

SAFETY DATA SHEET

DUREX® Extra Sensitive™ Smooth Condoms



HEALTH ▸ HYGIENE ▸ HOME

1. Product and company identification

Product name : DUREX® Extra Sensitive™ Smooth Condoms**Distributed by** : RB Health (US) LLC
Morris Corporate Center IV
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+1 973 404 2600RB Health (Canada) Inc.
1680 Tech Avenue, Unit #2
Mississauga, Ontario L4W 5S9
CANADA
Telephone: +1 905 283 7000**Emergency telephone number (Medical)** : 1-800-338-6167**Emergency telephone number (Transport)** : 1-800-424-9300 (U.S. & Canada) CHEMTREC
Outside U.S. and Canada (North America), call Chemtrec:703-527-3887**Website:** : <http://www.rbnainfo.com>**Product use** : Medical devices.

This SDS is designed for workplace employees, emergency personnel and for other conditions and situations where there is greater potential for large-scale or prolonged exposure, in accordance with the requirements of USDOL Occupational Safety and Health Administration.

This SDS is not applicable for consumer use of our products. For consumer use, all precautionary and first aid language is provided on the product label in accordance with the applicable government regulations, and shown in Section 15 of this SDS.

SDS # : D8331644 v4.0**Formulation #** : 8321655 v3.0; GPA5000040

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

Identified usesMale Condom.
Consumer uses.

2. Hazards identification

Classification of the substance or mixture : Not classified.**GHS label elements****Hazard pictograms** : Not applicable.

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2. Hazards identification

Signal word	: No signal word.
Hazard statements	: No known significant effects or critical hazards.
<u>Precautionary statements</u>	
General	: Read label before use. Keep out of reach of children. If medical advice is needed, have product container or label at hand.
Prevention	: Not applicable.
Response	: Not applicable.
Storage	: Not applicable.
Disposal	: Not applicable.
Supplemental label elements	: None known.
Hazards not otherwise classified	: None known.

3. Composition/information on ingredients

Substance/mixture	: Medical device. Natural rubber latex condoms with silicone lubricant.
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There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

4. First aid measures

Description of necessary first aid measures

Eye contact	: Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.
Inhalation	: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur.
Skin contact	: Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.
Ingestion	: Wash out mouth with water. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

Most important symptoms/effects, acute and delayed

Potential acute health effects

Eye contact	: May cause eye irritation upon direct contact with eyes.
Inhalation	: No known significant effects or critical hazards.
Skin contact	: No known significant effects or critical hazards.
Ingestion	: No known significant effects or critical hazards.

Over-exposure signs/symptoms

Eye contact	: No specific data.
Inhalation	: No specific data.
Skin contact	: No specific data.
Ingestion	: No specific data.

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4. First aid measures

Indication of immediate medical attention and special treatment needed, if necessary

- Notes to physician** : Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.
- Specific treatments** : No specific treatment.
- Protection of first-aiders** : No action shall be taken involving any personal risk or without suitable training.

See toxicological information (Section 11)

5. Fire-fighting measures

Extinguishing media

- Suitable extinguishing media** : Use an extinguishing agent suitable for the surrounding fire.
- Unsuitable extinguishing media** : None known.
- Specific hazards arising from the chemical** : No specific fire or explosion hazard.
- Hazardous thermal decomposition products** : No specific data.
- Special protective actions for fire-fighters** : Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.
- Special protective equipment for fire-fighters** : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

- For non-emergency personnel** : No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Put on appropriate personal protective equipment.
- For emergency responders** : If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".
- Environmental precautions** : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Methods and materials for containment and cleaning up

- Small spill** : Move containers from spill area. Vacuum or sweep up material and place in a designated, labeled waste container. Dispose of via a licensed waste disposal contractor.
- Large spill** : Move containers from spill area. Prevent entry into sewers, water courses, basements or confined areas. Vacuum or sweep up material and place in a designated, labeled waste container. Dispose of via a licensed waste disposal contractor. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

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7. Handling and storage

Precautions for safe handling

- Protective measures** : Put on appropriate personal protective equipment (see Section 8).
- Conditions for safe storage, including any incompatibilities** : Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.
- Recommended Storage Temperature for 1 week** : 10 to 60 °C
- Recommended Storage Temperature for up to 6 weeks** : 50 °C

8. Exposure controls/personal protection

Control

Occupational exposure limits

Not applicable.

- Appropriate engineering controls** : Good general ventilation should be sufficient to control worker exposure to airborne contaminants.
- Environmental exposure controls** : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.
- Individual protection measures**
- Hygiene measures** : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.
- Eye/face protection** : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.
- Skin protection**
- Hand protection** : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary.
- Body protection** : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Other skin protection** : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Respiratory protection** : Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

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9. Physical and chemical properties

Appearance

Physical state	: Solid. [[Latex condom with liquid lubricant]]
Color	: Lubricant: Clear to Yellowish Liquid.
Odor	: Not available.
Odor threshold	: Not available.
pH	: Not available.
Melting point	: Not available.
Boiling point	: Not available.
Flash point	: Not available.
Evaporation rate	: Not available.
Flammability (solid, gas)	: Not available.
Lower and upper explosive (flammable) limits	: Not available.
Vapor pressure	: Not available.
Vapor density	: Not available.
Relative density	: Not available.
Solubility	: Not available.
Partition coefficient: n-octanol/water	: Not available.
Auto-ignition temperature	: Not available.
Decomposition temperature	: Not available.
Viscosity	: Not available.

10. Stability and reactivity

Reactivity	: No specific test data related to reactivity available for this product or its ingredients.
Chemical stability	: The product is stable.
Possibility of hazardous reactions	: Under normal conditions of storage and use, hazardous reactions will not occur.
Conditions to avoid	: No specific data.
Incompatible materials	: No specific data.
Hazardous decomposition products	: Under normal conditions of storage and use, hazardous decomposition products should not be produced.

11. Toxicological information

Information on toxicological effects

Acute toxicity

Not available.

Conclusion/Summary : Based on available data, the classification criteria are not met.

Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
CON9 / LUB60 [LUB SIL + ZEUS - 580mg]_D8331644_US	Skin - Edema	Rabbit	0	2.0 mL	48 hours

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11. Toxicological information

Conclusion/Summary

- Skin** : On basis of test data: Non-irritant to skin.
- Eyes** : Lubricating agents May cause eye irritation.
- Respiratory** : No known significant effects or critical hazards.

Sensitization

Product/ingredient name	Route of exposure	Species	Result
CON9 / LUB60 [LUB SIL + ZEUS - 580mg]_D8331644_US	skin	Guinea pig	Not sensitizing

Conclusion/Summary

- Skin** : On basis of test data: Non-sensitiser to skin.
latex rubber May cause allergic reactions in certain individuals.
- Respiratory** : No known significant effects or critical hazards.

Mutagenicity

Not available.

- Conclusion/Summary** : No known significant effects or critical hazards.

Carcinogenicity

Not available.

- Conclusion/Summary** : No known significant effects or critical hazards.

Reproductive toxicity

Not available.

- Conclusion/Summary** : No known significant effects or critical hazards.

Teratogenicity

Not available.

- Conclusion/Summary** : No known significant effects or critical hazards.

Specific target organ toxicity (single exposure)

Not available.

Specific target organ toxicity (repeated exposure)

Not available.

Aspiration hazard

Not available.

- Information on the likely routes of exposure** : Not available.

Potential acute health effects

- Eye contact** : May cause eye irritation upon direct contact with eyes.
- Inhalation** : No known significant effects or critical hazards.
- Skin contact** : No known significant effects or critical hazards.
- Ingestion** : No known significant effects or critical hazards.

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11. Toxicological information

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact	: No specific data.
Inhalation	: No specific data.
Skin contact	: No specific data.
Ingestion	: No specific data.

Delayed and immediate effects and also chronic effects from short and long term exposure

Short term exposure

Potential immediate effects	: Not available.
Potential delayed effects	: Not available.

Long term exposure

Potential immediate effects	: Not available.
Potential delayed effects	: Not available.

Potential chronic health effects

Not available.

Conclusion/Summary	: No known significant effects or critical hazards.
General	: No known significant effects or critical hazards.
Carcinogenicity	: No known significant effects or critical hazards.
Mutagenicity	: No known significant effects or critical hazards.
Teratogenicity	: No known significant effects or critical hazards.
Developmental effects	: No known significant effects or critical hazards.
Fertility effects	: No known significant effects or critical hazards.

Numerical measures of toxicity

Acute toxicity estimates

N/A

12. Ecological information

Toxicity

Not available.

Conclusion/Summary	: No known significant effects or critical hazards.
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Persistence and degradability

Not available.

Bioaccumulative potential

Not available.

Mobility in soil

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12. Ecological information

Soil/water partition coefficient (K_{oc}) : Not available.

Other adverse effects : No known significant effects or critical hazards.

13. Disposal considerations

Disposal methods : The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

14. Transport information

	DOT Classification	TDG Classification	IMDG	IATA
UN number	Not regulated.	Not regulated.	Not regulated.	Not regulated.
UN proper shipping name	-	-	-	-
Transport hazard class(es)	-	-	-	-
Packing group	-	-	-	-
Environmental hazards	No.	No.	No.	No.

Special precautions for user : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

Transport in bulk according to Annex II of MARPOL and the IBC Code : Not available.

15. Regulatory information

U.S. Federal regulations : **TSCA 8(a) CDR Exempt/Partial exemption:** Not determined
United States inventory (TSCA 8b): All components are listed or exempted.

Clean Air Act Section 112 (b) Hazardous Air Pollutants (HAPs) : Not listed

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15. Regulatory information

Clean Air Act Section 602 Class I Substances : Not listed

Clean Air Act Section 602 Class II Substances : Not listed

DEA List I Chemicals (Precursor Chemicals) : Not listed

DEA List II Chemicals (Essential Chemicals) : Not listed

SARA 302/304

Composition/information on ingredients

No products were found.

SARA 304 RQ : Not applicable.

SARA 311/312

Classification : Not applicable.

Composition/information on ingredients

No products were found.

State regulations

Massachusetts : None of the components are listed.

New York : None of the components are listed.

New Jersey : None of the components are listed.

Pennsylvania : None of the components are listed.

Label elements

CPSC

Signal word : Not applicable

Hazard statements : Not applicable.

Precautionary measures : Not applicable

CCCR

Signal word : Not applicable

Hazard statements : Not applicable
Not applicable

Precautionary measures : Not applicable

Cosmetics. / Medicinal products

Signal word ; Not applicable.

Precautionary measures : **Safety Label Language:**

Use as directed

Keep out of reach of children

Avoid contact with eyes, broken skin or wounds

If you feel discomfort or irritation, stop use.

Do not use if you, or your partner, have an allergy to latex.

If you or your partner develop a rash or irritation, such as burning or itching, discontinue use. If symptoms persist consult a doctor.

Use a condom only once. Reuse may increase risk of failure or infection.

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15. Regulatory information

Additional information / Recommendations

Additional information : No known significant effects or critical hazards.

Recommendations : No known significant effects or critical hazards.

Recommendations : No known significant effects or critical hazards.

16. Other information

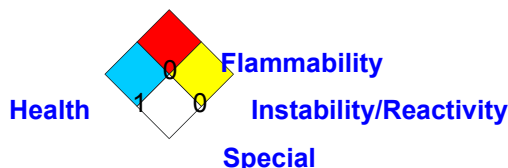
Hazardous Material Information System (U.S.A.)

Health	/	1
Flammability		0
Physical hazards		0

Caution: HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. Although HMIS® ratings and the associated label are not required on SDSs or products leaving a facility under 29 CFR 1910.1200, the preparer may choose to provide them. HMIS® ratings are to be used with a fully implemented HMIS® program. HMIS® is a registered trademark and service mark of the American Coatings Association, Inc.

The customer is responsible for determining the PPE code for this material. For more information on HMIS® Personal Protective Equipment (PPE) codes, consult the HMIS® Implementation Manual.

National Fire Protection Association (U.S.A.) :



NFPA (30B) aerosol Flammability No known significant effects or critical hazards.

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Copyright ©2001, National Fire Protection Association, Quincy, MA 02269. This warning system is intended to be interpreted and applied only by properly trained individuals to identify fire, health and reactivity hazards of chemicals. The user is referred to certain limited number of chemicals with recommended classifications in NFPA 49 and NFPA 325, which would be used as a guideline only. Whether the chemicals are classified by NFPA or not, anyone using the 704 systems to classify chemicals does so at their own risk.

Key to abbreviations :

- ATE = Acute Toxicity Estimate
- BCF = Bioconcentration Factor
- GHS = Globally Harmonized System of Classification and Labelling of Chemicals
- IATA = International Air Transport Association
- IBC = Intermediate Bulk Container
- IMDG = International Maritime Dangerous Goods
- LogPow = logarithm of the octanol/water partition coefficient
- MARPOL = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)
- UN = United Nations

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16. Other information

Date of issue : 10/15/2019
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Prepared by : Reckitt Benckiser India Ltd
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✔ Indicates information that has changed from previously issued version.

Notice to reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.



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