



Material Safety Data Sheet Dewaxed Shellac Flake

In compliance with Regulation (EC)1907/2006 (REACH)

1) Identification of substance/preparation and of the company undertaking

1.1) Product Identifier

Material	Dewaxed Shellac Flake
Synonyms	Shellac
Reach Registration No	Pre-Registration No. Shellac: 05-2114511069-55-0000 According to our investigations shellacs meet the definition of polymers under (EC) 1907/2006 (REACH) and are exempted from registration.
CAS No	9000-16-2
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1.2) Use of the substance/preparation:

Tablet and other pharmaceutical coatings (controlled drug release, microcapsules, glazes)

1.2.1) Additional Identified uses:

- SU3: Industrial uses: Uses of substances as such or in preparations* at industrial sites
- SU4: Manufacture of food products
- SU5: Manufacture of textiles, leather, fur
- SU6a: Manufacture of wood and wood products
- SU6b: Manufacture of pulp, paper and paper products
- SU10: Formulation (mixing) of preparations and/or re-packaging
- SU12: Manufacture of plastics products, including compounding and conversion
- SU18: Manufacture of furniture
- SU19: Building and construction work
- SU20: Health services
- SU21: Consumer uses: (Private house=general public=consumers)
- SU22: Professional uses: Public domain (administration, education, entertainment, services, craftsmen)
- SU24: Scientific research and development

1.2.2) Uses advised against:

At present we have no details for the uses advised against. By availability this data will be included in the material safety data sheet.

2) Hazard Identification**2.1) Hazards descriptions:**

Not to be classified according to EC preparations Directive 1999/45/EC

GHS 1272/2008:

Hazard classes/Hazard categories	Hazard statements	Classification procedure
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67/548/EWG and 1999/45/EG

Hazard classes/Hazard categories	Risk phrases
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The full text of the risk phrases are mentioned in section 16.

2.2) Information pertaining to special dangers for human and environment:

According to the current knowledge of the manufacturer and if properly handled the product will not cause hazards for human health and environment. Handle in accordance with good industrial safety practice.

Labelling (Regulation (EC) No 1272/2008):**Hazard pictograms:**

Signal words: None

Hazard statements: None

Precautionary statements: None

3) Composition/Information of Ingredients**3.1) Preparation/mixture related information****Chemical Characterization:**

Description: Natural resin of animal origin, decolorised and dewaxed

CAS No.: 9000-59-3

EC No: 232-549-9

3.2) Hazard ingredients:

Constituent: None

Classification: None

3.3) Components with prescriptive EC-Limits:

Constituent: None

Classification: None

4) First Aid Measures

General: Change all contaminated clothing.

After Inhalation: Remove person to fresh air. In case of complaints consult a physician.

After skin contact: Wash off with plenty of water and soap.

After eye contact: Rinse with plenty of water. Should irritation continue call in ophthalmologist.

After swallowing: Rinse mouth with water and drink plenty of water. Never give anything to an unconscious person. Induce vomiting as long as affected person is conscious. Immediately get medical help.

INFORMATION TO PHYSICIAN

Symptoms: No information available

Hazards: No information available

Treatments: Symptomatic treatment. No information available

5) Firefighting Measures

Extinguishing media: Water spray jet, extinguishing foam, extinguishing powder, carbon dioxide (CO₂).

Unsuitable extinguishing media: Direct water jet.

Special exposure hazards arising from the substance or preparation itself, combustion products resulting gases: Incomplete combustion may generate hazardous gases (carbon monoxide).

Special protective equipment for fire –fighting: Stay in danger area only with self-contained breathing apparatus. Prevent skin contact by keeping a safe distance or be wearing suitable clothing.

Further information: Prevent fire extinguishing water from contaminating surface water or ground water system. Fire residues and contaminated fire extinguishing water must be disposed in accordance with local regulations. Collect contaminated fire extinguishing water separately. This must not be discharged into drains.

6) Accidental Release Measures

Personnel precautions: Wear protective clothing. Avoid contact with skin and eyes. Do not ingest or inhale.

Environmental precautions: Do not empty into drains, surface water or ground water. Contact local authorities if product pollutes soil or vegetation.

Methods for cleaning up: Usual procedures for collecting powdery or granular materials. Clean up affected area. All alkaline cleaning agents are suitable.

Additional information: Protective equipment see section 8.

7) Handling and Storage

Safe Handling:

Keep container tightly closed.

Wear adequate protective clothing (see section 8).

Avoid contact with eyes and skin.

Hygiene measures:

Keep away from food, beverages and feed.

When using do not eat, drink or smoke.
Wash hands before breaks and after work.
Remove contaminated clothing. Work clothes separately.
Avoid contact with skin, eyes and clothing.

Storage:

Technical measures and storage conditions:

Stable under recommended storage conditions. Shelf life: Minimum 2 years (at <20°C and 50% rel. humidity)

Requirements for storage rooms and vessels:

Store dry and in the original tightly sealed containers.
Store locked up.
Storage class (VCI-Concept): 11 combustible solids

Storage compatibility:

Do not store together with: food, drink and animal feeding stuffs.

8) EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure limit values

Components with occupational exposure limits:

Component:

Occupational exposure limits:

8.2) EXPOSURE CONTROLS/PERSONAL PROTECTION

Additional information about design of technical facilities:

Provide sufficient ventilation at processing equipment, e.g by local extractor fan. If these measures are not sufficient for keeping particle and/or solvent concentration below limiting values (MAK) suitable protective breathing equipment has to be used. Technical measures and appropriate working operations should be given priority over the use of personal protective equipment.

Personal protective equipment:

General protective measures:

Keep away from foodstuffs and drinks. Do not eat, drink or smoke during work.
Wash hands before breaks and at the end of the work.
Avoid contact with skin, eyes and clothing. Do not inhale dust. Remove contaminated clothing immediately.

Respiratory protection:

Not required

Hand protection:

The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374.

Glove material: Butyl Rubber

Break through time: ≥ 8 h
Glove thickness: 0.5mm

Glove material: Poly Vinyl Chloride
Break through time: ≥ 8 h
Glove thickness: 0.5mm

Glove material: Fluor Rubber
Break through time: ≥ 8 h
Glove thickness: 0.4mm

Glove material: Nitril rubber
Break through time: ≥ 8 h
Glove thickness: 0.35mm

Eye Protection:

Safety glasses with protective shields (EN 166, BGR 192, ZH 1/703)

Hygiene measures:

Apply preventative skin protection.

Immediately change contaminated clothing.

Wash hands and face after working with substance.

Do not inhale substance.

Handle in accordance with good industrial hygiene and safety practice.

9) Physical/Chemical Properties

9.1) Appearance

Physical state: Solid

Colour: Yellowish

Odour: Nearly odourless

9.2) Important health, safety and environmental information

Safety relevant basic data:

pH Value (20°C): n/a

Melting range (°C): 65-77

Boiling point (°C): n/a

Flash point (°C): >300

Vapour pressure (°C): n/a

Density (g/cm³): n/a

Bulk density at 20°C (kg/m³): 400

Water solubility: Insoluble

Partition coefficient: n/a

n-octano l/wasser (log Pow): n/a

Viscosity, dynamic (mPa s): n/a

Explosive risk: Product does not present an explosion hazard

Lower explosion limit: n/a

Upper explosion limit: n/a

10) Stability/Reactivity

Thermal decomposition/conditions to be avoided: Stable under recommended storage and handling conditions.

Chemicals to be avoided: Not known

Hazardous decomposition products: None if stored and handled according to specifications.

11) Toxicological Information

11.1) Toxicokinetics, metabolism and distribution

Component:

Shellac CAS-Nr: 9000-59-3

Acute inhalation toxicity:

Method:

Dose:

Exposition time:

Typ of value:

Species:

No references to toxic effects by shellac studies with rabbits.

Acute oral toxicity:

Method:

Dose: >5000mg/kg

Exposition time:

Typ of value: LD 50

Species: Rat

Acute dermal toxicity:

Database:

Dose: >10000mg/kg

Typ of value: LD 50

Species: Rabbit

Toxicological information:

No data available for the product itself. The description of possible hazardous effects is based on experience from practice and/or toxicological properties of single components. Acute toxicity potential, skin irritation potential, mucous membrane irritation potential, mutagenic potential and skin sensitising potential of the substance/preparation has been evaluated by the manufacturer based on available data for the main components. However, in some cases, data for particular main components are incomplete. According to the experience of the manufacturer no other hazards have to be expected than those already mentioned on the label.

11.2) Irritation

Skin:

Not known

Eyes:

Contact with eyes may cause irritation.

Sensitation:

After inhalation: Not known

After skin contact: Not known

Subacute to chronically toxicity:

Not known.

CMR effects (Carcinogenity, mutagenicity and toxicity for reproduction)

Shellac CAS Nr: 9000-59-3

Carcinogenicity: Not known

in-vitro Mutagenicity: Not known

in-vivo Mutagenicity: Not known

Genotoxicity: Not known Toxicity for reproduction: Not known

Additional information:

If used properly no hazards for human health are known or have to be expected. Shellac is an approved food additive (E904) and has been toxicologically tested accordingly for legislation.

12) Ecological Information

12.1) Ecotoxicity:

Aquatic toxicity- Acute algae toxicity:

Effect dose: LC50

Exposure time: 24h

Species: Algae

Method:

Evaluation: 400mg/l

Aquatic toxicity- Acute daphnia toxicity:

Effect dose: EC50

Exposure time: 24h

Species: Daphnia

Method:

Evaluation: 500mg/l

12.2) Mobility:

No information available.

12.3) Persistence and degradability:

Abiotic Degradation: No information available.

Physical and photo chemical elimination: No information available.

Biodegration:

Degration rate %: 34

Time (d): 28

Method: OECD-301D

Evaluation: moderately degraded

Remark: Shellac

Bioaccumulative potential:

No information available.

Bioconcentration factor (BCF):

No information available.

Longterm-Ecotoxicity:

No information available.

12.4) Results of PBT assessment:

No information available.

12.5) Other adverse effects:

No information available.

12.6) Further ecological information:

AOX-Value: The product does not contain organically bound halogens (AOX)

VOX-content: <1%

Do not flush into surface water or sanitary sewer system.

13) Disposal Consideration

13.1) Appropriate disposal/Product:

If recycling is not possible, dispose in accordance with local waste regulations. Classification with waste codes according to EC waste catalogue (EWC) has to be realised by branch and process. The waste producer is responsible for correct encoding and designation of his waste. The waste producer has to get assigned a waste code according to EWC by individual arrangement with the local authorities and a waste disposal specialist. The waste has to be delivered to an authorised waste disposal company.

13.2) Waste codes/waste designations according to EWC/AVV:

080112 – Waste paint and varnish other than those mentioned in 080111 – waste paint and varnish containing organic solvents or other dangerous substances.

13.3) Packaging:

Completely emptied packaging may be reused after proper cleaning or supplied to local recycling facilities. Recommended cleaning agent. Soapy water or alkaline cleaning agent. Unclean packaging or packaging's which cannot be cleaned. Dispose like the product itself.

14) Transport Information

14.1) Land transport (ADR/RID/GGVSE): not applicable

14.2) Sea transport (IMDG-Code/GGVSee): not applicable

14.3) Air transport (ICAO-IATA/DGR): not applicable

14.4) Further information: Not subject to international transport regulations for dangerous goods.

15) Regulatory Information

15.1) EU regulations Chemical Safety Assessment:

Labelling (Regulation (EC) No. 1272/2008

Hazard components for labelling: No hazard components.

Hazard pictograms:

Signal words:

Hazard statements:

Precautionary statements:

Hazard components for labelling:

Other EU regulations:

Information of the Directive 1999/13/EC on the limitation of emissions volatile organic compounds (VOC-RL): Volatile organic compounds (VOC): <1%

16) Other Information

Training advice: Provide adequate information, instruction and training for operators. This product should be stored, handled and used in accordance with good hygiene practices and in conformity with any legal regulations. This information contained herein is based on the present state of knowledge and is intended to describe our product from the point of view of safety requirements. It should therefore not be construed as guaranteeing specific properties.

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

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