



FOLLOW-UP Asbestos in several make-up products

Risk assessment requested by: Netherlands Food and Consumer Product Safety Authority
Risk assessment performed by: RIVM
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Subject

After the discovery of asbestos fibers in talc-containing cosmetic products from one brand, samples were also taken from (cosmetic) products of other brands. Asbestos has been demonstrated in some products (contouring palette, face crayon, face paint, eye shadow). Several producers have carried out a risk assessment and forwarded these to the NVWA. In earlier requests the NVWA asked RIVM for independent reviews of these assessments (RIVM, 2018a-c).

On request of the NVWA, TNO has performed asbestos fibers counts in seven products.

Question

What are, in view of the results of the quantitative TNO analyses, the risks to consumers related to the exposure to asbestos of using the tested products?

For the risk assessment, the results from the quantitative analyses will be used as starting points for the calculations. For the methodology, reference will be made to a previous RIVM review of talc-containing make-up products for children (RIVM, 2018d).

Conclusion

Presence of asbestos fibers has been shown in several make-up products. Asbestos is a substance which presence in cosmetic products is prohibited (Cosmetics Regulation EC 1223/2009). Asbestos is a carcinogenic substance. Based on the available analytical results, some asbestos exposure is expected for the user.

The extent of the risk resulting from asbestos exposure is determined by the type of asbestos, the concentration of respirable asbestos fibers in the air and the duration of exposure. During use of the make-up product 1 (face powder), and product 2 (the eye palette), estimated air concentration are above the MTR for life-time exposure, a value for the maximum permissible risk. This comparison does not take into account the short duration of exposure, so the risk might be overestimated. In order to provide more insight in the risk taking into account differences in exposure duration, an additional assessment has been made based on cumulative exposure.

Based on this risk assessment, it is determined for both make-up products that for daily use for one year the cumulative lifetime exposure to the MTR air concentration is not exceeded.

Based on the performed risk assessments, we conclude that the risk of asbestos-related diseases for users of the make-up products product 1 (face powder), and product 2 (the eye palette) is likely to be limited. However, it is important to prevent further exposure as much as possible.

Introduction

Asbestos has been shown in several make-up products that contain talc powder. Asbestos is a substance which presence in cosmetic products is prohibited (Cosmetics Regulation EC 1223/2009).

This risk assessment follows the approach of the earlier performed risk assessment for asbestos containing make-up products for children (RIVM, 2018d; in Dutch).

The seven products of interest with the available measured results are presented in Table 1. To facilitate the comparison, the analytical results of the make-up products for children are included in the table (products 8, 9 and 10).

A first qualitative/semi-quantitative assessment of asbestos in the products was performed in accordance with NEN 5896 (Polarization Microscopy (PLM)) and Scanning Electron Microscopy (SEM)). Based on the PLM analyses in combination with SEM identification, it is possible to distinguish asbestos from other fibrous constituents and to determine the type of asbestos. The content as a weight fraction was estimated by comparison with reference materials of known composition. The results from these analyses did not provide information with respect to the number of asbestos fibers per kilogram of product.

A quantitative determination of asbestos fibers in a product is performed with the scanning electron microscopy (SEM) method according to ISO 14966 and NEN-ISO 22662-2. Based on the SEM analyses it is possible to determine the number of respirable fibers per kg product. The TNO report presents the results of the quantitative analyses of 7 products using the SEM method.

Table 1. Overview of tested products 1-7 containing talc with a positive test using PLM (Sanitas reports, 2018a-f), with asbestos concentration in w/w%, as well as in respirable fibers/kg product (TNO report, 2018b). Results for make-up products 8, 9 and 10 for children were added for comparison (TNO, 2018a).

| | Product | Type | Analysed samples | Asbestos (w/w% product) | Asbestos (10⁸ respirable fibers/kg product) highest concentration found (range) |
|----|----------------|----------------------------|---------------------------------------------------------------|--------------------------------|---------------------------------------------------------------------------------------------------|
| 01 | Product 1 | Face powder | All 6 colours | 0.1-2 | 20 (0.64-20) |
| 02 | Product 2 | Eye palette | Colours 3, 6, 7, 9, 10, 11, 12 (in total 12 colours) | ? | 6.9 (<0.1-6.9) |
| 03 | Product 3 | Eye shadow | colours 8 and 15 (total 15 colours) | 0.1-2 | < 1.2 |
| 04 | Product 4 | Talc powder | 1 type | 0.1-2 | < 1.2 |
| 05 | Product 5 | Face crayon and face paint | colour green (in total 6 colours) | 0.1-2 | < 0.9 |
| 06 | Product 6 | Face crayon and face paint | Colour white from package with 3 colours (in total 4 colours) | 0.1-2 | < 0.9 |
| 07 | Product 7 | Face crayon and face paint | Colour orange (in total 4 colours) | 0.1-2 | < 0.6 |
| | Product 8 | Contour powder | 8 colours | 0.1-2 | 540 (25-540) |
| | Product 9 | Compact powder | 1 colour | 2-5 | 1200 (410-1200) |
| | Product 10 | Make-up product | ? | 0.1-2 | 580 (220-580) |

Toxicology

Asbestos can cause mesothelioma (thoracic and abdominal cancer), lung cancer and cancer in the larynx and ovaries. In addition, a positive association has been observed

with cancer in the throat, stomach and colon. The International Agency for Research on Cancer (IARC) further states that all forms of asbestos are proven human carcinogens (Group 1) (IARC, 2012).

The hazardous properties of asbestos are caused by asbestos fibers being small enough to penetrate deep into the lungs. Because asbestos fibers are very inert, the fibers remain intact and accumulate in the tissue. This can lead to prolonged inflammatory response, fibrosis and eventually tumor formation. Between the exposure to asbestos and the occurrence of cancer are usually decades (Gezondheidsraad, 2010).

The assessment of the health risks for users of the products only includes the exposure by inhalation. The extent of the risk is mainly determined by the type of asbestos, the concentration of asbestos fibers in the air and the duration of exposure. The estimate of the concentration of respirable asbestos fibers in the air is a crucial part of the assessment of health risks.

In the Netherlands two limit values for asbestos are possible for this risk assessment: the MTR (maximum allowable risk) and the VR (negligible risk). MTR and VR are policy-level risk levels for exposure of the general population. In 2010, the Health Council made recommendations for new MTR and VR values of asbestos (Gezondheidsraad, 2010). MTR and VR values are applicable for life-time exposure for the general population, and are expressed in fibers per m³ measured by TEM (Transmission Electron Microscopy). The values are based on the endpoints of mesothelioma and lung cancer together (Gezondheidsraad, 2010). At the level of the MTR value, the additional cancer risk is 1 case per 10,000 life-time exposed individuals.

For the asbestos fibers in the make-up products, identified as tremolite, the MTR or VR for 100% amphibole fibers are applicable. The newly proposed MTR value for amphibole fibers has been used in this risk assessment (300 fibers/m³ (MTR), 3 fibers/m³ (VR)).

Exposure

The exposure to asbestos fibers from make-up products is estimated based on the outcome of the quantitative analysis by TNO and worst-case assumptions of the use and asbestos fiber concentrations in the products.

The detection limits (lower determination limits) are determined on the basis of the Poisson statistics in accordance with NEN-ISO 14966. If no fibers are found during the analysis, 3 fibers should be used as the lower limit. Not the entire product has been examined; the analysis is only performed on a random sample of the total product. That the average content is sometimes lower than the detection limit for another product has to do with the amount of material tested and the number of analyzed image fields. In addition, only a few (1 - 2) fibers have been found in a number of products and the limit of determination is based on 3 fibers. An exposure estimation is performed for the two products for which the fiber count was above the detection limit; product 1 (face powder) and product 2 (eye palette). The respective fiber amounts are $20 \cdot 10^5$ and $6.9 \cdot 10^5$ fibers/g.

The methodology used for exposure calculation is the same as in a previous exposure estimation for asbestos containing make-up products for children (RIVM, 2018).

Table 2. Exposure scenario and exposure assessment, parameters, values and outcome.

| Parameter | Unit | Face powder | Eye palette | Reference |
|------------------------------------------------|-----------------------|-------------|---------------|--------------------------------|
| Amount of fibers | fibers/g product | $20 * 10^5$ | $6.9 * 10^5$ | TNO, 2018b |
| Amount of product used | g | 0.2 | 0.02 | RIVM, 2018d; RIVM, 2018b |
| Air volume | m ³ | 1 | 1 | Assumption made in RIVM, 2018d |
| Resulting air concentration during product use | fibers/m ³ | $4 * 10^5$ | $0.14 * 10^5$ | |

Based on the assumption that the total amount of fibers of the used make-up product disperses uniformly over 1 m³ of air results in the following estimates of air concentration during product use of:

$4.0 * 10^5$ fibers/m³ (face powder) and,
 $0.14 * 10^5$ fibers/ m³ (eye palette).

These are worst-case exposure estimates, as ventilation is not included and it is assumed that all asbestos fibers present in the used amount of product, will disperse over 1 m³ of air. This is probably not the case, but no data are available to determine the fraction of the asbestos fibers in the product that will disperse in air. It may be anticipated that the actual concentration of asbestos fibers in the air will be lower and that therefore the actual risk will be lower than estimated. The extent of the overestimation of the risk cannot be established.

Risk assessment

To determine the risk, the exposure to asbestos fibers is compared to the MTR value for amphibole asbestos fibers of 300 fibers/m³. For life-time exposure to the MTR, the risk of cancer due to asbestos exposure is 1 in 10,000 (see above).

The risk of inhalation of the asbestos fibers from make-up products has been assessed in two ways. In the first method, the estimated air concentration during product use is directly compared with the MTR. In the second method, the cumulative exposure (= total exposure as a result of product use) to asbestos fibers from repeated use of the make-up is compared to the cumulative exposure that corresponds to the life-time exposure to the MTR.

The first method follows the more classic risk assessment methodology. However, this method is less suitable for the risk assessment of make-up products containing the impurity asbestos because a short-term exposure, such as when using make-up, is compared to a health value (MTR) calculated for life-time exposure.

For that reason, the second method is also used to obtain more insight in the risk, when correcting for the exposure duration.

Direct comparison with the MTR

Based on the above assumptions, the estimated air concentration during use are $4.0 * 10^5$ fibers/m³ (face powder) and $0.14 * 10^5$ fibers/m³ (eye palette). These estimated air concentrations are approximately 1300 and 46 times, respectively, above the MTR of 300 fibers/m³ for life-time exposure, as recommended by the Health Council (Gezondheidsraad, 2010).

It should be noted that there are assumptions and uncertainties in this risk estimation, such as:

- The concentration of fibers used was the highest in the measured range.
- There are realistic worst-case assumptions made for the amount of make-up.

- It is assumed that all the asbestos fibers in the amount of product used will be dispersed over 1 m³.

- Ventilation of the room and thus spreading into a larger space is not included.

These assumptions result in a conservative exposure estimate.

Additionally, the MTR is an asbestos concentration associated with an acceptable risk level assuming life-time exposure, 7 days a week 24 hours a day. In the case of these make-up products, the exposure is daily, short-term (5 minutes) and for about one year (assumption of the availability of the contaminated product on the market). Since the short duration of exposure has not been taken into account here, the direct comparison between exposure concentration during product use and MTR will overestimate the actual risk.

Comparison of cumulative exposure

For more insight in the potential risk associated with the use of asbestos-containing make-up products, a second calculation has been performed. This method calculates the fiber concentration in air that should be reached during the use of the make-up products to get at the total life-time MTR exposure over the time that the exposure occurred.

The starting point is that users of these make-up products have used these during 365 days, once a day for 5 minutes. So, the total exposure time is 1825 min (5 * 365).

Life-time exposure in the context of MTR would be for: 100 years for: 100 years, 365 days, 24 hours, 60 minutes = 52560000 minutes.

When exposed to the MTR, there is a cumulative exposure of 300 fibers/m³ for 52560000 minutes. To achieve the same exposure in 1825 minutes, the concentration in the air must be equal to: $300 * 52560000 / 1825 = 8.6 * 10^6$ fibers/m³.

The air concentrations of both products, based on analysis and worst-case assumptions, remain below the cumulative MTR (with 22 and 620 times respectively). The risk is limited, on the basis of this calculation.

It should be noted that this comparison with the cumulative exposure over the entire life span is not a common application of these limit values.

Risk assessment summarized

The extent of the risk resulting from asbestos exposure is determined by the type of asbestos, the concentration of asbestos fibers in the air and the duration of exposure.

The above reviews confirm that tremolite fibers should not be used in make-up. During the use of the tested products, the estimated air concentration is undesirably high.

The estimated air concentrations are above the MTR for lifetime exposure, a value for the maximum permissible risk. This comparison does not take into account the short duration of exposure, which could result in a gross overestimation of the actual risk.

In order to obtain more insight in the risk when taking into account the difference between the actual exposure time and the exposure time for which the MTR has been derived, a risk assessment has been made based on cumulative exposure. In addition, the cumulative exposure (= total exposure throughout the period) to asbestos fibers when using the make-up is compared to the cumulative exposure that corresponds to life-time exposure to the MTR.

Assuming daily use for one year (5 min per day), the cumulative lifetime exposure to the MTR air concentration is not exceeded.

The exposure estimation used in this risk assessment is likely to overestimate the actual exposure. This is due to uncertainties with regard to the amount of used product, the fraction of the fibers from the product coming into the air, not including spreading in a larger room, and the duration of use of these specific products.

A key factor in the exposure estimate is the determination of the asbestos content of the make-up products. For each product, only one sample is taken to estimate the number of

asbestos fibers per gram of product. Consequently, sample homogeneity cannot be taken into account, and an assessment based on only one sample may equally well over-estimate as under-estimate the actual risk.

Given the uncertainties mentioned in the risk assessment, the risk cannot exactly be quantified. Our approach indicates that during product use exposure higher than the MTR cannot be excluded. On the other hand, the approach where cumulative exposure to asbestos fibers from cosmetic products is compared to the life-time cumulated exposure to asbestos fibers at air concentrations equivalent of the MTR would indicate that the cumulative MTR is not exceeded.

It should be noted that there is no safe exposure to asbestos: the risk to develop an asbestos-related condition depends on the level of exposure.

Based on the performed risk assessment we conclude that the risk of asbestos-related diseases for consumers using the make-up product 1 (face powder), and product 2 (the eye palette) is likely to be limited. However, it is important to prevent further exposure as much as possible.

Summary

Presence of asbestos fibers has been shown in several make-up products. Asbestos is a substance which presence in cosmetic products is prohibited (Cosmetics Regulation EC 1223/2009). Asbestos is a carcinogenic substance. Based on the available analytical results, some asbestos exposure is expected for the user.

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References

Gezondheidsraad (2010). Asbest: Risico's van milieu- en beroepsmatige blootstelling. Publicatienr. 2010/10. ISBN 978-90-5549-800-0. Beschikbaar via: <http://www.gezondheidsraad.nl/sites/default/files/201010ASBEST.pdf>.

IARC (2012). Asbestos (Chrysotile, amosite, crocidolite, tremolite, actinolite and anthophyllite). Available at: <http://monographs.iarc.fr/ENG/Monographs/vol100C/mono100C-11.pdf>.

RIVM (2018a). Front Office Food and Products Safety: Risk assessment asbestos in face crayon and face paint. April 17, 2018.

RIVM (2018b). Front Office Food and Products Safety: Risk assessment asbestos in contouring palette. April 17, 2018.

RIVM (2018c). Front Office Food and Products Safety: Risk assessment asbestos in eye shadow. June, 2018. In draft.

RIVM (2018d). Advies Asbest in make-up. (in Dutch) <http://www.rivm.nl/dsresource?objectid=d5202c54-42bf-4d49-8134-9f45bc23aafb&type=pdf&disposition=inline>

Sanitas (2018a). Rapportage identificatie asbest. Document nr. 1848362/17/1.1

Sanitas (2018b). Rapportage identificatie asbest SEM. Document nr. 1848532/1/1.1

Sanitas (2018c). Rapportage identificatie asbest. Document nr. 1848362/47/1.1.

Sanitas (2018d). Rapportage identificatie asbest SEM. Document nr. 1848566/1/1.1.

Sanitas (2018e). Rapportage identificatie asbest. Document nr. 1848362/63/1.1

Sanitas (2018f). Rapportage identificatie asbest SEM. Document nr. 1848864/1/1.1

TNO (2018a). Kwantitatieve bepaling van de hoeveelheid respirabele asbestvezels in 4 monsters make-up met behulp van SEM/RMA. TNO-rapport TR 2018/0063. 16 mei 2018.

TNO (2018b). Kwantitatieve bepaling van de hoeveelheid respirabele asbestvezels in zeven talkhoudende producten met behulp van SEM/RMA. TNO-rapport TR 2018/0067. 21 juni 2018.