Red Yeast Rice Extract (Monascus purpureus) – Monacolin K 0.4–3%

Monascus purpureus · Monascaceae

DOCUMENT	PRODUCT CODE	DOCUMENT NO.	REVISION
Safety Data Sheet	AP0763	SDS-AP0763	1.0 · 24 October 2026

FORMAT
UN GHS Rev. 10 · US OSHA HCS (2024) · EU REACH Annex II

1 Identification of the substance/mixture and of the company

Product identifier	Red Yeast Rice Extract (Monascus purpureus) – Monacolin K 0.4–3%
Product code	AP0763
Other names	Red yeast rice
Recommended use	Raw material for the manufacture of nutraceuticals & supplements products. Industrial and professional use only.
Uses advised against	Not for direct use by consumers as supplied. Not for medicinal use unless the user holds the required authorisation.
Supplier	CHOLAD PRIVATE LIMITED (trading as Extrakte) C 22/4, 2nd & 3rd Floor, Sector-57, Noida-201301, Uttar Pradesh, India
Telephone / e-mail	+91 817 8117 600 · choladco@gmail.com · extrakte.com
Emergency telephone	24-hour emergency (CHOLAD PRIVATE LIMITED): +91 81781 17600. Medical advice: National Poisons Information Centre, AIIMS New Delhi (24 h): 1800 116 117 (toll-free in India) / +91 11 2658 9391; outside India, your national poison centre.

2 Hazard identification

2.1 Classification (UN GHS / EU CLP Regulation (EC) No 1272/2008 / US OSHA HCS 29 CFR 1910.1200, as amended 2024)

H361	Reproductive toxicity, Category 2 — Suspected of damaging fertility or the unborn child.

2.2 Label elements

GHS08

Signal word
WARNING

Hazard statements

H361	Suspected of damaging fertility or the unborn child.

Precautionary statements

P203	Obtain, read and follow all safety instructions before use.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P318	IF exposed or concerned, get medical advice.
P405	Store locked up.

P501	Dispose of contents/container in accordance with local, regional, national and international regulations.

2.3 Other hazards

- **US OSHA (combustible dust):** signal word WARNING — May form combustible dust concentrations in air. Fine powder may cause mechanical irritation of the eyes and respiratory tract.
- PBT / vPvB assessment: not carried out (botanical substance of unknown or variable composition).

Basis of classification. Calculated for the product at its highest grade using the GHS mixture rules (additivity formula and generic concentration limits), from the classification of: Monacolin K (PubChem CID 53232; up to 3%): H361 — ECHA C&L Inventory aggregated notifications (codes reported by ≥50% of notifiers).

3 Composition / information on ingredients

Botanical fungal & fermented extract of *Monascus purpureus* (a substance of unknown or variable composition, UVCB), standardised as stated on the label (0.4%, 3%). For classification it is treated as a mixture of its constituents.

COMPONENT	CAS	CONCENTRATION	CLASSIFICATION (PURE COMPONENT)
Extract of *Monascus purpureus* (other)	—	to 100%	Not classified as a whole
Monacolin K	75330-75-5	≤ 3%	H361

Concentrations refer to the highest grade offered. Full text of H-statements in section 16.

4 First-aid measures

Inhalation	Move to fresh air and keep at rest. Get medical advice if symptoms such as coughing or breathing difficulty persist.
Skin contact	Remove contaminated clothing immediately. Wash with plenty of soap and water. Get medical advice if irritation or rash develops.
Eye contact	Rinse cautiously with water for at least 15 minutes, holding eyelids open; remove contact lenses if easy to do. Get medical advice if irritation persists.
Ingestion	Rinse mouth with water. Do not induce vomiting unless directed by medical personnel. Get medical advice if a large amount is swallowed or if you feel unwell.
Most important symptoms	No specific symptoms known; dust may cause mechanical irritation.
Immediate medical attention	Not normally required. Treat symptomatically.

5 Fire-fighting measures

Suitable extinguishing media	Water spray, alcohol-resistant foam, dry chemical powder, carbon dioxide.
Unsuitable extinguishing media	High-volume water jet (may disperse dust and create an explosive dust cloud).
Specific hazards	Fine dust dispersed in air in sufficient concentration may form an explosive mixture with an ignition source. Hazardous combustion products: carbon monoxide, carbon dioxide.
Advice for firefighters	Wear self-contained breathing apparatus and full protective clothing. Cool containers exposed to fire with water spray.

6 Accidental release measures

Personal precautions	Use the personal protective equipment in section 8. Avoid raising dust. Ensure adequate ventilation.

Environmental precautions	Prevent large quantities entering drains or watercourses.
Methods for clean-up	Collect mechanically (sweep gently or use a vacuum cleaner fitted with a HEPA filter); avoid dry sweeping that creates dust. Place in labelled, closed containers for disposal (section 13). Wash the area with water.

7 Handling and storage

Precautions for safe handling

- Avoid contact with skin and eyes and inhalation of dust or mists.
- Use with local exhaust ventilation at points where dust or vapour may be generated.
- Do not eat, drink or smoke in work areas; wash hands after handling.
- Prevent dust accumulation; ground and bond equipment when handling large quantities to avoid electrostatic discharge.
- Handle in a closed system or ventilated enclosure; restrict access to trained personnel.

Conditions for safe storage

- Store in a cool (below 25 °C), dry place, protected from light.
- Hygroscopic: reseal immediately after use and minimise exposure to humid air.
- Keep away from strong oxidising agents.

8 Exposure controls / personal protection

Control parameters

Product	No occupational exposure limits established.
Dust (particulates not otherwise specified)	ACGIH TLV: 10 mg/m³ inhalable, 3 mg/m³ respirable · OSHA PEL: 15 mg/m³ total, 5 mg/m³ respirable

Exposure controls

Engineering controls	Local exhaust ventilation; general ventilation for small quantities.
Eye / face	Safety glasses with side shields (EN 166 / ANSI Z87.1).
Hands	Nitrile rubber gloves, ≥ 0.11 mm (EN ISO 374); change when contaminated. Double gloving recommended.
Body	Laboratory coat or protective work clothing.
Respiratory	P2 / N95 particulate respirator where dust may be generated.
Hygiene	Wash hands before breaks and at the end of work. Keep work clothing separate.

9 Physical and chemical properties

Physical state	Solid (powder)
Colour / appearance	Brown to yellowish-brown fine powder
Odour	Characteristic
Odour threshold	No data available
Melting point / range	Not applicable
Boiling point / range	No data available
Flammability	Combustible solid; may form explosive dust-air mixtures
Lower / upper explosion limit	No data available

Flash point	Not applicable (solid)
Auto-ignition temperature	No data available
Decomposition temperature	No data available
pH	Not determined (aqueous dispersion typically 4–7)
Kinematic viscosity	Not applicable
Solubility	Partially soluble to dispersible in water; soluble in hydro-alcoholic solutions (grade-dependent)
Partition coefficient n-octanol/water	No data available
Vapour pressure	Negligible
Density	Bulk density typically 0.40–0.70 g/mL
Particle characteristics	Typically ≥ 95% < 180 µm (80 mesh)

10 Stability and reactivity

Reactivity	No dangerous reactions known under normal conditions of use.
Chemical stability	Stable under the recommended storage conditions.
Possibility of hazardous reactions	Dust explosion if dispersed in air near an ignition source.
Conditions to avoid	Heat, direct sunlight, moisture, dust formation.
Incompatible materials	Strong oxidising agents.
Hazardous decomposition products	See section 5.

11 Toxicological information

Acute toxicity	Based on available data, the classification criteria are not met.
Skin corrosion / irritation	Based on available data, the classification criteria are not met.
Serious eye damage / irritation	Based on available data, the classification criteria are not met.
Respiratory or skin sensitisation	Based on available data, the classification criteria are not met.
Germ cell mutagenicity	Based on available data, the classification criteria are not met.
Carcinogenicity	Based on available data, the classification criteria are not met.
Reproductive toxicity	Reproductive toxicity, Category 2 (H361)
STOT – single exposure	Based on available data, the classification criteria are not met.
STOT – repeated exposure	Based on available data, the classification criteria are not met.
Aspiration hazard	Based on available data, the classification criteria are not met.

Information on constituents

- Monacolin K ($C_{24}H_{36}O_5$, CAS 75330-75-5, PubChem CID 53232): reported classification H361 — ECHA C&L Inventory aggregated notifications (codes reported by ≥50% of notifiers).
- Contains a pharmacologically active substance that is regulated as a medicine (often prescription-only) in many markets. Supplied only to qualified businesses after a compliance review.

12 Ecological information

Toxicity	No data available. Not classified as hazardous to the aquatic environment.
Persistence and degradability	Botanical material; expected to be biodegradable.
Bioaccumulative potential	No data available.
Mobility in soil	No data available.
PBT / vPvB	Not assessed.
Other adverse effects	Avoid release to the environment in large quantities.

13 Disposal considerations

Product	Dispose of via a licensed waste contractor in accordance with local, regional and national regulations. Treat as hazardous waste.
Packaging	Empty containers completely; recycle or dispose of in the same way as the product.
Sewage disposal	Do not discharge to drains.

14 Transport information

Classification	Not regulated as dangerous goods for transport (ADR/RID, IMDG Code, IATA DGR, US DOT).
Environmental hazard	No
Note	Based on the calculated classification of the product. Bulk shipments of combustible powders should be protected from ignition sources.

15 Regulatory information

- **Pharmaceutical active:** Contains a pharmacologically active substance that is regulated as a medicine (often prescription-only) in many markets. Supplied only to qualified businesses after a compliance review.
- EU REACH: botanical extract (UVCB substance). The EU importer must confirm the registration or exemption status for the import route.
- US TSCA: inventory status not determined; the importer must confirm before import for non-exempt uses (food, supplement, cosmetic and drug uses are outside TSCA).
- Chemical safety assessment: not carried out.

16 Other information

Revision	1.0 — first issue, 24 October 2026
Prepared by	CHOLAD PRIVATE LIMITED (Extrakte) — choladco@gmail.com
Key data sources	PubChem (NIH) GHS classification summaries of the ECHA C&L Inventory and EU CLP Annex VI; supplier product specifications.
Training advice	Handle only after reading this SDS. Users should be trained in the handling of fine powders and chemical raw materials.

Full text of H-statements referred to in sections 2 and 3

H361	Suspected of damaging fertility or the unborn child.

Abbreviations: ACGIH – American Conference of Governmental Industrial Hygienists; ATE – acute toxicity estimate; CID – PubChem compound identifier; CLP – Regulation (EC) No 1272/2008; GHS – Globally Harmonized System; OSHA – US Occupational Safety and Health Administration; PEL – permissible

exposure limit; STOT – specific target organ toxicity; TLV – threshold limit value.

This Safety Data Sheet was prepared by CHOLAD PRIVATE LIMITED (trading as Extrakte) on the basis of the product's composition and published classification data for its marker constituents (PubChem GHS summaries of ECHA C&L Inventory notifications and EU CLP Annex VI harmonised entries). It describes the product as supplied, for professional and industrial users, and does not replace the user's own risk assessment. The information is believed to be correct at the date of issue but is given without warranty. Certificates of Analysis are issued per lot and are available on request.