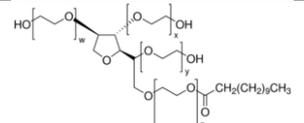
n-Dodecyl β -D-maltoside		69227-93-6	Expensiveness
n-Octylglucoside		29836-26-8	Expensiveness
Digitonine		11024-24-1	Toxicity toward human health

n-Dodecyl β -D-maltoside** and **n-Octylglucoside** were selected due to their non-ionic detergents properties frequently used to isolate proteins. A precise assessment of the economic impacts of these alternatives could not be carried out, but it is expected that the implementation of these alternatives might lead to a substantial increase of operating costs. As a matter of fact, the price of 1 Kg of **n-Dodecyl β -D-maltoside** (or **n-Octylglucoside**) displayed by Sebia's current supplier is 40 times (30 times) higher than the price for 1 Kg of Triton X-100. This increase would necessarily affect the price of the kits. **These substances have thus been rejected.

Digitonin** was selected due to its non-ionic detergents properties frequently used to solubilized membrane proteins without denaturing them but, in the light of the potential risk for the human health with the use of Digitonin, **this alternative is dismissed.

*Consequently, only the **Brij and Tween families** will be shortlisted.*

b. Shortlisted alternatives

Nom	Formula	N° CAS	Reason for rejection
Tween Ex: Tween 20		9005-64-5	None
Brij Ex: Brij 35	$\text{CH}_3(\text{CH}_2)_{10}\text{CH}_2(\text{OCH}_2\text{CH}_2)_n\text{OH}$ n ~ 23	9002-92-0	None

Feasibility tests are currently performed for the Capillary range (Hba1C) with le Tween 20. In case of failure of one of these shortlisted alternatives, the applicant is of course open to investigate on any new other alternative that might occur during the review period.

RAC related questions

2.2. Question 2

2.2.1. Committees' question

In the applicant's response to Question 1, it is mentioned that the default release estimate is 44 kg/year meanwhile in the CSR the value of 4.4kg/year is mentioned. Please clarify.

2.2.2. Applicant's answer

Apologize, it is a typo mistake in the response. The good value is 4.4 kg/year as mentioned in the CSR (ERC2 = 2% of release on 222 t).

2.3. Question 3

2.3.1. Committees' question

In response to Question 5 the applicant stated that at the site of Paladru and Rome to date, glassware is rinsed at least two times and washing water are collected in the dedicated containers for incineration. Please can you inform when the second rinse collection was implemented at these sites? Was it before or after the monitoring measurements of OPnEO were performed?

2.3.2. Applicant's answer

The collection of the second rinse has been implemented on both sites after the submission of the initial document and during the preparation of the first answer session. To date, workers have been informed and apply this easy and complementary procedure.

However, monitoring campaigns were performed during the preparation of the AfA, thus before the full collection of the second rinse. Regarding the potential concentration and quantity of the substance expected to be present in the second rinse of equipment, monitoring measurements are not expected to drastically change with the implementation of this new procedure. Furthermore, Monitoring campaigns are programmed yearly on both sites (summary_RMM).

2.4. Question 4

2.4.1. Committees' question

What happens with the sludge of the STPs of the different sites? According to the figure 1 (Question 1) the SPT sludge is used for agricultural purposes. But in the CSR it is mentioned "Sludge application on agricultural soil at the local and regional scale is a default parameter kept in the estimates presented above. However, in the applicant context, no sludge application are expected at least at the local scale". Please clarify

2.4.2. Applicant's answer

Few information regarding sludge application are available for the STPs connected to the three production sites. As no official and relevant data have been found for any STPs, Sludge application was kept in the EUSES models and thus in the different figures proposed. Under EUSES, default values for sludge application are extremely conservative (5 tons/ha/year for 10 years) are considered and thus are potentially linked to an important overestimation of the PECsoil calculated (sludge application is an important parameter in the PECsoil calculation). However, in the applicant context, similar sludge applications (high rate) are not expected to be performed in the different local environment of the production sites. The production sites of LISSES and ROME are situated in highly urbanised area where agricultural activities are not extended. Thus, in the applicant context, as sludge application are generally managed at a local scale (local farmers use sludge of local STPs) and as local environments are highly urbanized, sludge application are thus expected to be limited compared to them used in the default assessment. Concerning the production site of Paladru, activities involving OPnEO are limited during the year, and thus OPnEO contamination of sludge in this context too.

Nevertheless, the applicant agrees that the initial sentence "However, in the applicant context, no sludge application is expected at least at the local scale" was confusing and should be replaced by "However, in the applicant context, sludge application is expected to be limited compared to default assumption kept in the model"

2.5. Question 5

2.5.1. Committees' question

Please can you give information about what treatment is given to the digester sludge from the site?

2.5.2. Applicant's answer

The applicant is not sure about the meaning of "digester sludge from the site". The only material that could be compared to sludge would be the concentrates coming from the evapo-concentrator present in the production site of LISSES. These sludges

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are collected in Osmofilms (plastic bags) and stored on retention in the external area outside the site. Sludges are dehydrated by evaporation in the Osmofilms (during 1 month on summer / 2 month on winter), and then collected by the certified company in charge of the dispose of via incineration.

2.6. Question 6

2.6.1. Committees' question

In your answers to our previous questions, it not clear where the measurements at the Rome site were taken. On one hand it is mentioned that "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)" (Q9) and on the other hand it is mentioned that "Monitoring measurements are performed on wastewater going to collective sewage network afterwards treated by local STPs." (Q7). Please clarify.

2.6.2. Applicant's answer

For INTERLAB, samples obtained and presented in the AfA have been taken in the tank of the collected washing waters of a whole production day. However, the applicant is actually investigating a way to get the samples at the point of reject in the public sewage network. The next monitoring campaigns (November 2019) will be performed with samples taken in the public sewage network going to STP.

Thus, the sentence "Monitoring measurements are performed on wastewater going to collective sewage network afterwards treated by local STPs." will be respected on the site of INTERLAB during the review period and has been kept in the AfA. This condition is already respected on the production sites of LISSES and PALADRU.

2.7. Question 7

2.7.1. Committees' question

Will the measurement of release of NPE (Use 4) be continued during the review period like for the release of OPE?

2.7.2. Applicant's answer

Yes, monitoring campaigns for NPE are programmed as for OPE during all the review period.