in accordance with 29 CFR 1910.1200 and ANSI standard Z400.1-2010

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Ottobock. 636N9 - OTTO BOCK Quick Drying Rubber Cement

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1. Product and company identification

Product identifier

Trade name: 636N9 - OTTO BOCK Quick Drying Rubber Cement

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

Adhesive for orthopedic procedures. General use:

Only for industrial users.

Details of the supplier of the safety data sheet

Company name: Otto Bock Health Care Street/POB-No.: 3820 W. Great Lakes Drive Postal Code, city: Salt Lake City, UT 84120

USA

www: www.ottobockus.com Telephone: +1 (801) 956-2400 Telefax: +1 (801) 956-2401

Dept. responsible for information:

Quality Department,

Telephone: +1 (801) 954-2304 (7 AM – 3 PM, Mountain Time),

Email: USRegulatory@ottobock.com

Additional information: Corporate headquarters:

> Ottobock SE & Co. KGaA Max-Näder-Straße 15

Duderstadt Germany

Emergency phone number

CHEMTREC, Telephone: +1 (800) 424-9300

CONSULTANK Lutz Harder GmbH (Contract QUALI003)

Telephone: +49 (0)178-4337434 (from USA: 01149 178 4337434)

2. Hazards identification

Emergency overview

Odor:

Appearance Form: liquid

> Color: yellow characteristic

Classification: Flammable Liquid - Category 2; Skin Irritation - Category 2; Eye Irritation -

Category 2A; Reproductive toxicant - Category 2;

Specific Target Organ Toxicity (Single Exposure) - Category 3; Specific Target Organ Toxicity (Repeated Exposure) - Category 2;

Aquatic toxicity - chronic - Category 2;

in accordance with 29 CFR 1910.1200 and ANSI standard Z400.1-2010

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Hazard symbols:









Signal word: Danger

Hazard statements: Highly flammable liquid and vapor.

Causes skin irritation.

Causes serious eye irritation.

May cause drowsiness or dizziness. Suspected of damaging the unborn child.

May cause damage to organs through prolonged or repeated exposure.

Toxic to aquatic life with long lasting effects.

Precautionary statements:

In case of fire: Use dry powder, foam or carbon dioxide for extinction.

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No

smokina.

Do not breathe vapors.

Avoid release to the environment.

Wear protective gloves/protective clothing/eye protection/face protection.

IF exposed or concerned: Get medical advice/attention.

Store in a well-ventilated place. Keep container tightly closed.

Regulatory status

This material is considered hazardous by the U.S. OSHA Hazard Communication Standard (29 CFR 1910.1200) and SIMDUT in Canada.

Hazards not otherwise classified

Potentially explosive vapor/air mixtures may form.

Inhaling can lead to irritations of the respiratory tract and mucous membrane.

Narcotic effect in case of higher doses or prolonged exposure.

see section 11: Toxicological information

3. Composition / Information on ingredients

Chemical characterization: Mixture of the substances listed below with non-hazardous additions

in accordance with 29 CFR 1910.1200 and ANSI standard Z400.1-2010

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Relevant ingredients:

CAS No.	Designation	Content	Classification
CAS 64742-49-0	Special petrol	10 - 25 %	Flammable Liquid - Category 2. Skin Irritation - Category 2. Specific Target Organ Toxicity (Single Exposure) - Category 3. Aspiration Toxicity - Category 1. Aquatic toxicity - chronic - Category 2.
CAS 141-78-6	Ethyl acetate	10 - 25 %	Flammable Liquid - Category 2. Eye Irritation - Category 2A. Specific Target Organ Toxicity (Single Exposure) - Category 3.
CAS 108-88-3	Toluene	10 - 25 %	Flammable Liquid - Category 2. Skin Irritation - Category 2. Reproductive toxicant - Category 2. Specific Target Organ Toxicity (Single Exposure) - Category 3. Specific Target Organ Toxicity (Repeated Exposure) - Category 2. Aspiration Toxicity - Category 1.
CAS 1314-13-2	Zinc oxide	< 1 %	Aquatic toxicity - acute - Category 1. Aquatic toxicity - chronic - Category 1.

4. First aid measures

Take off immediately all contaminated clothing. General information:

Move victim to fresh air; if necessary, provide artificial respiration or oxygen. Do not allow In case of inhalation:

victim to become chilled. Keep victim warm.

Seek medical attention. If victim is at risk of losing consciousness, position and transport

on their side.

Immediately clean with water and soap followed by thorough rinsing. Do not use solvents Following skin contact:

or thinners. In case of skin reactions, consult a physician.

After eye contact: Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids

apart. Subsequently consult an ophthalmologist.

After swallowing: Consult physician immediately. Do not induce vomiting. Keep victim resting calmly.

Most important symptoms/effects, acute and delayed

Causes skin irritation. Causes serious eye irritation. May cause drowsiness or dizziness. The following symptoms may occur: Dizziness, headache, irritation to respiratory tract, fatigue, Impaired consciousness, Nausea, vomiting, breathing paralysis.

Information to physician

Symptoms of poisoning may develop several hours following exposure. Victim should be under medical observation for at least 48 hours after exposure.

Treat symptomatically.

5. Fire fighting measures

Flash point/flash point range:

-13 °F (DIN 53213)

Auto-ignition temperature: not self-igniting

in accordance with 29 CFR 1910.1200 and ANSI standard Z400.1-2010

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Suitable extinguishing media:

In case of fire, use carbon dioxide, sand or dry chemical powder. Never use water.

Extinguishing media which must not be used for safety reasons:

Water

Specific hazards arising from the chemical

Highly flammable liquid and vapour

In case of fire, explosive mixtures may form with air. Toxic gases may form.

In case of fire may be liberated: Carbon monoxide and carbon dioxide.

Protective equipment and precautions for firefighters:

Wear self-contained positive pressure breathing apparatus and full firefighting protective

clothing.

Additional information: Cool endangered containers with water spray and, if possible, remove from danger zone.

Heating will lead to pressure increase: Danger of bursting and explosion.

Do not allow water used to extinguish fire to enter drains, ground or waterways.

6. Accidental release measures

Eliminate all ignition sources if safe to do so. Personal precautions:

Avoid contact with the substance. Provide adequate ventilation.

Keep unprotected people away. Wear appropriate protective equipment.

Do not breathe vapors.

Take off immediately all contaminated clothing and wash it before reuse.

Environmental precautions

Do not allow to enter soil, sewage, water bodies, lower level rooms or pits. If necessary

notify appropriate authorities.

Methods for clean-up: Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal

binding agents). Do not remove residual product with water and detergent.

Additional information: Use only non-sparking tools. Take precautionary measures against static discharges.

7. Handling and storage

Handling

Advices on safe handling: Provide good ventilation and/or an exhaust system in the work area.

Avoid contact with the substance. Wear appropriate protective equipment.

Do not breathe vapors.

Precautions against fire and explosion:

Keep away from sources of ignition - No smoking.

Take precautionary measures against static discharges.

Use explosion-proof equipment and non-sparking tools/utensils.

Vapors are heavier than air and will travel at floor level. Vapors form explosive mixtures with air.

Storage

Requirements for storerooms and containers:

Keep container tightly closed in a cool, well-ventilated place. Keep container dry.

Store at room temperature in a dry and well ventilated area.

Protect from heat and direct sunlight.

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Hints on joint storage:

Keep away from strong acids and bases as well as oxidizing agents. Keep away from food, drink and animal feedingstuffs.

8. Exposure controls / personal protection

Exposure guidelines

Occupational exposure limit values:

CAS No.	Designation	Туре	Limit value
141-78-6	Ethyl acetate	USA: ACGIH: TWA USA: NIOSH: TWA USA: OSHA: TWA	1440 mg/m³; 400 ppm 1400 mg/m³; 400 ppm 1400 mg/m³; 400 ppm
108-88-3	Toluene	OSHA: Ceiling USA: ACGIH: TWA USA: NIOSH: STEL USA: NIOSH: TWA USA: OSHA: TWA	300 ppm 75 mg/m³; 20 ppm 560 mg/m³; 150 ppm 375 mg/m³; 100 ppm 200 ppm
1314-13-2	Zinc oxide	NIOSH: Ceiling USA: ACGIH: STEL USA: ACGIH: TWA USA: NIOSH: STEL USA: NIOSH: TWA USA: OSHA: TWA USA: OSHA: TWA	15 mg/m³ 10 mg/m³ 2 mg/m³ 10 mg/m³ 5 mg/m³ 5 mg/m³ 15 mg/m³

Biological limit values:

CAS No.	Designation	Туре	Limit value	Parameter	Sampling
108-88-3	Toluene	USA: ACGIH-BEI, blood	0.02 mg/L	Toluene in blood	Prior to last shift of workweek
		USA: ACGIH-BEI, urine	0.03 mg/L	Toluene in urine	end of exposure or end of shift
		USA: ACGIH-BEI, urine	0.3 mg/g creatinine	o-Cresol in urine	end of exposure or end of shift

Engineering controls

Use only explosion-protected equipment/instruments.

Provide adequate ventilation, and local exhaust as needed.

Vent high concentrations of aerosols and/or fumes from the work area.

See also information in chapter 7, section storage.

Personal protection equipment (PPE)

Eye/face protection Tightly sealed goggles according to OSHA Standard - 29 CFR: 1910.133 or ANSI

Z87.1-2010.

Skin protection Wear suitable protective clothing.

In case of handling larger quantities: Flame-resistant antistatic protective clothing

in accordance with 29 CFR 1910.1200 and ANSI standard Z400.1-2010

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Protective gloves according to OSHA Standard - 29 CFR: 1910.138.

Glove material: Fluororubber (Viton) or butyl caoutchouc (butyl rubber)-Layer thickness:

>= 0.5 mm

Breakthrough time >480 min.

Observe glove manufacturer's instructions concerning penetrability and breakthrough time.

Respiratory protection must be worn whenever the TLV (WEL) levels have been exceeded. Respiratory protection:

Use filter type A (= against vapors of organic substances) according to OSHA Standard -

29 CFR: 1910.134 or ANSI Z88.2.

General hygiene considerations:

Keep away from food, drink and animal feedingstuffs. Take off immediately all contaminated clothing. Wash hands before breaks and after work.

Do not breathe vapors.

Avoid contact with skin and eyes.

9. Physical and chemical properties

Information on basic physical and chemical properties

Appearance: Form: liquid

Color: yellow

characteristic Odor: Odor threshold: No data available

at 68 °F: 7.0 pH value: Melting point/freezing point: No data available

Initial boiling point and boiling range: 168.8 °F

Flash point/flash point range: -13 °F (DIN 53213) Evaporation rate: No data available

Flammability: Highly flammable liquid and vapor.

Explosion limits: LEL (Lower Explosion Limit): 1.00 Vol-%

UEL (Upper Explosive Limit): 10.50 Vol-%

Vapor pressure: at 68 °F: 245 hPa

at 122 °F: 920 hPa

Vapor density: No data available

Density: at 68 °F: 0.90 g/mL (DIN 51757) Water solubility: at 68 °F: insoluble, slightly miscible

Partition coefficient: n-octanol/water: No data available Auto-ignition temperature: not self-igniting Thermal decomposition: No data available

Viscosity, dynamic: at 68 °F: 2200 mPa*s (RheometerSTV,MS3/200)

Viscosity, kinematic: at 68 °F: 115 s

Explosive properties: Potentially explosive vapor/air mixtures may form.

905 °F Ignition temperature: Solvent content: 70.3 %

Solid content: 29.1 % (DIN 53216)

in accordance with 29 CFR 1910.1200 and ANSI standard Z400.1-2010

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10. Stability and reactivity

Highly flammable liquid and vapor. Reactivity:

Stable under recommended storage conditions. Chemical stability:

Possibility of hazardous reactions

Vapors are heavier than air and will travel at floor level. In case of fire, explosive mixtures may form with air.

Heating will lead to pressure increase: Danger of bursting and explosion.

Keep away from heat sources, sparks and open flames. Conditions to avoid:

Incompatible materials: Keep away from strong acids and bases as well as oxidizing agents.

Hazardous decomposition products:

Toxic gases may form.

In case of fire may be liberated: Carbon monoxide and carbon dioxide.

Thermal decomposition: No data available

11. Toxicological information

Toxicological tests

Toxicological effects: Acute toxicity (oral): Lack of data.

> Acute toxicity (dermal): Lack of data. Acute toxicity (inhalative): Lack of data.

Skin corrosion/irritation: Skin Irritation - Category 2 = Causes skin irritation.

Serious eye damage/irritation: Eye Irritation - Category 2A = Causes serious eye irritation.

Sensitisation to the respiratory tract: Lack of data.

Skin sensitisation: Lack of data.

Germ cell mutagenicity/Genotoxicity: Lack of data.

Carcinogenicity: Lack of data.

Reproductive toxicity: Reproductive toxicant -

Category 2 = Suspected of damaging the unborn child.

Effects on or via lactation: Lack of data.

Specific target organ toxicity (single exposure): Specific Target Organ Toxicity (Single

Exposure) - Category 3 = May cause drowsiness or dizziness.

Specific target organ toxicity (repeated exposure): Specific Target Organ Toxicity

(Repeated Exposure) -

Category 2 = May cause damage to organs through prolonged or repeated exposure.

Aspiration hazard: Lack of data.

Other information: Toluene:

Reproduction toxicity: Lower foetal body weight at birth (longterm animal experiment).

in accordance with 29 CFR 1910.1200 and ANSI standard Z400.1-2010

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Symptoms

The following symptoms may occur: Dizziness, headache, irritation to respiratory tract, fatigue, Impaired consciousness, Nausea, vomiting, breathing paralysis.

In case of inhalation: Narcotic effect in case of higher doses or prolonged exposure.

After contact with skin: Danger of cutaneous absorption.

After eye contact: Splashing may cause eye irritation and reversible damage.

12. Ecological information

Ecotoxicity

Aquatic toxicity: Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic

environment.

Avoid spills and leaks. Very small amounts contaminates drinking water.

Information about Special benzine:

Fish toxicity: LC50 Oncorhynchus mykiss: 8,41 mg/L/96h (OECD 203).

Daphnia toxicity: EC50 Daphnia magna (Big water flea): 4,7 mg/L/48h (OECD 202). Algae toxicity: EC50 Pseudokirchneriella subcapitata (green algae): 12,4 mg/L/72h

(OECD 201).

Information about Zinc oxide:

EC50 Selenastrum capricornutum: 0,14 - 0,17 mg/L/72h. Daphnia toxicity: EC50 Daphnia magna : > 1000 mg/L/48h. Fish toxicity: LC50 Oncorhynchus mykiss: 1,1 mg/L/96h.

Mobility in soil

No data available

Persistence and degradability

Further details: Highly biodegradable in adapted medium. Part of the material has to be separated

mechanically before.

Additional ecological information

Volatile organic compounds (VOC):

70.3 % by weight

General information: Do not allow to enter into ground-water, surface water or drains.

13. Disposal considerations

Product

Recommendation: Incinerate as hazardous waste according to applicable local, state, and federal regulations.

Do not dispose of with household waste. Do not empty into drains.

Contaminated packaging

Recommendation: Dispose of waste according to applicable legislation.

Incinerate as hazardous waste according to applicable local, state, and federal regulations.

in accordance with 29 CFR 1910.1200 and ANSI standard Z400.1-2010

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14. Transport information

USA: Department of Transportation (DOT)

Identification number: UN1133

UN 1133, UN 1133, adhesives Proper shipping name:

Hazard class or Division: 3 Ш Packing Group: Labels: 3

B1, B52, IB3, T2, TP1 Special provisions:

Packaging - Exceptions: 150 Packaging - Non-bulk: 173 242 Packaging - Bulk: Quantity limitations - Passenger aircraft / rail:

60 L 220 L Α

Vessel stowage - Location: Vessel stowage - Other:

Sea transport (IMDG)

Quantity limitations - Cargo only:

UN 1133 UN number:

UN 1133, Adhesives Proper shipping name: Class or division, Subsidary risk: Class 3, Subrisk -

Packing Group: Ш

EmS: F-E, S-D Special provisions: 223, 955 Limited quantities: 5 L Excepted quantities: E1

P001, LP01 Contaminated packaging - Instructions:

Contaminated packaging - Provisions: PP1 IBC - Instructions: IBC03 IBC - Provisions: Tank instructions - IMO: T2 Tank instructions - UN: TP1 Tank instructions - Provisions:

Stowage and handling: Category A.

Properties and observations: Adhesives are solutions of gums, resins, etc., usually volatile due to the

solvents. Miscibility with water depends upon their composition.

Marine pollutant: yes Segregation group: none

Air transport (IATA)

UN/ID number: **UN 1133**

Proper shipping name: UN 1133, Adhesives

Class or division, Subsidary risk: Class 3 Packing Group: Ш

Hazard label: Flamm. liquid

Excepted Quantity Code:

Passenger and Cargo Aircraft: Ltd.Qty.: Pack.Instr. Y344 - Max. Net Qty/Pkg. 10 L Passenger and Cargo Aircraft: Pack.Instr. 355 - Max. Net Qty/Pkg. 60 L Cargo Aircraft only: Pack.Instr. 366 - Max. Net Qty/Pkg. 220 L

Special provisions: **A3** Emergency Response Guide-Code (ERG): 3L



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15. Regulatory information

National regulations - U.S. Federal Regulations

Special petrol: TSCA Inventory: listed; UVCB

> TSCA HPVC: not listed TSCA: listed - UVCB

TSCA Inventory: listed; EPA flags T Ethyl acetate:

> TSCA HPVC: not listed Other Environmental Laws: CERCLA: RQ 5000 lbs.

RCRA Hazardous Wastes: Code U112

NIOSH Recommendations:

Occupational Health Guideline: 0260

Toluene: TSCA Inventory: listed

> TSCA HPVC: not listed Carcinogen Status: IARC Rating: Group 3 OSHA Carcinogen: not listed NTP Rating: not listed

Clean Air Act:

Hazardous Air Pollutants: Code XOV

SOCMI Chemical: yes

Clean Water Act:

Hazardous Substances: RQ 1000 lbs.

Priority Pollutant: yes Other Environmental Laws: CERCLA: RQ 1000 lbs.

RCRA Hazardous Wastes: Code U220

RCRA Groundwater Monitoring: Methods 8020, 8240 / PQL 2, 5

SARA Title III Section 313, Toxic Release: Conc. 1.0% / Threshold Standard

NIOSH Recommendations:

Occupational Health Guideline: 0619

Zinc oxide: TSCA Inventory: listed

> TSCA HPVC: not listed NIOSH Recommendations:

Occupational Health Guideline: 0675*

in accordance with 29 CFR 1910.1200 and ANSI standard Z400.1-2010

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National regulations - U.S. State Regulations

Ethyl acetate: Delaware Air Quality Management List:

DRQ: 5000 - RQ State: Federal Regulations Apply

Idaho Air Pollutant List:

Title 585: AAC: 70 - EL: 93.3 - OEL: 1400 - Title 586: -

Main Hazardous Air Pollutants: Me 2005: HAP - Hap Rpt: 20000

Massachusetts Haz. Substance codes: 2,4,5,6 F8

Minnesota Haz. Substance:

Codes: AO - Ratings: 6.83 - Status: Title III.

New York List of Hazardous Substances:

RQ-Air: 5000 - RQ-Land: 1 - Note: No Note Associated with this chemical.

Pennsylvania Haz. Substance code: E

Washington Air Contaminant: TWA: 400 ppm - 1400 mg

California Proposition 65 code: D Toluene:

Delaware Air Quality Management List:

DRQ: 1000 - RQ State: Federal Regulations Apply

Idaho Air Pollutant List:

Title 585: AAC: 18.75 - EL: 25 - OEL: 375 - Title 586: -

Maine Hazardous Air Pollutants: Me 2005: HAP - Hap Rpt: 2000

Massachusetts Haz. Substance codes: 2,4,5,6 F7 F8 F9

Michigan Critical Material:

Note: - - CMR: 32 - Parameter: 00108-88-3 - Annual Usage Parameter: 100

Minnesota Haz. Substance:

Codes: ANO - Ratings: 8.64 - Status: Air Pollutant Title III. TRI. Water Pollutant

New Jersey RTK Hazardous Substance: DOT: 1294 - Sub No.: 1866 - TPQ: -New York List of Hazardous Substances:

RQ-Air: 1000 - RQ-Land: 1 - Note: No Note Associated with this chemical.

Pennsylvania Haz. Substance code: E

Washington Air Contaminant:

TWA: 100 ppm - 375 mg - STEL: 150 ppm - 560 mg

California Proposition 65: developmental

Rhode Island HSL: listed

National regulations - Great Britain

Hazchem-Code: •3YE

16. Other information

Contains 10 - 25 % Special petrol, 10 - 25 % Ethyl acetate, 10 - 25 % Toluene, < 1 % Text for labeling:

Zinc oxide. Safety data sheet available on request.

in accordance with 29 CFR 1910.1200 and ANSI standard Z400.1-2010

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Hazard rating systems: NFPA Hazard Rating:



Health: 2 (Moderate) Fire: 3 (Serious) Reactivity: 0 (Minimal) HMIS Version III Rating:

Health: 2 (Moderate) - Chronic effects

Flammability: 3 (Serious) Physical Hazard: 0 (Minimal)

Personal Protection: X = Consult your supervisor

Changes in section 1.3: Corporate headquarters Reason of change:

10/30/1994 Date of first version:

Department issuing data sheet

Contact person: see section 1: Dept. responsible for information

The information in this data sheet has been established to our best knowledge and was up-to-date at time of revision. It does not represent a guarantee for the properties of the product described in terms of the legal warranty regulations.

