Contact Lenses

The United States Adopted Name (USAN) Council became involved in polymer nomenclature in 1971 and formulated the first rules for nonproprietary names to contact lens materials in 1972. Based on polymer technology at that time and information from the U.S. Food and Drug Administration, lens polymers were divided into the filcon (hydrophilic) and the focon (hydrophobic) series. These rules update the initial guidelines incorporating many of the guiding principles under the rules for coining pharmaceutical names.

General Rules

A nonproprietary name for a contact lens material should be useful primarily to practitioners, specifically ophthalmologists, optometrists, opticians, educators and other eye care and eye care device specialists. Please take note of the following general rules:

1. For nomenclature purposes, contact lens materials are divided into hydrophilic and hydrophobic groups, depending on their water content. Materials with water content greater than or equal to 10% by weight at ambient temperature are assigned "-filcon" names. The "-focon" stem is assigned to hydrophobic lens materials with water content less than 10%.
2. In addition to water content, nomenclature for contact lens materials depends primarily on the polymeric composition, i.e., the repeating monomer units comprising the lens material. These repeating units include linear monomers. However, initiators, catalysts, fillers, chemically or physically bound or entrapped color additives, UV absorbers and other additions are excluded in establishing the polymer composition for nomenclature purposes.
3. The first member of a series is assigned a unique nonproprietary name containing the proper -filcon or -focon suffix stem. A separate capital letter "A" is added after each parent designation. Subsequent designations for polymers consisting of identical monomers receive the same parent name but a different appended letter (B, C and D, etc.). These letters are needed to differentiate between polymers of identical monomeric units but with different ratios of units that have different physiochemical properties, as determined by water content, oxygen permeability [Dk] value, specific gravity, refractive index, surface charge, wetting angle, elasticity and toughness of the lens.
4. A contact lens material having the same repeating monomers as a named substance but made by a different manufacturing process (e.g., lathe-cut versus cast-molded) will not receive a new USAN if the lens material has the same water content and oxygen permeability as the initially
5. Because water content and oxygen permeability values affect assignment of a name, experimental error must be included for both to indicate the precision of the measurement. In the USAN Council’s opinion, if they do not indicate a statistically significant difference from existing compounds, then the USAN Council may choose not to assign a USAN to the material.

6. CAS numbers must be submitted for each monomer as well as the entire polymer. If submitting for a hybrid material consisting of 2 or more polymer components, CAS numbers must be supplied for both components and every monomer.

7. Corrections and revisions to formulas and structures are to be submitted electronically in MS Word or Chemdraw files.

8. The addition of a surface treatment to an existing lens material that has been assigned a USAN will not result in assignment of a new USAN.

9. A new USAN will not be assigned to contact lens material containing either chemically bound or physically entrapped color additives. The USAN Council defers to FDA labeling rules to identify color additives used to make tinted lenses.

10. A new USAN will not be assigned to contact lens materials containing either chemically bound or physically entrapped ultraviolet absorbers. The USAN Council defers to the FDA labeling rules to identify UV absorber used to make these lenses.

11. A revision of the guiding principles regarding the publication timeframe of USAN for contact lens materials was approved by the USAN Council at their Feb. 10, 2003 meeting. Therefore, information on USAN for contact lens materials will not be published until after the manufacturer files a premarket approval (PMA) application with the FDA Center for Devices and Radiological Health and this notice appears in the database.

12. Please note that contact lens materials are not assigned nonproprietary names by the World Health Organization International Nonproprietary Names Expert Group. Names for contact lens materials have USAN status only.

13. Deferred negotiations:

   a. The USAN Council Secretariat will defer an ongoing negotiation for 6 months, plus 1 additional 3-month extension upon request of the manufacturer. If the USAN Council has selected a name candidate and recommended this name to the manufacturer, the maximum deferral is one 6-month period.

   b. The negotiation will be canceled after the maximum 9-month deferral has lapsed.

   c. If the negotiation is to be reopened at a later time, it will be treated as a new application and will receive a new USAN file. The manufacturer will be expected to submit a new USAN application form, update the background information and submit the appropriate fee.

      1. Identical negotiations submitted by 2 or more manufacturers will be conducted in accordance
with the Council's practice of maintaining confidentiality. The applicants involved will not be notified of the multiple sources of the submission. However, the name selected by the USAN Council will need to be accepted by each manufacturer involved in the negotiation process.

Guiding Principles for Coining Contact Lens Names

Since the stems of contact lenses are already established—either a "-filcon" or "-focon" stem—it is mainly the prefix that presents a challenge. Please use the following guiding principles when considering a prefix:

1. A nonproprietary name for a contact lens material should be useful primarily to health care practitioners and eye care specialists.
   
a. The primary criterion for judging usefulness is suitability, including safety for use in routine relevant communications throughout the United States.

b. The second criterion is suitability for use in educational programs and in scientific and lay publications.

c. Although contact lenses do not receive an INN, the third criterion is suitability for use internationally and translation into different languages.

   1. Attributes that contribute to usefulness are simplicity (brevity and ease of pronunciation), euphony and ready recognition and recall.

a. A contact lens prefix should be no more than 3 syllables. The contact lens name thus should have no more than 5 syllables.

   1. Hybrid lenses only may have more than 1 word in the name. Only hybrid lens names may contain hyphens.

   2. Because of the international exchange of information, specific guidelines have been formulated to ensure appropriate translation of nonproprietary names into other languages. The following rules of preferred spelling should be used when coining USAN designations for contact lenses:

a. The letter "f" should be used instead of "ph"

b. The letter "t" should be used instead of "th"

c. The letter "e" should be used instead of "ae" or "oe"
d. The letter "i" should be used instead of "y"

e. "ar," "rac," "lev," "dex," or "es" are reserved for stereochemical configurations and should not be used for contact lenses

1. Additionally, these letter combinations are restricted until further notice. Please avoid the following prefixes:

a. The beginning letter combination of "me"

b. The beginning letter combination of "str"

c. "z" or "x" as a beginning letter

1. A name should reflect characteristics and relationships that will be of practical use to the users. However, this does not allow for prefixes that would proffer an unfair competitive or marketing advantage. For example, names that seek to claim the product is the "greatest," "No. 1," "ecologically-friendly," "environmentally friendly," "nature-friendly" or imply a "professional/expert" endorsement over other products; or names that connote light, sun, illumination, water and other various environmental attributes and properties either in English or in other languages are not allowed and will not be accepted by the USAN Council.

2. Numbers cannot be part of the contact lens prefix (digits, spelled-out numbers, numeric prefixes or numbers in other languages are no longer accepted).

3. A name should be free from conflict with other nonproprietary names and with established trademarks and should be neither confusing nor misleading.