Working Group Meeting on Silicone

Revision of EU Ecolabel criteria for the product group:

Absorbent Hygiene Products (AHP)

24th November 2021

Online Meeting (Webex)

Minutes of the Meeting

Contents

Agenda

1. *Tour de table* (all)
2. Update on timeline (JRC)
3. Criterion 6.3 – silicone release manufacture (introduction by JRC + open discussion)
4. Criteria for reusable menstrual cups (introduction by JRC + open discussion)
5. Closure and next steps

List of participant organizations

EC- DG JRC
EC- DG ENV
Evonik
ITASA
Mondi Group
Wacker Chemie AG

Note to readers

The meeting was run in a web meeting format using the WEBEX platform. The meeting was carried out in an interactive way: JRC would present each point in the agenda and participants would take the floor to express orally their opinion on the open discussion.

Introduction

Introductory points

The JRC briefly provided an overview of the aim of the meeting and requested a tour de table where each participant introduced him/herself.

JRC gave an update on the project timeline: the prolongation of the current criteria until December 2023 was highlighted. The presentation was structured in two parts:

- *Part I: Criterion 6.3.h – Silicone*
- *Part II: Possible criteria areas for Reusable Menstrual Cups*

Part I: Criterion 6.3.h – Silicone

JRC followed on with the Part I: Criterion 6.3.h – Silicone. The sections of AHPs where silicone is located within AHPs and the silicone function were discussed first by JRC and after by stakeholders.

Stakeholder discussion:

A stakeholder mentioned the silicone is only present in the releaser liner and its function is to act as a repellent of the adhesive in the release liners.

Another stakeholder pointed out that basically the silicone is used to cover the release liner as a protection from the adhesive.

Another stakeholder explained the silicone helps to have a control in the release.

Another stakeholder confirms that the silicone protect the adhesive and enables the release of the AHPs before their use.

JRC acknowledged the comments. Then JRC presented the text of the criterion 6.3.h- Silicone, which had not been modified respect the First Ad-Hoc Working Group Meeting (last October). The criteria presented is set below:

(i) Solvent-based silicone coatings must not be used.

(ii) Octamethyl cyclotetrasiloxane D4 (CAS 556-67-2), decamethyl cyclopentasiloxane D5 (CAS 541-02-6) and Dodecamethylcyclohexasiloxane D6 (CAS 540-97-6) shall not be present in the silicone mixture in concentrations above 800 ppm (0,08 % by weight).

With respect to point (i) it is proposed to ban the use of solvent-based silicone coatings.

Stakeholder discussion:

A stakeholder clarified that the primary ingredient is not silica but silicone.

With respect to point (ii), JRC explained that there was a confusion over the wording and the definition of silicone mixture. It was clarified that the limit of 100 ppm of D4/D5 relates to the release liner. On the other hand, to align with other ecolabels such as Nordic Swan or Blue Angel, the limit for cyclosiloxanes in the silicone mixture would be 800 ppm. Stakeholders were asked about the influence of coating techniques on the cyclosiloxanes levels and the value chain.

Stakeholder discussion:

A stakeholder confirmed that the supply chain shown by JRC was correct while he also explained the limit in the release liner is usually below the limit of detection so the cyclosiloxanes would be tested in the silicone mixture.

Another stakeholder clarified that the coating technique does not provide differences in the values of cyclosiloxanes but the chemistry would.

Another stakeholder also acknowledged the supply chain, however explained it is important to understand what you are looking for and the wording used. The silicone mixture would have very different values from the formulation on the release after curing treatments are applied. It is very important to see if wording refers to the point of view of the chemicals used or the final product.

JRC proposed: to add the reference to 'silicone mixture'; to increase the limit of D4 and D5 to 800 ppm; to add D6 to the restriction.

A stakeholder asked if the limit was to each or all the Di (i=4,5,6).

JRC clarified the limit is 800 ppm for each, thus 800 ppm for D4, 800 for D5 and 800 for D6.

Another stakeholder pointed out there was room for interpretation so please clarify further in the new criterion proposal.

JRC presented a comparison of the EU Ecolabel criterion, Nordic Swan and Blue Angel. An introductory sentence will be add in order to align with other ecolabels.

A stakeholder explained 'treatment' would not be correct but 'coating' instead so please be careful with the wording, for instance the wording in Blue Angel is more accurate

JRC asked about how to refer to cyclosiloxanes D4, D5, D6 if as 'impurities' (Nordic Swan) or 'chemicals not intentionally added' (Blue Angel).

A stakeholder explained that the cyclosiloxanes D4, D5, D6 are not intentionally added but are also impurities that they try to remove (or strip) so actually both referrals are correct.

JRC requested clarification about if D4, D5, D6 are added to the silicone mixture.

A stakeholder explained the cyclosiloxanes D4, D5, D6 are not added but during the chemical reaction of the polymer they are produced so they in fact try to distillate them or strip them.

Another stakeholder mentioned to check the Nordic Swan wording which is more complicated.

Another stakeholder pointed out that it can get confusing when it says in Blue Angel 'not intentionally added' as if they are formed but cannot prevent them so better mention only the limit to be respected.

Another stakeholder explained that release liner manufacturers do not add the cyclosiloxanes D4, D5, D6. It is important to see if cyclosiloxanes D4, D5, D6 are analysed in the chemicals or in the final product. In industrial reality, the fine coating concentration set on the release liners cannot be measured in the laboratory. He also advised to be careful with the sentence from Blue Angel on adhesive strip: actually the silicone is coated on the release liner not on the adhesive strip. The values of cyclosiloxanes D4, D5, D6 in the release liner would be much lower than 800 ppm however values under 100 ppm in the final product are difficult to measure with today's technology.

Another stakeholder explained that cyclosiloxanes D4, D5, D6 are formed in the reaction with no intention and 800 ppm for each would help to meet the criteria.

JRC summarised that silicone mixture where cyclosiloxanes D4, D5, D6 limits are 800 ppm for each is a better approach.

A stakeholder asked for clarification of 800 ppm for each cyclosiloxane D4, D5, D6 for a better understanding.

JRC proposed a definition for 'silicone mixture': a liquid mixture composed of two or more silicone raw materials that is used as a coating on the protective paper or the protective film used for the release liner (adhesive or peel-off strips) on some feminine hygiene products (e.g. panty liners and sanitary towels) or on nappy tapes.

A stakeholder mentioned the proposal for the definition is right, however the crosslinking agents wording is confusing (not used in the definition though). Then, he clarified that the silicone mixture contains the raw material or silicone material, the crosslink agents (also silicone based) and a catalyst to help with the formation of the silicone complex. There may be also some other chemicals.

Another stakeholder also acknowledged the definition however believed the 'adhesive or peel-off strips' is not really necessary or in all cases only peel-off strip.

JRC thanked for the comments and explained the 'Assessment and Verification' (A&V) text (which was not added to the background paper sent to stakeholders). JRC asked if in the A&V the method to manufacture the silicone should be mentioned as it is maybe not so relevant but what it is important is the 'declaration from the silicone supplier explaining that requirement (ii) has been fulfilled'.

A stakeholder pointed out that it does not add value to explain the method to manufacture the silicone. Other stakeholder provided the same thoughts.

JRC thanked for the comments and useful session.

Stakeholders also thanked JRC for the opportunity to participate in the definition of the criterion.

Part II: Possible criteria areas for Reusable Menstrual Cups

JRC moved on the second part of the meeting as the scope of this product group has been extended to cover also reusable menstrual cups. Mainly silicone reusable menstrual cups would be discussed. JRC explained the regulatory framework and the two main points to clarify: materials and the manufacturing process of the Reusable Menstrual Cups (RMC).

As per the comments received to the technical documents presented in the first Ad-Hoc Working Group meeting, types of silicones for medical applications and food applications are differentiated. Regarding materials, the intention is not to mention food-grade or medical-grade silicone, but probably criteria on biocompatibility test. About the manufacturing, JRC requested information on the process of injection moulding in order to set relevant criteria

A stakeholder explained that biocompatibility test is the best path to follow. There is no regulation while medical regulation is not very appropriate. About injection moulding, menstrual cups manufacturers would be of more help.

JRC clarified some manufacturers were contacted and hopefully it could be clarified with them.

JRC presented the possible areas for the criteria development on RMC.

CRITERION 1 would be the product description in a similar way as for AHP.

CRITERION 2 would relate to colouring agents, for which there is a positive list however is also to note that other colouring agents are not used in AHP. The question to stakeholders would be type of colouring agents used in the manufacture of silicone for RMCs either coloured or transparent.

A stakeholder acknowledged the possible criterion 1. In regards to criterion 2, she explained that they provide the raw materials in different set ups and in general there are two different materials, A and B, separated and to be mixed by the silicone RMC manufacturer. Then the colour products or pigments are added. Biocompatibility tests (the ISO 10993 series) can be performed to the colouring products separately. Probably adding the pigments is a marketing technique as RMC can get coloured with the use. RMC manufacturers should also share their opinion.

JRC asked for the biocompatibility tests to perform.

A stakeholder answered that first thing is to get the approval from the pigment manufacturer with the declaration that a certain pigment is approved for medical or food contact applications. Then they do their own test. However the process is sometimes subject to case by case application.

JRC suggested contacting pigment suppliers.

Then for the silicone area on a possible CRITERION 3, JRC asked if the formulation of criterion 6.3.h (for AHP) would be of any use here (100 ppm threshold for instance for a RMC) on the presence of solvents or cyclosiloxanes.

A stakeholder explained that silicone elastomers for RMC are viscous polymers (mixture of silicone, inhibitor and catalyst). The cyclosiloxanes will be present as well as impurities which will be evaporated during the curing of the menstrual cups. However, the RMC manufacturer should provide another point of view. In principle 100 ppm seems ok however it depends if a post-curing after the crosslinking is carried out. In general, an adequate post-curing process would eliminate all volatile components.

JRC explained that many manufacturers for RMC were contacted however any of them have provided input so silicone manufacturers were asked to please forward the information in order to get further discussion with them.

The next area to study is a possible CRITERION 4 on the emissions of VOCs for which JRC does not have any data to set a requirement (probably to be asked to RMC manufacturers) and the possible CRITERION 5 on emissions of CO_2 from the production of RMCs or maybe on energy requirements.

A stakeholder explained that VOCs are formed during the crosslinking stage while the posterior curing stage at high temperature would eliminate them. In general, the highest the temperature, the highest consumption of energy while a highest elimination of VOCs is reached.

JRC mentioned that in criterion 5, the energy source could play an important role (e.g. renewable sources).

JRC explained the area for a possible CRITERION 6 on excluded and restricted substances (horizontal and similar to criterion 6 for AHP). For CMRs and SVHCs in AHP (and reusable menstrual cups) a value lower than 0.01% w/w is being investigated. It was pointed out that for substances derogation, article 6(7) of the EU Ecolabel Regulation must be followed. This criterion covers also the exclusion of nanosilver particles. The question raised was on regards to the feasibility of following this for RMCs as well.

A stakeholder pointed not being aware of the use of nanosilver particles. In general, this criterion could be applied.

JRC mentioned an area for a possible CRITERION 7 on material efficiency in the manufacturing (as for criterion 7 for AHP) and asked if the quantity of waste generated during the manufacture and packaging of the products could be not larger than 5%.

However this question could not be answered by stakeholders.

JRC also presented an area for a CRITERION 8 on packaging in a similar way to criterion 8 for AHP and explained that minimum 80% recycled content and 95% recyclable content were under discussion.

These requirements could not be answered by stakeholders either.

JRC asked for an area related to a possible CRITERION 9 on the guidance on the packaging and product disposal.

A stakeholder pointed out that in general silicone cannot be recycled as the elastomers are difficult to recycle after use.

JRC presented an area related to CRITERION 10 or fitness for use and quality of the product which would assess not only the testing methods as for instance tests for biocompatibility according to ISO 10993 but leakage and comfort tests.

Stakeholders were not aware of these type of tests.

Then, the last area presented by JRC was in relation to Corporate Social Responsibility with regards to Labour Aspects which could be similar to criterion 11 for AHP.

No comments were received.

JRC explained that an additional work to be done would be a PEF study of RMCs for which information on the value chain and data from the manufacturing process are needed. All the information requested would be anonymised while other JRC colleagues would carry out the study (in the same way as the study for baby diapers and feminine care pads was performed

and can be checked in the last Preliminary Report from September 2021). JRC requested if information could be shared with manufacturers.

Next steps

The JRC thanked the participants for their time and contributions and explained next steps:

- *Stakeholders can provide comments on discussions before 10th December 2021.*
- *JRC can be contacted for any issues that may arise.*

Main items for 2022:

- *April/May 2022: 2nd AHWG meeting.*

Stakeholders also thank for the organisation of the silicone working group.

Meeting finalised.

Note to readers

An email was sent to stakeholders one week after the meeting where it was mentioned:

- Presentation was made available via website: https://susproc.jrc.ec.europa.eu/product-bureau//product-groups/415/documents.
- Minutes of the meeting were shared via email. A week was given for possible comments. Then the minutes will be made available via website.