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The Process for Qualification and Approval of a new or alternate source of Cosmetic Talc

Introduction.

Cosmetic grades of talc to be used in Johnson & Johnson products must meet standards for both mineralogical and microbial purity. The Regional specification must describe the properties for non-sterile talc and will typically include parameters for appearance, color, odor, fineness, acid solubles heavy metals, bulk density and related properties. Recognizing that there may be minor differences in the properties of talc from various sources around the world, it is the responsibility of the Regional R&D/QA to define the raw material finished product specification, based on the particular source of talc.

There are however certain parameters for which a minimum standard must be maintained on a global basis. These consist of:

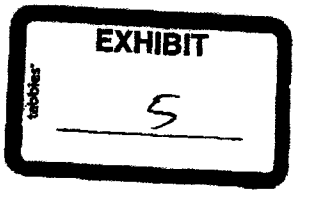
1. Freedom from asbestos and amphibole minerals
2. A minimum amount of free silica or quartz
3. A minimum standard for microbial purity of non-sterile talc.

Although an ongoing sampling of talc for mineral and microbial purity standards is useful, it is recognized that the results of a regular sampling must be supported by additional evidence as described in the Checklist process.

A Checklist is described below that relates specifically to the processes required to ensure that the above key parameters, 1, 2, and 3 are maintained in the Qualification of a new talc source.

Documentation.

It is vital that all documentation relating to the Qualification process is maintained and archived indefinitely. There should be a records and documentation system in place to ensure that the Company can demonstrate that the highest standards are always maintained.



Checklist of Activities to ensure Qualification of Talc.

1. Microbial Standards

As part of the initial qualification process, the mine or pit should be audited by a local Johnson & Johnson QA.
The principles are similar to an audit of a factory or manufacturing site. However it is recognized that an open cast mine or deep pit is very different from a factory and consequently there will be a very different approach.

The objective of an audit to ensure adequate **microbial standards** requires that there is an absence or minimal chance of contamination from pathogenic organisms, eg *Salmonella*, *E. Coli* or pathogenic *Pseudomonas species*.

The following should be considered as part of the Checklist:

1. Location of latrines/toilets for employees. Must be well clear of mining operations.
2. Adequate hand washing facilities for employees, especially those involved in handling talc.
3. Outflow from toilets/latrines must not contaminate the areas of mining or handling of talc.
4. Where process water is used on site there should be adequate drainage to avoid contamination of the talc operations from Pseudomonas and other water-borne microbes often present in water effluent.
5. Where process water is used on site as part of the washing process or as part of any flotation process for separation of talc, there should be a documented procedure to ensure that the talc is not contaminated by microbes. Typically the water used in a flotation process may be sanitized by chlorine or similar agents.
6. There must be no opportunity for fecal/urine contamination from either wild or domestic animals. Wild dogs, cats, deer and rodents must be controlled.
7. All employees handling talc should be given a basic training in good hygiene practices. There should be a written and documented training procedure for employee hygiene practices. This needs to be no more than a simple process describing hand washing and similar hygiene practices.

Mineralogical Standards.

The objective is to ensure freedom from asbestos and amphibole minerals and to ensure that the amount of free quartz/silica is kept to within a specified limit. Typically a "best practice" limit for silica is < 0.05%, while some talc sources will contain much less than this level.

The following should be considered as part of the Checklist:

1. There should be an audit of the mine geology, conducted either by an independent geologist or by a geologist employed by the mine owners. The purpose of the geology report is to identify the presence of non-talc minerals in the mine workings. The report should include the results from samplings taken at various locations in the mine/pit. Particular attention should be made to the presence of free silica or asbestos minerals.
2. Where non-talc minerals are present, there must be a well-documented and validated procedure for the separation of such minerals.
3. The procedure for separation of non-talc minerals should include a training program for those employees who undertake this task. The training program should be documented and there should be evidence that named employees have been adequately trained in the separation of non-talc minerals.
4. Talc sampling:

(a) As part of the initial qualification program, samples of talc, eg preferably a minimum of 3 taken over at least one-month mining should be forwarded to the laboratory of RJ Lee at 350, Hochberg Road, Monroeville, Pennsylvania, 15146, USA. RJ Lee should be requested to conduct a mineralogical examination to ensure freedom from asbestos and to report on the % of free silica as quartz.
(b) Similarly as part of an ongoing qualification process, a sample of talc as delivered to Johnson & Johnson should be sent to the laboratory of RJ Lee for mineralogical examination on a 3-month basis for the first 18 months following approval of a new talc source.
(c) Thereafter mineralogical sampling by Johnson & Johnson should be conducted with a minimum of one sample on an annual basis. It is the responsibility of Regional QA to initiate the mineralogical examination.

The results of the above from (a), (b) and (c) should be considered in association with the results of a mineralogical audit/ examination as conducted on a regular batch basis by the mine operator or agent. All results of mineralogical assay should be archived indefinitely.

Flow Chart for Talc Ore Segregation.

The Flow Chart for Talc ore segregation at the Ghewaria Mines, of Golcha Talc, India is given below. The Flow Chart is typical and is similar to the processes at other mines and the audit processes will be applicable to other talc sources.

Stage 1: Mined Ore from Mines
↓
Stage 2: Transportation to ROM-sorting Yard
↓
Stage 3: Manual Sorting of talc lumps in different grades based on
↓
Stage 4: Visual comparison, classification of talc ore into grades A, B, C, D, E & F
↓
Stage 5: Washing of talc ore lumps.

Action checklist for Qualification procedure:

Stage 2: The audit should confirm that there all reasonable care is taken to avoid microbial contamination, especially contamination from fecal microbes.

Stage 3: The audit should confirm that all reasonable care is taken that manual handling does not result in microbial contamination, especially from fecal microbes.

Stage 4:
(a). There should be a written description of exactly what constitutes a classification of A, B, C, D, E and F grades of talc.
(b). There should be a documented Test Method that describes this activity.
(c). There should be documented evidence that the employees who are involved in classification of talc ore into the above grades have been adequately trained to conduct this operation.

Stage 5: The audit should confirm that all reasonable care is made to avoid microbial contamination from harmful microbes that may be carried via the water.

Flow Chart of Manufacturing Process

The Flow Chart for the manufacturing process at the Golcha Talc Mines, India is given below. The Flow Chart is typical and is similar to the processes at other mines and the audit processes will be applicable to other talc sources.

Manufacturing Process

Stage 1: Sorted & washed talc lumps from mines
↓
Stage 2: Size reduction in Crusher
↓
Stage 3: Crushed chips transported to grinding plant
↓
Stage 4: Testing of chips for quality
↓
Stage 5: Feed to roller mill
↓
Stage 6: Product to cyclone and collected in hopper
↓
Stage 7: Testing of product for its quality
↓
Stage 8: Packing in paper bags via automatic packing machine
↓
Stage 9: Material ready for shipment.

Action checklist for Qualification Procedure

All stages: Care should be taken at all stages to ensure that the talc is not contaminated by harmful microbes.

Stage 4: The audit should confirm that there is a documented Test Method to determine Quality of talc chips. There should be a definition of what constitutes an acceptable quality and what constitutes a failed quality.
There should be documented evidence that employees involved in testing are adequately trained.

Stage 7:
(a). The audit should confirm that there is a documented Test Method to determine Quality of talc finished product. There should be a definition of what constitutes an acceptable quality and what constitutes a failed quality.
(b). There should be documented evidence that employees involved in testing talc finished product are adequately trained.

Archiving and Record Maintenance

All documentation from the above Qualification process should be archived together in a Manual, either as paper copy or electronically.

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