

**DOCUMENTS CONTAINING TECHNICAL SUMMARY OF THE MEDICAL
DEVICES**

SEED Co., Ltd.

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Product: **SEED MonthlyPure moisture for Astigmatism**

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No.	Heading	Content														
1	Description of medical devices															
1.1	Description of medical devices	<p>SEED MonthlyPure moisture for Astigmatism shows aspherical bifocal lens design and is available as an astigmatic (toric) lens for single vision. These lenses are daily wear, monthly replacement disposable soft contact lens and wear lenses only while awake and remove them before sleeping. After removing your lenses from your eyes, please follow the proper lens care regimen by using chemical disinfection system.</p> <p>This material is a copolymer of 2-Hydroxyethyl methacrylate, Methacrylamidopropyl trimethylammonium chloride, 2-Methacryloyloxyethyl succinic acid and Methylmethacrylate cross-linked with Ethylene glycol dimethacrylate, initiated by Azobisisobutyronitrile. An UV absorbing compound 2-(2'-Hydroxy-5'-methacryloxyethylphenyl)-2H-benzotriazole is incorporated into the lens polymer. All disposable soft contact lens with visible tint are tinted with blue using Phthalocyanine blue to make the lens more visible for handling.</p> <p>SEED MonthlyPure moisture for Astigmatism is a design of toric lens and it is indicated for the correction of vision in phakic persons with non-diseased eyes with refractive ametropia (myopia or hyperopia) and astigmatism. It also helps protect against transmission of harmful UV radiation to the cornea and into the eye.</p> <p>• Dimension of lenses</p> <table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th style="text-align: center;">Name of parts</th> <th style="text-align: center;">Dimension</th> </tr> </thead> <tbody> <tr> <td>Base curve</td> <td>6.00 to 12.00 mm</td> </tr> <tr> <td>Diameter</td> <td>11.00 to 15.00 mm</td> </tr> <tr> <td>Center thickness</td> <td>0.02 to 1.00 mm</td> </tr> <tr> <td>Spherical power</td> <td>+5.00 to -25.00D</td> </tr> <tr> <td>Cylindrical power</td> <td>-0.25 to -5.00 D</td> </tr> <tr> <td>Cylinder axis</td> <td>0°to 180°</td> </tr> </tbody> </table>	Name of parts	Dimension	Base curve	6.00 to 12.00 mm	Diameter	11.00 to 15.00 mm	Center thickness	0.02 to 1.00 mm	Spherical power	+5.00 to -25.00D	Cylindrical power	-0.25 to -5.00 D	Cylinder axis	0°to 180°
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• Physical properties

Items	Specification	Unit
Luminous transmittance	> 93	%
Oxygen permeability	24 to 36	*
Refractive index	1.401 to 1.411	—
Water content	56 to 60	%

* $\times 10^{-11}(\text{cm}^2/\text{sec})(\text{mL}(\text{O}_2)/(\text{mL} \cdot \text{mmHg}))$

• Chemical properties

Leaching amount of ingredients (Sample weight/Extract vehicle: Methanol = 1g/10mL)		
Ingredient	Specification	Unit
2-hydroxyethyl methacrylate	2 or less	μg/mL
Methacrylamidopropyl trimethylammonium chloride	1 or less	
2-Methacryloyloxyethyl succinic acid	1 or less	
Methylmethacrylate	4 or less	
Ethylene glycol dimethacrylate	0.5 or less	
2-(2'-Hydroxy-5'-methacryloxyethylphenyl)-2H-benzotriazole	0.2 or less	
Phthalocyanine blue	0.5 or less	

Leaching amount of extractables		
Extraction vehicle	Specification	Unit
Pure water	4 or less	%
Hexane	2 or less	

Ingredients and additives

• Ingredients

Chemical name	Function
2-hydroxyethyl methacrylate	Monomer ingredient
Methacrylamidopropyl trimethylammonium chloride	Monomer ingredient
2-Methacryloyloxyethyl succinic acid	Monomer ingredient
Methylmethacrylate	Monomer ingredient
Ethylene glycol dimethacrylate	Cross-linker

• Other additives

(for the total weight of the above ingredients)

Chemical name	Function
2,2'-Azobisisobutyronitrile	Polymerization initiator
2-(2'-Hydroxy-5'-methacryloxyethylphenyl)-2H-benzotriazole	UV absorbent
Phthalocyanine blue	Colorant

SEED MonthlyPure moisture for Astigmatism is a tinted soft contact lens which contains a color additive (phthalocyanine blue), or colorless one which does not contain color additives.

Packing solution

Ingredients	Function
Sodium chloride	Tonicity agent
Boric acid	Buffering agent
Sodium borate decahydrate	Buffering agent
Disodium dihydrogen ethylenediamineteraacetate dihydrate	Chelating agent
Alginic acid	Moisturizing agent
Polyoxyethylene (196) polyoxypropylene (67) glycol	Surfactant agent
Purified water	-

Packaging materials

Blister pack	
Blister pack components	Ingredient name
Casing body	Polypropylene
Lid	Aluminum + Polyethylene terephthalate

1.2	List of accessories and fittings	N/A
1.3	Purposes/Instruction	Correction of vision in phakic persons with non-diseased eyes with refractive ametropia (myopia or hyperopia) and astigmatism, within the spherical power from +5.00~-25.00D and cylinder power from -0.25~-5.00D.
1.4	Instruction	SEED MonthlyPure moisture for Astigmatism is daily wear soft contact lens and it is intended for a correction of vision in

phakic persons with non-diseased eyes with refractive ametropia (myopia or hyperopia) and astigmatism, within the spherical power from +5.00~-25.00D and cylinder power from -0.25~-5.00D. Monthly replacement lenses must strictly be replaced a month after opening. Please wear lenses only while awake and remove them before sleeping. For monthly replacement lenses, after removing your lenses from your eyes, please follow the proper lens care regimen by using either chemical or heat disinfection system.

• Instructions on handling lenses

1. Keep your fingernails short and smooth to avoid scratching your eye or your lenses.
2. Always wash your hands with soap and rinse carefully before handling your lenses. Lenses may become contaminated if you do not wash your hands properly.
3. Always handle your lenses somewhere that is well-lit, clean and sterile.
4. Your contact lenses may become damaged depending on how you handle them.

• Checking the lenses and blister packaging

1. Check which lenses are for the right eye and which lenses are for the left eye.
2. Check if there is anything wrong with the lenses and blister packaging before opening. If there is anything wrong, for example, if there is any damage or leakage, do not open and contact the point of purchase.

• Removing the lenses from the blister packaging

1. Break off the blister packaging by folding down the sides.
2. Remove the label, keeping a firm hold on the blister packaging and the label. When doing this, be careful not to cut your hand on the blister packaging or label. Also note that the lens storage solution inside the blister packaging may splash upon removal of the label.
3. Remove the lens from the blister packaging by sticking the lens to the pad of your index finger. Alternatively, turn the blister packaging upside down and empty the lens together with the storage solution into the palm of your hand. Take care, because if you dig your nail into the lens or scrape the

lens on the rim of the blister packaging on removal, the lens may be damaged.

•Checking the lenses

1. Hold the edges of the lens from the side and gently move up and down to remove the liquid.
2. Put the concave surface on the index finger of your dominant hand and check which the right and wrong sides of the lens are. A lens has a right side and a wrong side. Ensure that the lens is not inside out. Place the lens on your right index finger and verify the shape. (fig. 1 and 2)

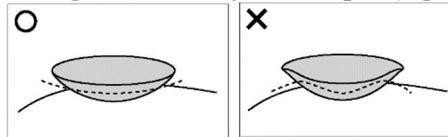


fig. 1

fig. 2

3. Check if there is anything wrong with the lens, for example, deformation, discolouration, foreign matter, damage, scratches and dirt, and do not wear the lens if there is anything wrong with it.

•Inserting lenses

1. Put the lens onto your finger, and, with the middle finger of the same hand, pull down your lower eyelid. With the index finger of your other hand, pull up your top eyelid. If you put your finger on your eyelash line, you can open your eyes wide.
2. Look in the mirror so that your cornea comes into the center of your eye. Slowly bring the lens close to your eye and put it gently in place, still looking in the mirror. If you glance upwards when doing this, the lens will not be properly centered on your cornea.
3. When you have placed the lens properly on the cornea, slowly remove your index finger and then remove your fingers which had been holding your eyelids, starting with the bottom lid first and then the top lid. If you remove your fingers quickly and blink your eye shut, the lens may change position or fall out.
4. Check in the mirror that the lens is on top of your cornea and, covering the opposite eye with your hand, check your sight in your right and left eyes.
5. Follow the same procedure to fit the lens in your other eye.

• Removing the lenses

1. Check the position of the lens in the mirror.
2. Looking straight in the mirror, hold the mirror upward and look at the eye reflected in the mirror.
3. With your middle finger, slowly pull your lower lid down, and with the index finger of the same hand, move the lens down from the cornea.
4. In this position, use the pads of your thumb and index finger to gently take hold of the bottom of the lens.

To avoid scratching your eye, take care not to touch your eye directly with the tips of your fingers or your fingernails. If you are unable to remove the lens, blink several times and then try again.

• Lens care

1. Since protein and lipids present in your tears will become attached to the surface of your contact lenses as you wear them, it is important to follow the lens care regimen for washing, rinsing, disinfecting and storing your lenses. Failure to follow the lens care regimen will result in lenses becoming dirty and may result in serious eye disorders or eye infections.
2. Use lens care products suitable for soft contact lenses. You can use a chemical disinfection system.
3. Use lens care products according to their Instructions for Use.
4. The extent to which lenses become dirty varies from person to person. If your lenses tend to become dirty, try rubbing your lenses with a cleaning solution or using a protein removal liquid. If the dirt will not come off, even if you have not worn the lens for a full one month, replace it with a new one.
5. When following the lens care regimen, use a plug or contact lens sink mat to prevent the lenses from being washed away.
6. Empty and clean contact lens cases with digital rubbing using fresh, sterile disinfecting solutions/contact lens cleaner (never use water), followed by rinsing with fresh,

		<p>sterile disinfecting solutions (never use water) and wiping the lens cases with fresh, clean tissue is recommended.</p> <p>7. Replace your lens case roughly every one or two months. Prolonged use will result in a proliferation of bacteria due to the build-up of dirt, rendering disinfection inadequate and leading to eye disorders or infections.</p> <p>8. Do not change the contact lens care system without consulting an eye care professional.</p>
1.5	Contraindications	<p>1. Medical conditions Acute and sub-acute inflammation of the anterior eye, Eye infection, Uveitis, Reduced corneal sensitivity, Dry eye or lacrimal apparatus disease to an extent that poses a problem for wearing lenses, Eyelid disorder, Allergy to an extent that affects the wearing of lenses, Other diseases which would hinder use of contact lenses.</p> <p>2. Environmental conditions Anyone living or working in dry environments. Anyone living or working in an environment where dust or chemicals are likely to enter the eye.</p> <p>3. Personal qualities Anyone who cannot follow the recommendations of their eye care practitioner, anyone who cannot use contact lenses properly, anyone who fails to attend regular check-ups, anyone who cannot follow the hygiene routine required to wear contact lenses, anyone who has an extremely nervous disposition.</p>
1.6	Warnings and cautions	<p>WARNINGS</p> <ul style="list-style-type: none"> • Even when used properly, wearing contact lenses may cause eye disorders such as the following, and if left untreated, these eye disorders may become serious or may result in loss of sight. To wear your contact lenses safely, be sure to read this Instructions for Use carefully and to follow the instructions of your eye care practitioner and the proper methods for handling contact lenses. <p>Example for eye disorders</p> <ul style="list-style-type: none"> • Corneal edema • Corneal ulcer • Corneal infiltration • Corneal epithelial erosion • Keratitis (including infectious keratitis) • Conjunctivitis (including giant

papillary conjunctivitis) • Possibility of speeding up reduction in corneal endothelial cells • Possibility of changing the shape of the cornea

- Lenses may be damaged or become damaged. If you have inadvertently worn a lens which is damaged or otherwise faulty, or if a lens becomes damaged while you are wearing it, remove the lens immediately and consult your eye care practitioner immediately, regardless of whether you have any subjective symptoms.

PRECAUTIONS

- Be sure to read this Instructions for Use carefully before using your contact lenses, and if you are in any doubt about the terms or information contained herein, please consult your eye care practitioner for clarification before using the lenses.
 - Retain this Instructions for Use for future reference.
1. Avoid direct sunlight and avoid freezing, store at room temperature.
 2. Do not wear contact lenses that are damaged.
 3. Do not use contact lenses past their expiration date.
 4. Do not wear contact lenses for longer than the recommended wearing period.
 5. Use contact lenses properly in accordance with recommended methods for handling contact lenses.
 6. Always attend regular contact lens check-ups.
 7. If you experience any problem at all, consult your eye care practitioner immediately.
 8. Always insert lenses promptly after opening, as lenses may become contaminated. If you do not use the lenses straight away, store them according to the instructions of the lens care products.
 9. Avoid rubbing your eyes while wearing lenses, as this may result in scratches to your eyes or displacement of the lenses.
 10. Do not mix up right and left lenses, as doing so may result in impairment of vision and discomfort.
 11. Make sure you have appropriate glasses to use in case you are unable to wear your contact lenses due to the condition of your eyes or for other reasons, or after you have worn your lenses for the wearing period recommended by your eye care

practitioner. Continuing to wear your contact lenses regardless may cause eye disorders or other problems.

12. Do not wear contact lenses for driving or operating machinery until you are used to them.
13. If a lens becomes decentered or falls out while you are driving or operating machinery, stop driving or operating the machinery promptly after making sure that it is safe to do so.
14. Follow the instructions of your eye care practitioner if using eye drops while wearing contact lenses.
15. Do not allow cosmetics, pharmaceuticals or other substances to come into contact with your lenses. If cosmetics (eyeliner, cleansing products, etc.) become attached to your lenses through your tears, this may result in discolouration or deterioration in the quality of the lenses, making them unusable.
16. When your eyes are exposed to strong wind (when riding a motorbike or bicycle, skiing, in strong wind, etc.), always use some kind of protection against the wind such as sunglasses or goggles. Failure to do so may result in uncomfortably dry lenses or the loss of a lens.
17. Consult the eye care professional about wearing lenses during sporting and water related activities. Exposure to water while wearing contact lenses in activities such as swimming, water skiing, and hot tubs may increase the risk of ocular infection, including but not limited to Acanthamoeba keratitis.
18. Never allow contact lenses to come into contact with non-sterile liquids (including tap water and saliva) as microbial contamination can occur, which may lead to permanent eye damage.
19. Always remember to take spare lenses and glasses with you when you go on a trip, etc. in case you lose or damage your lenses.
20. Never wear someone else's lenses or give your lenses to someone else, as this may result in problems such as use of the wrong lenses or eye disorders.
21. Do not wear on top of other lenses, as doing so may result in problems such as eye disorders.
22. Do not use anything other than lens care products (for example, tap water) to care for your lenses. Also do not use a

		<p>mixture of different types of lens care products, as this may result in eye disorders or cause deformation of the lenses, making them unusable.</p> <p>23. Users who find it difficult to insert or remove contact lenses themselves such as children or elderly people should consult their eye care practitioner for appropriate guidance.</p> <p>24. Pregnant women may experience some difficulty wearing contact lenses that were once comfortable or experience a temporary deterioration in their vision, and they should seek appropriate guidance where necessary.</p> <p>25. People who suffer with allergies may be more prone to diseases of the eyes and skin than other users, and they should seek appropriate guidance where necessary.</p> <p>26. Use of contact lenses may be affected by illness, pregnancy, childbirth, use of medications, physical condition, eye conditions, and living environment. The conditions in which you wear contact lenses may also change after you have started wearing contact lenses. Always seek appropriate guidance where necessary.</p> <p>27. Always check the expiry and disinfect the contact lenses before wearing if they have not been worn for a length of time.</p> <p>28. Consult your eye care professional if you wish to change the lens type or parameters.</p>						
1.7	Possible bad effects	<p>—Until you are used to your lenses—</p> <p>Until you are used to your lenses, you may experience symptoms such as the following. Symptoms vary from person to person but will gradually diminish as you become used to your lenses. However, if you experience acute symptoms or if symptoms persist, stop wearing your lenses and promptly consult your eye care practitioner.</p> <ul style="list-style-type: none"> • Slight discomfort • Slightly bloodshot eyes • Unstable vision • Watering eyes • Itchy eyes 						
2	Information about products sold in various countries (if any)							
	<table border="1" data-bbox="321 1667 1398 1839"> <thead> <tr> <th data-bbox="321 1667 553 1709">Reference agency</th> <th data-bbox="553 1667 1019 1709">Product Name (Registration Name)</th> <th data-bbox="1019 1667 1398 1709">Registration status and date</th> </tr> </thead> <tbody> <tr> <td data-bbox="321 1709 553 1839">European Union</td> <td data-bbox="553 1709 1019 1839">SD02H-HUV</td> <td data-bbox="1019 1709 1398 1839">Registration No. JP20/819943412 approved on December 2, 2020</td> </tr> </tbody> </table>		Reference agency	Product Name (Registration Name)	Registration status and date	European Union	SD02H-HUV	Registration No. JP20/819943412 approved on December 2, 2020
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3	Instruction which has been registered in other countries (if any)			
	Reference agency	Product Name (Registration Name)	Issued Date	Registered Indication
	European Union	SD02H-HUV	December 2, 2020	Correct of vision
4	Information about the noticeable safety/operation of medical devices products			
	<p>There is no report on death or severe impairment all over the world related to the use of SEED MonthlyPure moisture for Astigmatism when the product is used correctly as the product owner indicates. There has been no recall/ post-marketing adjustment (FSCA) all over the world until now.</p> <p>The product contains no cell, animal or human tissue or their derivatives used as not alive; contains no cell, tissues or derivatives from micro-organism or recombination.</p>			

SEED Co., Ltd. - undertake that the information provided is truthful and we will take legal responsibility for such information.

Legal representative of product owner



URAKABE Masahiro, President & CEO