

Safety Data Sheet

according to Regulation (EG) Nr. 1907/2006

Pink Ultra II (base + catalyst)

Revision date: 22.09.2023

Product code: 107C

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Pink Ultra II (base + catalyst)

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture

Impression material for use in audiology.

1.3. Details of the supplier of the safety data sheet

Company name: JKR Laboratories, Inc.
Street: 10701 W. Kellogg St.
Place: Wichita, KS 67209
Telephone: 316-722-6343
Fax: 316-722-5908
Email: info@jkrlab.com
Responsible Department: This number is only obtainable during office hours
Monday-Friday 8:00 a.m. - 5:00 p.m.

1.4. Emergency telephone number

316-650-8510

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture Regulation (EG) Nr. 1272/2008

Aquatic Chronic 3; H412

Full text of hazard statements: see SECTION 16.

2.2. Label elements

Regulation (EG) Nr. 1272/2008

Hazard statements

H412 Harmful to aquatic life with long lasting effects.

Precautionary statements

P273 Avoid release to the environment.

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

Additional advice on labelling

According to Regulation (EC) 1272/2008, art.1 No. 5 (d) this product as a medical product must not be labelled!

2.3. Other hazards

The mixture contains the following substances fulfilling the PBT criteria according to UK REACH:
Octamethylcyclotetrasiloxane.

The mixture contains the following substances fulfilling the vPvB criteria according to UK REACH:
Octamethylcyclotetrasiloxane.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Contains polydimethylsiloxane with functional groups. + fillers and pigment
catalyst: additionally platinum complex compound.

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Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (Regulation (EG) Nr. 1272/2008)			
14464-46-1	cristobalite flour			20 - < 40 %
	238-455-4			
	STOT RE 1; H372			
8042-47-5	paraffin oil			5 - < 20 %
	232-455-8		01-2119487078-27	
	Asp. Tox. 1; H304			
556-67-2	Octamethylcyclotetrasiloxane			< 0,05 %
	209-136-7	014-018-00-1	01-2119529238-36	
	Flam. Liq. 3, Repr. 2, Aquatic Chronic 1; H226 H361f H410			
2390-63-8	3,6-bis(diethylamino)-9-[2-(ethoxycarbonyl)phenyl]xanthylum chloride			< 0.1 %
	219-233-6			
	Acute Tox. 3, Acute Tox. 4, Eye Dam. 1, Aquatic Acute 1, Aquatic Chronic 1; H301 H332 H318 H400 H410			

Full text of H and EUH statements: see section 16.

Specific Conc. Limits, M-factors and ATE

CAS No	EC No	Chemical name	Quantity
		Specific Conc. Limits, M-factors and ATE	
8042-47-5	232-455-8	paraffin oil	5 - < 20 %
		inhalation: LC50 = >5 mg/l (vapours); dermal: LD50 = >2000 mg/kg; oral: LD50 = >5000 mg/kg	
556-67-2	209-136-7	Octamethylcyclotetrasiloxane	< 0,05 %
		inhalation: LC50 = 36 mg/l (vapours); dermal: LD50 = >2400 mg/kg; oral: LD50 = 4800 mg/kg Aquatic Chronic 1; H410: M=10	
2390-63-8	219-233-6	3,6-bis(diethylamino)-9-[2-(ethoxycarbonyl)phenyl]xanthylum chloride	< 0.1 %
		inhalation: ATE = 11 mg/l (vapours); inhalation: ATE = 1,5 mg/l (dusts or mists); oral: ATE = 100 mg/kg Aquatic Acute 1; H400: M=100 Aquatic Chronic 1; H410: M=10	

SECTION 4: First aid measures

4.1. Description of first aid

measures After inhalation

Provide fresh air.

After contact with skin

Wash with plenty of water. Take off contaminated clothing and wash it before reuse. Remove product mechanically with cloth or paper. Wash with plenty of water and soap. In case of visible changes on the skin or complaints, seek medical advice (if possible have label or safety data sheet with you).

After contact with eyes

Rinse immediately carefully and thoroughly with eye-bath or water.

After ingestion

Rinse mouth immediately and drink 1 glass of water. Rinse mouth immediately and drink plenty of water. Let water be drunken in little sips (dilution effect).

Do not induce vomiting. If you feel unwell, seek medical advice.

4.2. Most important symptoms and effects, both acute and delayed

No information available.

4.3. Indication of any immediate medical attention and special treatment needed

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Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Co-ordinate fire-fighting measures to the fire surroundings.

5.2. Special hazards arising from the substance or mixture

Non-flammable.

5.3. Advice for firefighters

In case of fire: Wear self-contained breathing apparatus.

Additional information

Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency

procedures General advice

Use personal protection equipment.

6.2. Environmental precautions

Do not allow to enter into surface water or drains.

6.3. Methods and material for containment and cleaning

up For cleaning up

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents). Treat the recovered material as prescribed in the section on waste disposal.

Other information

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents). Treat the recovered material as prescribed in the section on waste disposal.

6.4. Reference to other sections

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13

SECTION 7: Handling and storage

7.1. Precautions for safe

handling Advice on safe handling

No special measures are necessary.

Advice on protection against fire and explosion

No special fire protection measures are necessary.

Advice on general occupational hygiene

Wash hands before breaks and after work. When using do not eat, drink, smoke, sniff. Take off contaminated clothing.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed.

Hints on joint storage

Do not store with acids, lyes, alcohols, metallic powders and metallic oxides (release of hydrogen is favoured).

Further information on storage conditions

Keep only in the original container in a cool, dry and well-ventilated place, away from foodstuffs.

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7.3. Specific end use(s)

Ear impression material.

For use by trained specialist staff.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.2. Exposure controls

Individual protection measures, such as personal protective equipment

Eye/face protection

Wear eye/face protection.

Hand protection

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

Suitable are gloves of the following material: NBR (Nitrile rubber)

Skin protection

Use of protective clothing.

Respiratory protection

In case of inadequate ventilation wear respiratory protection.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:	Paste		
Colour:	base: pink , catalyst: white		
Odour:	characteristic		Test method
		not determined	not determined
Melting point/freezing point:			
Boiling point or initial boiling point and boiling range:		not determined	not determined
Flammability:		determined	not determined
Lower explosion limits:			
limits: Upper explosion limits:			
Flash point:		>100 °C	DIN 51755
Auto-ignition temperature:		>400 °C	DIN 51794
Decomposition temperature:		>180 °C	
pH-Value:		not determined	
Viscosity / kinematic:		not determined	
Water solubility:	The study does not need to be conducted because the substance is known to be insoluble in water.		
Solubility in other solvents	not determined		
Partition coefficient n-octanol/water:		not determined	
Vapour pressure: (at 20 °C)			<10 hPa
Density (at 20 °C):		1,24 g/cm³	DIN 51757
Relative vapour density:		not determined	
Particle characteristics:		not applicable	

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9.2. Other information

Information with regard to physical hazard classes

Explosive properties

The product is not: Explosive.

Oxidizing properties

The product is not: oxidising.

Other safety characteristics

Evaporation rate:

not determined

Solid content:

not determined

Viscosity / dynamic: (at 23 °C)

45000 mPa·s BROOKFIELD

SECTION 10: Stability and reactivity

10.1. Reactivity

No hazardous reaction when handled and stored according to provisions.

10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

10.3. Possibility of hazardous reactions

Reacts with : Acids, alkalis, alcohols, powdered metals or metal oxides with release of hydrogen.

10.4. Conditions to avoid

Temperatures > 150°C/ 302 °F.

10.5. Incompatible materials

No information available.

10.6. Hazardous decomposition products

In case of thermic decomposition hydrogen is released.

At a temperature of approx. 150°C/ 302°F a small amount of formaldehyde can be released by oxidative degradation.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EG) Nr.

1272/2008 Acute toxicity

Based on available data, the classification criteria are not met.

For the product itself no toxicological data are available. In products with a comparable composition, a LD50 (orally, species rat) of > 5000 mg/kg has been found.

ATEmix calculated

ATE (oral) > 2000 mg/kg; ATE (dermal) > 2000 mg/kg; ATE (inhalation vapour) > 20 mg/l; ATE (inhalation dust/mist) > 5 mg/l

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CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
8042-47-5	paraffin oil				
	oral	LD50 mg/kg >5000	Rat	OECD	
	dermal	LD50 mg/kg >2000	Rabbit	OECD	
	inhalation (4 h) vapour	LC50 >5 mg/l	Rat	OECD	
556-67-2	Octamethylcyclotetrasiloxane				
	oral	LD50 mg/kg 4800	Rat		OECD 401
	dermal	LD50 mg/kg >2400	Rabbit		OECD 402
	inhalation (4 h) vapour	LC50 36 mg/l	Rat	GESTIS	OECD 403
2390-63-8	3,6-bis(diethylamino)-9-[2-(ethoxycarbonyl)phenyl]xanthylum chloride				
	oral	ATE mg/kg 100			
	inhalation vapour	ATE 11 mg/l			
	inhalation dust/mist	ATE 1,5 mg/l			

Irritation and corrosivity

Based on available data, the classification criteria are not met.

Sensitising effects

Based on available data, the classification criteria are not met.

Carcinogenic/mutagenic/toxic effects for reproduction

Based on available data, the classification criteria are not met.

STOT-single exposure

Based on available data, the classification criteria are not met.

Due to physical form (paste) classification with H372 is not appropriate. An inhalation of the product is not possible.

EC regulation 1272/2008 annex 1, section 1.1.1.5: "For the purpose of classification of health hazards (part 3), the route of exposure, information on mechanisms and metabolism studies are useful for determining the relevance of effects in humans. If this information raises doubts as to their relevance in humans, in spite of the indisputable data legitimacy and quality, a lower classification may be justified. When there is scientific evidence that the mechanism or mode of action is not relevant to humans, the substance or mixture should not be classified."

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.

SECTION 12: Ecological information

12.1. Toxicity

Harmful to aquatic life with long lasting effects.

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CAS No	Chemical name					
	Aquatic toxicity	Dose	[h] [d]	Species	Source	Method
8042-47-5	paraffin oil					
	Acute fish toxicity	LC50 mg/l	>1000	96 h	Leuciscus idus (golden orfe)	OECD
	Acute algae toxicity	ErC50 mg/l	>100	72 h	Pseudokirchneriella subcapitata	OECD
	Acute crustacea toxicity	EC50 mg/l	>100	48 h	Daphnia magna (Big water flea)	

12.2. Persistence and degradability

The product has not been tested.

The product has not been tested.				
CAS No	Chemical name			
	Method	Value	d	Source
	Evaluation			
8042-47-5	paraffin oil			
	OECD 301F/ ISO 9408/ EEC 92/69/V, C.4-D	31%	28	
	Not readily biodegradable (according to OECD criteria)			
556-67-2	Octamethylcyclotetrasiloxane			
		3,7%	29	
	Not readily biodegradable (according to OECD criteria)			

12.3. Bioaccumulative potential

The product has not been tested.

12.4. Mobility in soil

The product has not been tested.

12.5. Results of PBT and vPvB assessment

The mixture contains the following substances fulfilling the PBT criteria according to UK REACH:

Octamethylcyclotetrasiloxane.

The mixture contains the following substances fulfilling the vPvB criteria according to UK REACH:

Octamethylcyclotetrasiloxane.

Octamethylcyclotetrasiloxane (D4) fulfills the current criteria set forth under Annex XIII of the EU REACH Regulation for PBT and vPvB substances and was included in the candidate list of SVHCs. According to our knowledge of the state of the art, however, D4 cannot be compared with known PBT and/or vPvB substances. The interpretation of the available data by the silicone industry reveals that scientific evidence obtained from field tests essentially points out that D4 does not lead to biomagnification in aquatic and terrestrial food chains. In air, D4 is decomposed by naturally occurring processes in the atmosphere. D-residues which do not decompose in this way in the air are not expected to accumulate from the air in water, the soil or living organisms.

12.6. Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

12.7. Other adverse effects

No information available.

Further information

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.

SECTION 13: Disposal considerations

13.1. Waste treatment

methods Disposal recommendations

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil. Dispose of waste

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according to applicable legislation.

Contaminated packaging

Non-contaminated packages may be recycled. Handle contaminated packages in the same way as the substance itself.

SECTION 14: Transport information

Land transport (ADR/RID)

<u>14.1. UN number or ID number:</u>	No dangerous good in sense of this transport regulation.
<u>14.2. UN proper shipping name:</u>	No dangerous good in sense of this transport regulation.
<u>14.3. Transport hazard class(es):</u>	No dangerous good in sense of this transport regulation.
<u>14.4. Packing group:</u>	No dangerous good in sense of this transport regulation.

Inland waterways transport (ADN)

<u>14.1. UN number or ID number:</u>	No dangerous good in sense of this transport regulation.
<u>14.2. UN proper shipping name:</u>	No dangerous good in sense of this transport regulation.
<u>14.3. Transport hazard class(es):</u>	No dangerous good in sense of this transport regulation.
<u>14.4. Packing group:</u>	No dangerous good in sense of this transport regulation.

Marine transport (IMDG)

<u>14.1. UN number or ID number:</u>	No dangerous good in sense of this transport regulation.
<u>14.2. UN proper shipping name:</u>	No dangerous good in sense of this transport regulation.
<u>14.3. Transport hazard class(es):</u>	No dangerous good in sense of this transport regulation.
<u>14.4. Packing group:</u>	No dangerous good in sense of this transport regulation.

Air transport (ICAO-TI/IATA-DGR)

<u>14.1. UN number or ID number:</u>	No dangerous good in sense of this transport regulation.
<u>14.2. UN proper shipping name:</u>	No dangerous good in sense of this transport regulation.
<u>14.3. Transport hazard class(es):</u>	No dangerous good in sense of this transport regulation.
<u>14.4. Packing group:</u>	No dangerous good in sense of this transport regulation.

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: No

14.6. Special precautions for user

No dangerous good in sense of this transport regulation.

14.7. Maritime transport in bulk according to IMO instruments

No dangerous good in sense of this transport regulation.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture EU regulatory information

Authorisations (REACH, annex XIV):

Substances of very high concern, SVHC (REACH, article 59):

Octamethylcyclotetrasiloxane

Restrictions on use (REACH, annex XVII):

Entry 3, Entry 70, Entry 75

Information according to 2012/18/EU (SEVESO III):

Not subject to 2012/18/EU (SEVESO III)

Additional information

To follow: 850/2004/EC, 79/117/EEC, 689/2008/EC

The mixture contains substances of very high concern (SVHC candidates):

Octamethylcyclotetrasiloxane (D4), CAS no. 556-67-2

National regulatory information

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Employment restrictions:

Observe restrictions to employment for juveniles according to the 'juvenile work protection guideline' (94/33/EC)

Water hazard class (D):

3- high hazardous to water

15.2. Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information

Abbreviations and acronyms

ADR: Accord européen sur le transport des marchandises dangereuses par Route
(European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonized System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service
LC50: Lethal concentration, 50%
LD50: Lethal dose, 50%
CLP: Classification, labelling and Packaging
REACH: Registration, Evaluation and Authorization of Chemicals
GHS: Globally Harmonised System of Classification, Labelling and Packaging of Chemicals
UN: United Nations
DNEL: Derived No Effect Level
DMEL: Derived Minimal Effect Level
PNEC: Predicted No Effect Concentration
ATE: Acute toxicity estimate
LL50: Lethal loading, 50%
EL50: Effect loading, 50%
EC50: Effective Concentration 50%
ErC50: Effective Concentration 50%, growth rate
NOEC: No Observed Effect Concentration
BCF: Bio-concentration factor
PBT: persistent, bioaccumulative, toxic
vPvB: very persistent, very bioaccumulative
RID: Regulations concerning the international carriage of dangerous goods by rail
ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
(Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures)
EmS: Emergency Schedules
MFAG: Medical First Aid Guide
ICAO: International Civil Aviation Organization
MARPOL: International Convention for the Prevention of Marine Pollution from Ships
IBC: Intermediate Bulk Container
SVHC: Substance of Very High Concern
For abbreviations and acronyms, see: ECHA Guidance on information requirements and chemical safety assessment, chapter R.20 (Table of terms and abbreviations).
Flam. Liq: Flammable liquids
Acute Tox: Acute toxicity
Asp. Tox: Aspiration hazard
Eye Dam: Eye damage
Repr: Reproductive toxicity
STOT RE: Specific target organ toxicity - repeated exposure
Aquatic Acute: Acute aquatic hazard
Aquatic Chronic: Chronic aquatic hazard

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Classification for mixtures and used evaluation method according to Regulation(EG) Nr. 1272/2008

Classification	Classification procedure
Aquatic Chronic 3; H412	Calculation method

Relevant H and EUH statements (number and full text)

H226	Flammable liquid and vapour.
H301	Toxic if swallowed.
H304	May be fatal if swallowed and enters airways.
H318	Causes serious eye damage.
H332	Harmful if inhaled.
H361f	Suspected of damaging fertility.
H372	Causes damage to organs through prolonged or repeated exposure.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.

Further Information

The information is based on the present level of our knowledge. It does not, however, give assurance of product properties and establishes no contract legal rights. The receiver of our product is singularly responsible for adhering to existing laws and regulations.

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)