

1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product Identifier

Product Name: The Wildlife Series
Common Name: Elastomerics - Latex Elastics
Material: Natural Rubber Latex
Restrictions on Use: American Orthodontics' products are used for the treatment of malocclusions and craniofacial abnormalities as diagnosed by a trained dental professional or orthodontist. Federal law restricts this device to use by or on the order of a dentist or orthodontist.

EC No.: None
REACH Registration No.: None
CAS No. / IUPAC: None

1.2 Relevant Identified Uses/ Uses Advised Against

Relevant identified uses: Dental/Orthodontic use only
Uses advised against: Not for Consumer use. Please see "Restrictions on Use"

1.3 Details of the Supplier of the Safety Data Sheet

Company Name:
 American Orthodontics
 3524 Washington Avenue
 Sheboygan, WI 53081
 Phone: 920-457-5051
 Fax: 920-457-1485

E-mail: info@americanortho.com
National Contact: Safety Department

1.4 Emergency Telephone Number

Emergency Response Number:
 920-457-5051
 Only available during office hours: 8:00AM – 5:00PM (Central Time)
 Language of Phone Service: English

2. HAZARDS IDENTIFICATION

General Hazard Statement:

This product is a manufactured article as defined under REACH. No labeling is required for finished product.

This product is classified as "articles" and do not constitute a hazardous material in solid form und the definitions of the OSHA Hazard Communication Standard (29CFR1910.1200). Any articles manufactured from these solid products would be generally classified as non-hazardous.

3. COMPOSITION / INFORMATION ON INGREDIENTS

<u>Ingredient(s)</u>	<u>Wt. % Content (or Range)</u>
Natural Rubber	90-95
Colorant Encapsulated in Rubber	0.1-7.0
Vulcanizing Agents	3.0-5.0

4. FIRST-AID MEASURES

Description of First-Aid Measures

General Notes

Persons allergic to fruits or persons with spina bifida may be allergic to natural rubber.

Inhalation

N/A

Skin Contact

NIOSH Alert No. 97-135, June 1997: Workers exposed to latex gloves and other products containing natural rubber latex may develop allergic reactions such as skin rashes, hives, nasal, eye, or sinus symptoms, asthma, or (rarely) shock.

Eye Contact

N/A

Ingestion/Swallowing

Will not break down in the digestive system. All ingredients in this product meet FDA regulations per articles 177.26 for food contact.

5. FIRE AND EXPLOSION HAZARDS

Extinguishing Media: Use dry chemical CO2 or Foam or Water

Special Fire Fighting Procedures: Over exposure to thermal decomposition products may cause health hazard. An approved self-contained breathing apparatus should be worn.

6. ACCIDENTAL RELEASE MEASURES

None

7. HANDLING AND STORAGE

None

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Special Fire Fighting Procedures: Over exposure to thermal decomposition products may cause health hazard. An approved self-contained breathing apparatus should be worn

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Basic Physical & Chemical Properties

Appearance:	Solid, various colors
Odor:	Rubber odor
pH:	N/A
Melting Point/Freezing Point:	N/A
Initial Boiling Point & Boiling Range:	N/A
Evaporation Rate:	N/A
Vapor Pressure:	N/A
Vapor Density:	N/A
Relative Density:	N/A
Solubility(ies):	Not soluble in water
Partition Coefficient: n-octanol/water):	N/A

9.2 Other Information

Specific Gravity	0.923
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10. STABILITY AND REACTIVITY

Stability: Stable

Hazardous Polymerization: Will not occur

Conditions to Avoid: Avoid contact with flames or excessive heat. Will product oxides of carbon when burned.

Hazardous Decomposition Products: N/A

11. TOXICOLOGICAL INFORMATION**11.1 Information on Toxicological Information**

- **Respiratory/Skin Sensitization**
NIOSH Alert No. 97-135, June 1997: Workers exposed to latex gloves and other products containing natural rubber latex may develop allergic reactions such as skin rashes, hives, nasal, eye, or sinus symptoms, asthma, or (rarely) shock.
- **Carcinogenicity**
No ingredient in this product has been listed as carcinogenic.
- **Signs & Symptoms of Exposure**
NIOSH Alert No. 97-135, June 1997: Workers exposed to latex gloves and other products containing natural rubber latex may develop allergic reactions such as skin rashes, hives, nasal, eye, or sinus symptoms, asthma, or (rarely) shock.
- **Medical Conditions Generally Aggravated by Exposure**
Persons allergic to fruits or persons with spina bifida may be allergic to natural rubber.

11.1.1 Acute Toxicity

None

12. ECOLOGICAL INFORMATION

None

13. DISPOSAL CONSIDERATIONS

The generator of waste material has the responsibility for proper waste classification, transportation and disposal with accordance applicable federal, state/provincial and local regulations.

14. TRANSPORTATION INFORMATION

None

15. REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

National Regulations (USA):

The components of this product may be listed on “Proposition 65.”

This information depicts typical properties, test methods and references to the United States Code of Federal Regulations as listed under Title 21 of the Food and Drug Administration (FDA).

Physical Properties: ASTM D 412

Compliance Specification: A-A-52047 Type 1, 3, 4 and 5 and A-A-53848

Compound: All materials meet the recommended safe levels as specified in the United States FDA Code of Federal Regulations, Title 21, Food and Drug Administration.

These products have been used in medical applications for over thirty years and thus falls under a “Generally Recognized As Being Safe” (GRAS) classification.

Material 21CFR Section

Natural Rubber Latex 177.2600

Vulcanization Accelerator 177.2600

15.2 Chemical Safety Assessment:

No chemical safety assessment has been carried out for this substance/mixture by the supplier.

16. ADDITIONAL INFORMATION

16.1 Indication of changes/revision to SDS:

1. New format
2. Inclusion of EC Requirements
3. **Revision Date:** 09/16/2015

16.2 Abbreviations and acronyms:

None

16.3 Key literature references and sources for data

1. Guidance on the Compilation of Safety Data Sheets; European Chemical Agency (ECHA); Version 2.1, February 2014
2. Regulation (EC) No 1272/2008 of the European Parliament and the Council of 16 December 2008 on classification, labelling, and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

16.4 Classification and procedure used to derive classification for mixtures according to Regulation (EC) 1272/2008[CLP]:

None

Some of the information presented and conclusions drawn herein are from sources other than direct test data on the product itself. The information in the SDS was obtained from sources that we believe are reliable and is believed to be valid and accurate. American Orthodontics, however, makes no warranty, express or implied, regarding its correctness of the information provided. The conditions or method of handling, storage, use and disposal of the product are beyond our control and may be beyond our knowledge. For this and other reasons, we do not assume responsibility and expressly disclaim liability for loss, damage, or expense arising out of or in any way connected with the handling, storage, use or disposal of the product. If the product is used as a component in another product or used in a way other than recommended by the Company, this SDS information may not be applicable. **Reasonable safety precautions must always be observed.**