

## BARROSO Joao (JRC-ISPRA)

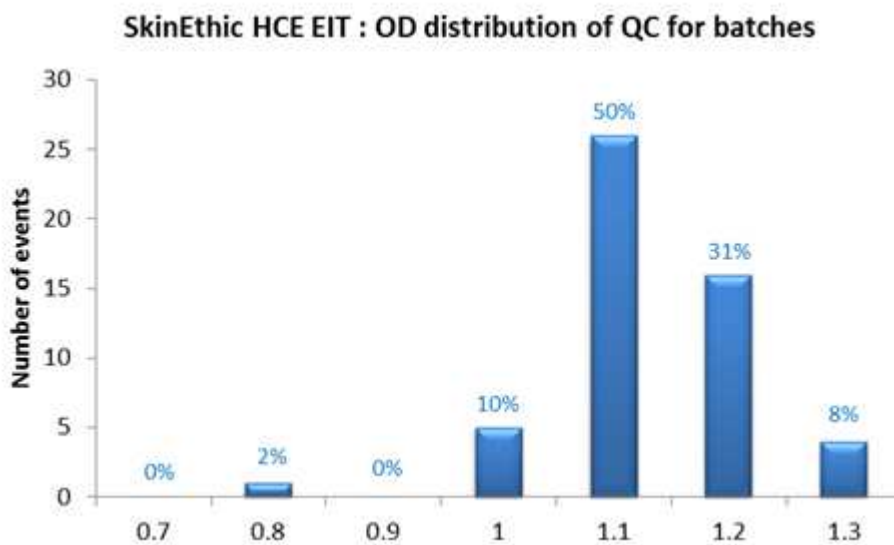
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**From:** ALEPEE Nathalie <NALEPEE@rd.loreal.com>  
**Sent:** 25 May 2016 12:24  
**To:** BARROSO Joao (JRC-ISPRA)  
**Subject:** RE: ESAC peer-review of SkinEthic HCE

Dear Joao,

As proposed in my previous mail, a retrospective analysis about the % repartition of the OD QC values was performed.

The testing on SkinEthic EIT test method was performed on 52 batches (including the multicenter studies). The repartition of the OD QC is represented in the Figure below:



No tissues batch with an OD QC of 0.7 was used for the testing.

Therefore, tissues from a batch released with an OD QC of 0.8 was used for the testing and gave an OD NC > 1.9.

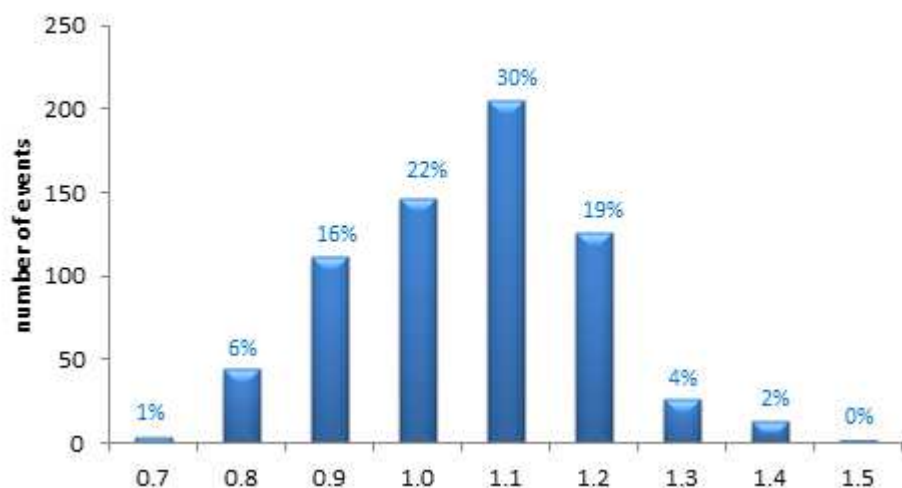
In other hand, the highest OD NC value was obtained with a tissue batch with an OD QC of 1.1.

So no strict relationship of these 2 measurements.

For comparison here is the distribution of the OD QC on 679 batches released between 2001 and 2016 (unpublished confidential data).

The OD QC of 0.7 (1%) is almost anecdotic: No SkinEthic HCE EIT study was performed on this tissue batch released.

**OD distribution for QC (2001-2016)**



Hope this might help. Please feel free to share this information with the ESAC peer review panel if needed.

Best regards,

Nathalie

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**De :** ALEPEE Nathalie

**Envoyé :** vendredi 13 mai 2016 15:38

**À :** 'Joao.BARROSO@ec.europa.eu'

**Objet :** RE: ESAC peer-review of SkinEthic HCE

Dear Joao,

During the conference call hold on May 11 with the peer review panel, one question was remained on the OD values.

Please find enclosed an Excel Table summarizing all the OD data values obtained during the experimental phases (training, transfer and validation phases for both solid/liquid protocols) in regards to the OD values of the tissue batch.

As notice in this document, the OD values of the QC Tissue release batches ranged from 1.0 to 1.3 (far from the acceptance cut off value of 0.7).

As such, I could not provide to the panel any experimental values for which the tissues batch release was close to the acceptance criteria of 0.7.

To attempt to provide additional elements for this question, the tissue manufacturer will check if any data are available in house (with no guaranties as they are not running on a routine base the SkinEthic HCE EIT study). Therefore, a retrospective analysis (from 2014, 2 years) about the % repartition of the OD QC values will be performed. This information will give some indication if the lowest value of 0.7 is rarely observed (or not) and be considered as an anecdotal value (low probability).

Knowing that I will be out-off my office next week with no possible connection, I will analyze these data on the week after (from May 23) and share this information with you by then.

Please let me know if any additional information is needed.

Best regards,

Nathalie

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**De :** Joao.BARROSO@ec.europa.eu [<mailto:Joao.BARROSO@ec.europa.eu>]

**Envoyé :** lundi 2 mai 2016 12:42

**À :** ALEPEE Nathalie

**Objet :** RE: ESAC peer-review of SkinEthic HCE

Dear Nathalie,

Thank you for your prompt reply. Since you are currently available for any time slot on the 11<sup>th</sup> of May, I suggest you block the 15:00 to 16:00 time slot in your agenda as primary choice. I will probably not be able to confirm until the actual day of the meeting (11<sup>th</sup> of May) if the call will be required or not because it will depend on the collective views of the Working Group and if they identify a need to get clarifications from you (the test method developer/submitter). If they do not request for any clarifications, then the call will not be necessary. I hope this is okay for you.

Best regards,  
João

**João BARROSO, Ph.D.**

Systems Toxicology Unit

EU Reference Laboratory for Alternatives to Animal Testing (EURL ECVAM)



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**From:** ALEPEE Nathalie [<mailto:NALEPEE@rd.loreal.com>]

**Sent:** Friday, April 29, 2016 7:11 PM

**To:** BARROSO Joao (JRC-ISPRA)

**Subject:** RE: ESAC peer-review of SkinEthic HCE

Dear Joao,

Great news !

I will be available on the 11th of May between 11:00 and 13:00 and between 15:00 and 16:00 to join the WG meeting by teleconference.

Please feel free to send me the conference call details (number and code access) at your convenience.

The presentation on the validation study of SkinEthic HCE was sent in a separate email via a File transfer system.

Please just let me know if there is any additional information that I can provide here.

Best regards,

Nathalie

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**De :** [Joao.BARROSO@ec.europa.eu](mailto:Joao.BARROSO@ec.europa.eu) [<mailto:Joao.BARROSO@ec.europa.eu>]

**Envoyé :** jeudi 28 avril 2016 14:10

**À :** ALEPEE Nathalie

**Objet :** ESAC peer-review of SkinEthic HCE

**Importance :** Haute

Dear Nathalie,

I would like to inform you that an ESAC Working Group has been established to peer-review the SkinEthic™ HCE test method and that they are currently reviewing all documents from your submission. A face-to-face WG meeting will occur at the JRC-Ispra on 11-13 May to discuss potential issues encountered by the members of the WG and to draft the WG report and the draft ESAC opinion. These draft documents will then be discussed and endorsed by ESAC at the next plenary meeting on 9-10 June.

On the basis of the above, I would like to ask you if you could be available on the 11th of May between 11:00 and 13:00 and/or between 15:00 and 16:00 to join the WG meeting by teleconference (in case of need) to provide clarifications to any questions WG members may have.

Many thanks,  
João

**João BARROSO, Ph.D.**

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