Bixin 3% — Bixa orellana (annatto)

Bixa orellana · Bixaceae

Prepared in accordance with Regulation (EC) No 1907/2006 (REACH) Annex II as amended by Commission Regulation (EU) 2020/878, and the UN GHS. The 16-section format also meets US OSHA HCS 29 CFR 1910.1200 Appendix D and Canada WHMIS 2015 (Hazardous Products Regulations, SOR/2015-17).

Section 1. Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product name	Bixin 3% — Bixa orellana (annatto)
INCI name(s)	Bixa Orellana Extract
Botanical source	*Bixa orellana*
Product code	WH-B3-BO
Type of product	Substance (natural complex substance / UVCB)

1.2 Relevant identified uses and uses advised against

Identified uses	Raw material for professional / industrial formulation of cosmetics & personal care, food & beverage, nutraceuticals (functional food, herbal tea & infusions, skincare, supplements).
Uses advised against	Uses other than those identified. Not for direct medicinal use. Not for use by the general public without further formulation and labelling.

1.3 Details of the supplier of the safety data sheet

Supplier	**CHOLAD PRIVATE LIMITED** C 22/4, 2nd & 3rd Floor, Sector-57 Noida 201301, Uttar Pradesh, India
Telephone	+91 817 8117 600
E-mail (competent person)	choladco@gmail.com
Website	https://thewholesaler.eu

1.4 Emergency telephone number

+91 817 8117 600 (24 h). In the EU you may also contact your national poison centre (Europe-wide emergency number 112).

Section 2. Hazards identification

2.1 Classification of the substance or mixture (Regulation (EC) No 1272/2008 (CLP) / UN GHS)

- Not classified as hazardous according to the criteria of Regulation (EC) No 1272/2008 (CLP) / UN GHS.

2.2 Label elements

No hazard pictogram, signal word or hazard statement required.

2.3 Other hazards

May form combustible dust concentrations in air (US OSHA: hazard not otherwise classified, HNOC). Does not contain substances assessed as PBT/vPvB or as endocrine disruptors at ≥ 0.1 %.

Section 3. Composition / information on ingredients

3.1 Substance

COMPONENT (INCI)	CAS	EC	CONCENTRATION	CLASSIFICATION
Bixa Orellana Extract Botanical ingredient	–	–	100 %	Not classified

Natural botanical material of variable composition. No other ingredients that are classified as hazardous and contribute to the classification are present at or above reportable thresholds, to the best of our knowledge.

Section 4. First-aid measures

Inhalation	Move to fresh air. If irritation of the airways or breathing difficulty persists, get medical advice.
Skin contact	Brush off and wash with soap and water. Get medical advice if irritation develops.
Eye contact	Rinse cautiously with water for several minutes; remove contact lenses if easy to do. Get medical advice if irritation persists.
Ingestion	Rinse mouth with water. Not expected to be harmful in small amounts; get medical advice if you feel unwell.
Most important symptoms	Dust may cause mechanical irritation of eyes and airways. Botanical dusts may cause allergic reactions in sensitised people.
Immediate medical attention	Not normally required. Treat symptomatically.

Section 5. Fire-fighting measures

Suitable media	Water spray, foam, dry chemical, carbon dioxide. Use a gentle spray to avoid raising dust.
Unsuitable media	Direct high-pressure water jet (may disperse dust).
Specific hazards	Combustible solid. Fine dust dispersed in air in sufficient concentration may form an explosive mixture with an ignition source. Combustion produces carbon monoxide and carbon dioxide.
Advice for firefighters	Wear self-contained breathing apparatus and full protective clothing.

Section 6. Accidental release measures

Personal precautions	Avoid creating and breathing dust. Wear suitable protective equipment (see Section 8).
Environmental precautions	Prevent large quantities entering drains or surface water.
Clean-up	Sweep or vacuum up (preferably with an explosion-protected vacuum) and place in a closed container for disposal. Avoid dry sweeping that raises dust.
Reference to other sections	See Sections 8 and 13.

Section 7. Handling and storage

Precautions for safe handling	Avoid dust formation and dust accumulation on surfaces. Keep away from ignition sources; ground equipment when transferring large quantities. Observe good hygiene; do not eat, drink or smoke in work areas.
Conditions for safe storage	Store in tightly closed original containers in a cool (below 25 °C), dry, well-ventilated place, away from direct sunlight, moisture, strong odours and incompatible materials.
Specific end uses	See Section 1.2.

Section 8. Exposure controls / personal protection

8.1 Control parameters

Inhalable dust (general)	Observe national occupational limits for nuisance/inert dust, e.g. ACGIH TLV (PNOS) 10 mg/m³ inhalable, 3 mg/m³ respirable; US OSHA PEL (PNOR) 15 mg/m³ total, 5 mg/m³ respirable.

DNEL / PNEC: no data available.

8.2 Exposure controls

Engineering controls	Use local exhaust ventilation where dust is generated.
Eyes protection	Safety glasses with side shields (EN 166 / ANSI Z87.1) where dust is generated.
Skin protection	Protective gloves (e.g. nitrile) for prolonged contact; work clothing.
Respiratory protection	Where dust is generated, a particle filter mask (EN 149 FFP2 / NIOSH N95).
Hygiene measures	Wash hands before breaks and after work. Do not eat, drink or smoke when handling.
Environmental exposure	Avoid release of large quantities to drains and the environment.

Section 9. Physical and chemical properties

Physical state	Solid (powder)
Colour	Characteristic
Odour	Characteristic
Melting point / freezing point	Not determined
Boiling point or initial boiling point	Not determined
Flammability	Combustible solid; not classified as a flammable solid
Lower and upper explosion limits	Not determined
Flash point	Not applicable (solid)
Auto-ignition temperature	Not determined
Decomposition temperature	Not determined
pH	Not determined

Kinematic viscosity	Not determined
Solubility	Not determined
Partition coefficient n-octanol/water	Not applicable (natural complex substance)
Vapour pressure	Not determined
Density and/or relative density	Not determined — see COA
Particle characteristics	80–100 mesh

Section 10. Stability and reactivity

Reactivity	Not reactive under normal conditions.
Chemical stability	Stable under recommended storage conditions.
Hazardous reactions	Dust explosion possible if dispersed in air near an ignition source.
Conditions to avoid	Heat, moisture, open flames, sparks, dust clouds.
Incompatible materials	Strong oxidising agents.
Decomposition products	Carbon monoxide and carbon dioxide on combustion.

Section 11. Toxicological information

No toxicological data are available for this specific product. The extract is standardised to the marker compound shown in the product name; based on the known properties of that marker compound at the stated concentration, the product is not expected to meet the criteria for classification for any health hazard class. Botanical dusts may cause allergic reactions in sensitised individuals.

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	Based on available data, the classification criteria are not met.
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.
Endocrine-disrupting properties	Not known to contain endocrine disruptors at ≥ 0.1 %.

Carcinogenicity listings: no component is listed by IARC, NTP or OSHA as a carcinogen, to the best of our knowledge.

Section 12. Ecological information

No ecotoxicity data are available. Natural material; expected to be readily biodegradable. Not considered PBT or vPvB. Not expected to be harmful to aquatic life at normal handling quantities.

Toxicity	No data available for this product.

Persistence and degradability	Expected to be biodegradable.
Bioaccumulative potential	Not expected to bioaccumulate.
Mobility in soil	No data available.
PBT / vPvB assessment	Not considered PBT or vPvB.
Endocrine-disrupting properties	None known.

Section 13. Disposal considerations

Dispose of in accordance with local, regional and national regulations. Uncontaminated material may be composted or disposed of as non-hazardous waste. Empty packaging may be recycled.

Section 14. Transport information

Not regulated as dangerous goods for transport (ADR/RID, IMDG, IATA, US DOT, Canada TDG).

UN number / ID	Not applicable
Proper shipping name	Not applicable
Transport hazard class(es)	Not applicable
Packing group	Not applicable
Environmental hazards / marine pollutant	No
Transport in bulk (IMO instruments)	Not applicable

Section 15. Regulatory information

European Union

REACH (EC) No 1907/2006	Natural botanical substance (UVCB). Registration obligations depend on the importer and annual tonnage. Not listed on the REACH Candidate List (SVHC) or Annex XIV/XVII, to our knowledge.
Cosmetics (EC) No 1223/2009	Check the INCI name and any restrictions before use in cosmetics.
Chemical safety assessment	Not carried out.

United States

OSHA HCS	Not hazardous under 29 CFR 1910.1200, except possible combustible dust (HNOC).
TSCA	Substances used solely in food, drugs or cosmetics are regulated by the FDA and excluded from TSCA. For other uses, contact the supplier for inventory status.
SARA Title III / CERCLA	No components listed under SARA 302/313 or CERCLA, to our knowledge.
California Proposition 65	Contact the supplier for a batch-specific statement.

Canada

WHMIS 2015 (HPR)	Not a hazardous product under the Hazardous Products Regulations (combustible dust to be considered).
DSL / NDSL	Contact the supplier for inventory status.

Where this product is imported into the EU/EEA by the customer, the importer is responsible for any REACH registration and for providing this SDS in the official language(s) of the Member State where it is placed on the market.

Section 16. Other information

Date of issue / revision	26 October 2026 — version 1.0, first issue
Basis of classification	Assessment of the product type (standardised botanical extract) and its components against the classification criteria.
Related documents	Technical Data Sheet TDS-WH-B3-BO. Certificate of Analysis on request.
Abbreviations	CAS: Chemical Abstracts Service; CLP: Classification, Labelling and Packaging; EC: European Community number; GHS: Globally Harmonized System; HNOC: hazard not otherwise classified; INCI: International Nomenclature of Cosmetic Ingredients; OEL: occupational exposure limit; PBT: persistent, bioaccumulative, toxic; UVCB: substance of unknown or variable composition; vPvB: very persistent, very bioaccumulative.

The information in this safety data sheet is based on our current knowledge and on the product type, and is intended to describe the product for health, safety and environmental purposes only. It does not constitute a guarantee of specific properties. Users are responsible for their own risk assessment and for complying with applicable laws.