Frequently asked Questions and answers.

1. What are the differences and benefits between Spherasorb™ and standard Soda Lime?

Spherasorb is a unique medical grade Soda Lime, with a unique chemical formulation and spherical shape. The differences to standard Soda Limes are:

- Contains less Sodium Hydroxide (1.5 %) than standard Soda Lime (3%).
- Contains Sodium-Zeolite to reduce the risk of drying out, standard Soda Limes do not. Spherasorb has only ever been dried out in deliberate studies.
- The Sodium Zeolite provides pH buffering, to allow a high CO_2 capacity even with a lower level of Sodium Hydroxide than standard Soda Limes.
- Spherical shape, to allow hexagonal close packing, for efficient gas flow and absorption.
- Reduces the risk of reaction with volatile anaesthetic agents to negligible levels while having much less NaOH and maintaining one of the highest CO_2 capacities.

2. What are the differences and benefits between LoFloSorb™ and standard Soda Lime?

LoFloSorb is a unique medical grade, Alkali-hydroxide-free absorbent with a unique chemical formulation and spherical shape. The differences to standard Soda Limes are:

- Contains no Alkali Hydroxides (no Sodium Hydroxide, Potassium Hydroxide or Lithium Hydroxide).
- There is nothing within LoFloSorb's chemical formulation that will cause any significant reaction with volatile anaesthetic agents even if it is completely dry.
- LoFloSorb has a higher porosity than standard Soda Lime and absorbs CO_2 by a direct reaction with Calcium Hydroxide.
- Spherical shape, to allow hexagonal close packing, for efficient gas flow and absorption.
- Like other alkali-hydroxide-free absorbents, LoFloSorb has a lower CO_2 capacity than conventional Soda Lime or Spherasorb.
- LoFloSorb gas a stable colour change.

3. Why don't Intersurgical absorbents contain Calcium Chloride?

Calcium Chloride ($CaCl_2$) is used in some absorbents to prevent drying out (in the same way that Zeolite is used in Spherasorb™).

However, $CaCl_2$ is a deliquescent humectant (it will absorb moisture from the air until it dissolves in the absorbed water). Therefore, absorbents that contain $CaCl_2$ also contain additional hidden water of crystallisation that is not detectable when tested to the United States Pharmacopoeia or British Pharmacopoeia for moisture content.

The additional water of crystallisation caused by $CaCl_2$, can cause moisture problems, clumping and channelling during use. This can cause premature exhaustion and unreliable/variable working times. Therefore, Intersurgical absorbents do not contain $CaCl_2$.

4. How long does the CO_2 absorbent last?

The length of use of any CO_2 depends totally on the conditions of use.

All of the following factors influence the length of use:

- **The absorber size and configuration**: Large single absorbers last longer and are more efficient than small single absorbers. Double absorbers can employ cartridge rotation and therefore achieve maximum capacity.
- **Fresh gas flow**: Low fresh gas flows equals less consumption of the volatile anaesthetic and so offers a large cost saving. However, at low flow, more of the patient CO_2 passes through the absorbent and therefore it is exhausted at a faster rate.
- **Minute volume (tidal volume x breaths per minute)**: Minute volume factors influence the residence time of gas within the absorber. Higher minute volumes reduce the available CO_2 capacity and so reduce usage times.
- **I:E ratio**: I:E also infuences the residence time and so affects usage times.
- **Patient CO_2 generation**: Larger patients produce more CO_2 and therefore the absorbent is consumed in less time.
- **Type of operation**: For example, laparoscopy increases patient expired CO_2 levels and the absorbent is consumed at a faster rate.

Unless the conditions of use are known, then the usage time cannot be predicted.

5. Is colour change a reliable indicator of exhaustion and when to change the CO_2 absorbent?

As the CO_2 absorbent becomes exhausted, the drop in pH causes a colour change of the pH sensitive indicator dye. However, moisture levels affect the strength and spread of colour change. In turn, moisture levels are affected by many factors, for example, fresh gas flow rate, absorber size, patient CO_2 output, minute volume, I:E, type of operation and in particular laparoscopy. For this reason, with all absorbents, colour change is only an approximate indicator of exhaustion and can be misleading.

$FiCO_2$ monitoring gives an accurate, advanced warning of exhaustion.

When inspired $FiCO_2$ is just seen to rise off the base line (usually detectable around 0.05 %), there are still a number of hours before clinically significant $FiCO_2$ is reached.

This is usually $FiCO_2$ 0.3 % to 0.5 %, depending on the clinical decision. (Conversion: 0.1 % is approximately 1 mmhg). Therefore, monitoring inspired $FiCO_2$ gives an accurate advanced indication that the absorbent is approaching exhaustion and should be changed at the next opportunity.

6. Why does the exhausted colour fade and/or disappear overnight?

Using white to violet Soda Lime as an example:

Soda Lime contains a pH sensitive dye called Ethyl Violet. Above pH10, the ET is colourless, below pH10, the ET is violet. Fresh Soda Lime has a high pH equal to, or close to pH14 and so the Ethyl Violet is colourless.

When a region of the Soda Lime becomes exhausted, the pH falls. This is because the Sodium Hydroxide level drops and also Calcium Hydroxide is mostly depleted. When the pH has fallen below pH10, the Ethyl Violet turns violet.

When the Soda Lime is no longer in use and not being challenged by CO_2, the chemical processes allow a slow regeneration of Sodium Hydroxide. After a period of time (depending on the moisture content), the Sodium Hydroxide regenerates just enough for the pH to once again exceed pH10. At this point, the Ethyl Violet returns to its colourless state.

This fading of colour is not regeneration of the Soda Lime. Re-use, will rapidly consume the tiny amount of regenerated Sodium Hydroxide, the pH will rapidly drop below pH10 again and the violet colour will return. If the Soda Lime was already exhausted, then $FiCO_2$ will rise rapidly.

In this way, failing to discard exhausted Soda Lime and subsequent colour regeneration, can lead to exhausted product being mistakenly re-used, resulting in the incorrect conclusion that the Soda Lime is not functioning and had a usage time of only a few minutes. For this reason, absorbents should be discarded as soon as exhaustion is determined.

7. Can CO_2 absorbents be regenerated?

No, CO_2 absorbents cannot be regenerated in any practical way.

Colour regeneration is not regeneration of its CO_2 absorption.

A major component of exhausted absorbents are carbonates, if the exhausted absorbent is heated to over 1000°C , it is theoretically possible to convert these carbonates to oxides. These oxides can then be hydrated back into the hydroxides, which can then absorb CO_2.

However, the above chemical regeneration process will result in loss of physical structure and the components would have to be re-processed into granules to allow use within an anaesthetic system. For this reason, the huge energy requirements, logistics of returning product to the manufacturer and additional re-processing requirements, prevents environmentally or commercially viable regeneration.

8. How does LoFloSorb™ absorb CO_2 without any alkali hydroxide?

In all absorbents, the CO_2 is ultimately converted into Calcium Carbonate. CO_2 will react directly with Calcium Hydroxide to form Calcium Carbonate. However, in Soda Lime, this direct reaction is too slow. Sodium Hydroxide enables an intermediate catalytic reaction step to speed up the conversion to Calcium Carbonate.

LoFloSorb has a higher porosity than standard Soda Limes or Spherasorb™. This higher porosity of LoFloSorb enables the direct reaction between CO_2 and Calcium Hydroxide to proceed rapidly enough that the catalytic step is not required and so Sodium Hydroxide is not needed.

However, it must be remembered that the absence of this catalytic step results in an earlier exhaustion of LoFloSorb and other alkali-hydroxide-free absorbents, compared to standard Soda Limes and Spherasorb™.

9. How does LoFloSorb™ achieve a stable colour change?

The colour change of LoFloSorb occurs in the same way as Soda Lime. When exhaustion approaches, the pH drops and the Ethyl Violet changes to violet.

However, LoFloSorb does not contain Sodium Hydroxide or any other alkali hydroxide. Therefore, LoFloSorb has no chemical mechanism available to produce a return to a higher pH. Therefore, colour regeneration does not occur.

10. Why does moisture build up, especially during low flow anaesthesia?

When one molecule of CO_2 is chemically absorbed, one molecule of H_2O is generated. This is regardless of the absorbent being used or the chemical formulation.

Lower fresh flows result in a larger proportion of expired gas passing through the absorbent, therefore, more of the patient's CO_2 passing through the absorbent. Therefore, with lower fresh flows, the Soda Lime is working harder and more H_2O is generated per unit time. Furthermore, at lower fresh flows the larger proportion of expired gas passing through the absorbent results in less venting through the APL valve. Therefore, at lower fresh gas flows, the moisture and humidity cannot escape from the anaesthetic system in the same way, so a greater volume/time of H_2O is retained within the system. This H_2O builds up in the downstream part of the absorber, within the anaesthetic machine and breathing system. The degree of H_2O build up in these different areas depends on the size of the absorber and other factors.

Laparoscopy results in higher levels of expired CO_2 therefore more moisture is generated.

11. What is the recommended disposal method for CO_2 absorbents?

The following information is a guideline only. Disposal of waste Absorbents must be in accordance with local authority regulations, following a risk analysis by the user.

Spherasorb™ and LoFoSorb™, or most other types of CO_2 absorbent, do not contain any toxic materials and xontain less than 4% Sodium Hydroxide. Therefore, they are not classified as a hazardous material. Most types of CO_2 absorbents, when exhausted (even alkali-hydroxide-free), will probably still contain slightly above 10% of Calcium Hydroxide and slightly above 1%, Sodium Hydroxide (in the case of Soda Lime). Therefore, most types of waste absorbents **that have not been clinically used**, would require disposal according to a chemical consisting of, or containing above, the allowed limits of Calcium Hydroxide and Sodium Hydroxide (depending on the type).

After clinical use of a CO_2 absorbent, consideration should be given to the consequence of its clinical use, especially with infectious patients (the history of patients will not always be known). The instructions for use of anaesthetic machines sometimes advise that reusable parts of the system are autoclaved, even when filters are used at the Y-piece or on the machine inspiratory and expiratory ports. Furthermore, used Soda Lime, even when remaining significantly alkaline, cannot be guaranteed to present an antibacterial environment.

Therefore, considering the above, Intersurgical advise that following clinical use of CO_2 absorbent, the user should conduct a risk assessment to assess the potential for it being waste whose collection and disposal is subject to special requirements in order to prevent infection.

Following this, clinically used CO_2 absorbents should be treated at source with minimal handling; this being incineration within a mixture of other clinical waste. In this way, pathogens are destroyed and any residual hydroxides are reduced to oxides and will be further dispersed within the other ash material.

12. Are there transport restrictions for CO_2 absorbents?

Most of the common CO_2 absorbents, including Intersurgical absorbents, contain less than 4 % Sodium Hydroxide.

Soda Lime/absorbents with less than 4% Sodium Hydroxide are not classified under the UN list of hazardous substances, Therefore under special provision 62, they are exempt from the requirements of the ADR (ADR European Agreement concerning the International Carriage of Dangerous Goods by Road) and the IATA (International Air Transport Association). Therefore there is no restriction for transport by road, rail or air.

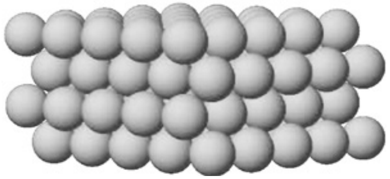
13. What is the benefit of a spherical shape?

While the chemical formulation of CO_2 absorbents is important for a high CO_2 capacity, in order to make use of this available capacity, the full capacity, the challenge gas must not channel through the absorbent. Instead the gas must pass through the absorbent evenly and efficiently to allow optimum surface contact.

In order to achieve optimum gas flow and absorption efficiency, the essential requirements are to:

- Achieve a good even packing of granules within the absorber.
- A uniform resistance to flow across the absorber bed.

Optimum packing is acheived by 'hexagonal close packing' of spheres of the same size.



Hexagonal close packing

Spherasorb™
Comprised of 3.5 mm spheres and achieves a close approach to Hexagonal close packing.

14. Are Intersurgical CO_2 absorbents compatible with all volatile anaesthetics and can they be used at minimal/basal fresh gas flows?

Yes, Intersurgical CO_2 absorbents meet all the requirements of the United States Pharmacopoeia. Intersurgical conducts its own research, development and manufacturing and. Our development, quality control and manufacturing are certificated to:

- ISO 9001: Standard control module for any industry.
- ISO 13485: Control module for Medical Device Industry.
- ISO 14001: Control module for Environmental Management.

Additionally, Spherasorb™ and LoFloSorb™ have been developed and formulated for additional safety with volatile anaesthetics.

Over the years, millions of kilos of Intersurgical absorbents have been sold and used in almost every country in the world. Intersurgical CO_2 absorbents have been used on all the common anaesthetic machines, with all the common volatile anaesthetics, from minimal fresh gas flow upwards.

15. What causes reaction with volatile anaesthetics?

Soda Lime contains alkali hydroxides. Historically various brands have contained either Potassium Hydroxide (KOH), or Sodium Hydroxide (NaOH), or a mixture of these two. Today, most commonly used standard Soda Limes contain 3% NaOH and KOH is not used. Alkali hydroxides are strong aggressive chemicals that provide a catalytic reaction to speed up absorption of CO_2. KOH is a much stronger alkali hydroxide than NaOH.

CO_2 absorbents within the anaesthetic machine absorber come into intimate contact with volatile anaesthetic vapour within the breathing circuit. Under normal circumstances and the vast majority of cases, there is no interaction between the Alkali hydroxides and the volatile anaesthetic.

Fresh Soda Limes typically contain 13–17% water. If the Soda Lime is allowed to become very dry by leaving high flows of fresh gas/oxygen running during long periods of non-use), there is a potential for reaction between the alkali hydroxide and the volatile anaesthetic when the next procedure begins.

KOH containing absorbents present a far greater potential for these unwanted reactions because they are more sensitive to moisture loss, can lead to higher levels of anaesthetic breakdown products, considerably higher temperatures, hydrogen gas and fires.

NaOH containing absorbents have to be much drier for any reaction to occur and if it does occur (less than 1.5% water content) and even if it does occur the level of anaesthetic breakdown products is much less, temperatures are much less, hydrogen is not produced and fires have not occurred.

It is only very dry Soda Lime that will potentially react with volatile anaesthetics. For Soda Limes containing 3% or less of NaOH, maintaining absorbent moistures above 1.5% prevents any reaction from occurring.

16. Why do only very dry CO_2 absorbents react with volatile anaesthetics?

When the CO_2 absorbent is very dry (below 1.5% for NaOH containing Soda Lime), the volatile anaesthetic is physically absorbed within the micropores of the absorbent. This allows a reaction between the volatile anaesthetic and the alkali hydroxide.

This physical adsorption process is identified by an absence of the volatile anaesthetic emerging from the absorbent for the first few minutes from turning on the vaporiser. In other words, there is a delay in achieving the target inhaled anaesthetic concentration. Once the dry absorbent is saturated with the anaesthetic, the concentration emerging from the absorbent will rise to the target value.

If just a tiny amount of water is present within the absorbent (above just 1.5% for NaOH containing absorbents), the physical adsorption of the anaesthetic does not occur and therefore, there is no opportunity for a reaction between the volatile anaesthetic and the alkali hydroxide within the absorbent. This is seen by the anaesthetic emerging from the absorbent very quickly and the target concentration reached in only a short (normal) time. Also no breakdown products are detected.

17. What is the critical level of dryness of the CO_2 absorbent at which reactions with volatile anaesthetics can occur?

Independent studies and research at Intersurgical have shown the following:

- Potassium Hydroxide (KOH) containing absorbents are much more sensitive to moisture loss. Moisture contents below 5% have been shown to cause a reaction with volatile anaesthetics.
- Sodium Hydroxide (NaOH) containing absorbents are much less sensitive to moisture loss.
- Sodium Hydroxide (NaOH) containing absorbents need to be below 1.5% before a reaction with volatile anaesthetic occurs. In other words, the absorbent has to be much drier, which is more difficult to do and takes longer.

18. Does normal use of absorbents within anaesthesia cause drying out?

No, independent studies and research at Intersurgical have shown the following:

- Normal use of CO_2 absorbents during anaesthesia does not produce extreme levels of dryness, even when high fresh gas flows are used.
- Extreme drying out occurs when high flows of dry oxygen/fresh gas are left running through the absorbent for long periods when the anaesthetic machine is not in use.
- Reports of reaction between absorbents and volatile anaesthetics have been widely reported after a long period of non-use of the anaesthetic machine with the oxygen left running. It is no coincidence that many incidents have often occurred during the first case of the day, particularly on a Monday morning.

19. How can drying out of CO_2 absorbents be completely avoided?

Always turn off the oxygen/fresh gas flow at the end of the day.

If in any doubt about the history of an absorber/canister, discard it and replace with fresh product.

Follow the one-month rule, discard the absorbent after one month regardless of usage.

For further protection, use an absorbent that contains an additive to prevent complete drying out.

20. Is it really necessary to use absorbents without any alkali-hydroxide to ensure safety with volatile anaesthetics?

No, it is not necessary to completely avoid alkali hydroxide, if it is Sodium Hydroxide (NaOH) that is used. The critical factor is to avoid complete drying out. Reactions between volatile anaesthetics and (NaOH) containing CO_2 absorbent will only occur if the water (H_2O) content drops below 1.5 %. This is very difficult to do. Consider an absorbent with an additive that prevents complete drying out. This will ensure safety with volatile anaesthetics, even if the CO_2 absorbent contains a low level of NaOH. Maintaining a tiny level of NaOH is beneficial in achieving a high carbon dioxide capacity and so maintaining cost effectiveness.

21. What are the storage condition limits for CO_2 absorbents?

- The absorbent should be stored in a clean, dry environment, in its sealed container, away from direct sunlight.
- Once opened, the jerican/bag/canister should be used within one month.
- Ideally, CO_2 absorbents should be stored at room temperature. However, absorbents can be stored at temperatures between -20°C to +50°C, providing they are in the sealed container, away from sunlight.
- Always ensure the absorbent is at room temperature before use.
- Do not use the CO_2 absorbent after its expiry date has passed.
- Do not use the CO_2 absorbent if the jerican/bag/canister is damaged or the sealing is breached or missing.
- Do not use the CO_2 absorbent if there is any sign of discolouration or other unusual appearance.

22. Is there a maximum time by which an absorber should be discarded regardless of degree of use?

Following the one-month rule:

- Once a jerican/bag is opened, any remaining contents should be discarded after one month.
- Once a disposable canister/refillable absorber has been fitted to the machine, it should be discarded after one month, regardless of usage.

The absorber should also never be use beyond the expiry date.

23. Which is the better to use, Spherasorb™ or LoFloSorb™?

The potential for reaction between Soda Lime and volatile anaesthetics is very rare, even with KOH containing absorbents. With standard 3% NaOH containing absorbents, it is even less of a risk and the absorbent has to dry out to below 1.5% water content for any reaction to occur. This is VERY difficult to do and while there remains a theoretical possibility, there are few if any reported incidents with NaOH containing absorbents.

Both Spherasorb™ and LoFloSorb™ achieve complete safety with volatile anaesthetics. They achieve this in slightly different ways.

LoFloSorb is alkali-hydroxide-free (no KOH, NaOH or LiOH) and will not react in any significant way with volatile anaesthetics even if totally dry. However, like other alkali-hydroxide-free absorbents, LoFloSorb has a lower CO_2 capacity.

Spherasorb offers the best of both worlds. Spherasorb contains a tiny level of NaOH (1.5%) and a sodium-zeolite. This offers safety with volatile anaesthetics, while maintaining a high CO_2 capacity.

24. What are the chemical reactions involved in absorbing CO_2?
Absorbents containing Sodium Hydroxide (NaOH)

$$1.\ H_2O + CO_2 \xrightarrow[\text{high pH}]{} H_2CO_3$$

$$2.\ H_2CO_3 + 2\,NaOH \xrightarrow[\text{high pH}]{} Na_2CO_3 + 2H_2O$$

$$3.\ Na_2CO_3 + Ca(OH)_2 \xrightarrow[\text{high pH}]{} CaCO_3 + 2\,NaOH$$

+ Heat

Reactions 1 and 2: Absorption of one molecule of CO_2 results in the net generation of one molecule of H_2O.
Reactions 2 and 3: A catalytic NaOH equalibrium maintains a high pH

Absorption reactions: Alkali-hydroxide-free absorbents

$$1.\ H_2O + CO_2 \xrightarrow[\text{high pH}]{} H_2CO_3$$

$$2.\ H_2CO_3 + Ca(OH)_2 \xrightarrow[\text{high pH}]{} CaCO_3 + 2H_2O$$

+ Heat

In the absence of the catalytic function of the NaOH, a considerably higher porosity is required to enable sufficient activity of a direct reaction between H_2CO_3 and $Ca(OH)_2$.

25. What is a sodium zeolite?

Zeolites are a large group of naturally occuring, or synthetic minerals consisting of hydrated aluminosilicates.

In the 1750's, the Swedish mineralogist Alex Cronstedt, discovered mineral that when rapidly heated, would release steam from the water held within. He named these minerals 'zeolites', from Greek words meaning 'boiling stones'. In the 1960's Japanese research established the agricultural use of zeolites to control the moisture content and buffer the pH of acid volcanic soils.

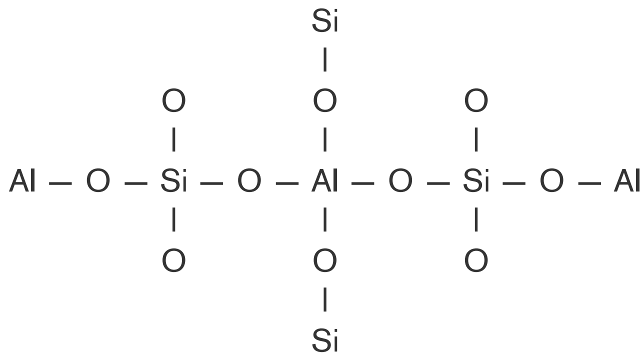
Certain zeolites also have the capacity remove specific gases when employing 'pressure swing adsorption'. This ability is put to use in oxygen concentrators, in which Nitrogen is extracted from air. Therefore, increasing the concentration of oxygen.

Zeolite often exist in combination with, ions of sodium, potassium, calcium, barium, or other +ve metal ions. Different metal ions species can be exchanged when conditions dictate.

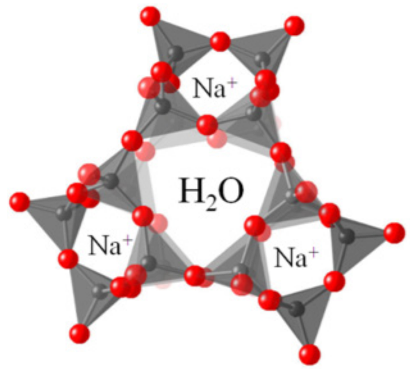
The ion exchange properties of Zeolites are put to use in the water treatment industry to soften water and act as pH buffers.

$$Ca(HCO_3)_2 + NaZeol \longrightarrow CaZeol + Na^+ \; HCO_3^-$$

Insoluble Calcium Bicarbonate in hard water	Soluble Sodium Bicarbonate



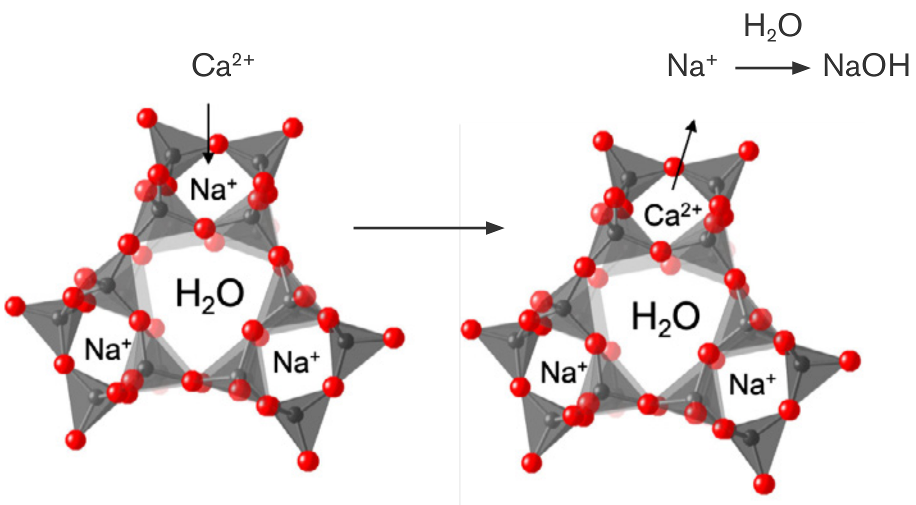
Basic zeolite structure



Representation of Sodium Zeolite

26. How does Sodium Zeolite act as a pH buffer in Spherasorb™?

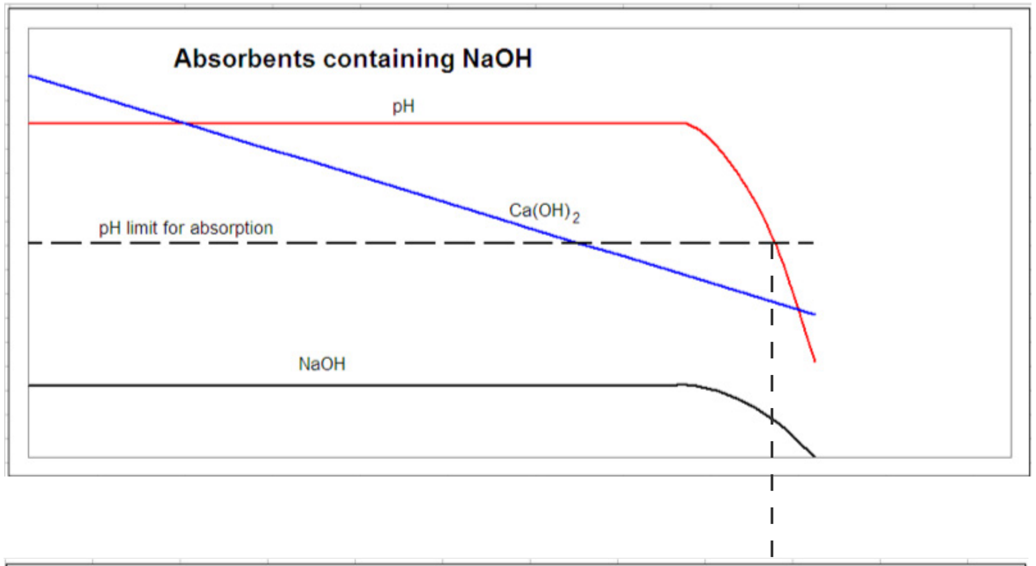
Ion exchange of zeolite is utilized in Spherasorb - A pH induced exchange of Na^+ ions for Ca^{2+} ions, enables pH buffering and compensates for lower level of NaOH. When exhaustion approaches, the NaOH level drops. However, the Na-zeolite responds with a pH enduced ion exchange. Na+ ions are released from within the Zeolite, in exchange for Ca^{2+} ions from Calcium Hydroxide. Therefore, although Spherasorb contains only 1.5 % NaOH, the pH buffering of the sodium zeolite, maintains sufficient pH and NaOH concentration for the catalytic NaOH equilibrium and the other chemical reactions to proceed rapidly enough and long enough for a high CO_2 capacity to be achieved.



27. How does Sodium Hydroxide (NaOH) enable a greater carbon dioxide capacity compared to Alkali-hydroxide-free absorbents

Absorbents containing NaOH

During the main lifetime of the absorbent, the NaOH equilibrium, maintains the pH above the lower pH limit for absorption. This high pH is maintained until the $Ca(OH)_2$ becomes too low to maintain the NaOH equilibrium.



Alkali-hydroxide-free absorbents

There is no NaOH and no equilibrium. The high pH relies on a sufficient level of $Ca(OH)_2$. However, $Ca(OH)_2$ becomes less abundent as soon as absorption begins. Therefore, the pH reaches the lower limit for absorption at an earlier time.